# Measuring Conflict of Interest in Prevention and Intervention Research – A Feasibility Study

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**(draft)**

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Over the past three decades there has been mounting confidence that we can advance crime prevention by learning from the combination of carefully designed experimental trials and systematic analyses of progress in the field. Many such systematic reviews have been conducted during the past 10 years. Most of them arrive at the encouraging conclusion that many types of universal, selective and indicated prevention can be effective in reducing crime and antisocial behaviour (Beelmann & Lösel, 2006; DuBois, Holloway, Valentine, & Cooper, 2002; Farrington & Welsh, 2003; Lipsey, 1995; Lipsey & Cullen, 2007; Lösel & Schmucker, 2005; Sherman, Farrington, Welsh, & MacKenzie, 2002; Wilson, Lipsey, & Derzon, 2003; Wilson, Lipsey, & Soydan, 2003).

However, in recent years there has also been concern about whether the two most powerful instruments of evidence-based criminology – experimental primary studies and secondary meta-analyses – produce unbiased estimates of the truth (e.g. Eisner, 2009; Gandhi, Murphy-Graham, Petrosino, Chrismer, & Weiss, 2007; Gorman, 2005; Littell, 2005; Petrosino & Soydan, 2005). Eisner (2009), for example, suggested that results found in meta-analyses may be affected by systematic bias, which is associated with a conflict of interest that arises when researchers act as programme disseminators and evaluators at the same time. However, the study also concluded that little is currently known on the extent of potential conflict of interest in our field, and its association with reported evaluation results.

The present paper therefore proposes a short instrument designed to measure potential conflict of interest that could be implemented in criminology-related meta-analyses. The feasibility of the proposed instrument is examined by applying it to 54 studies comprised in the meta-analysis by Piquero et al. (2009) of early family and parenting programmes.

## Background

Most extant research on the relationship between economic conflict of interest and research outcomes has been conducted in the biomedical sciences. At least three reviews of reviews have summarized the findings in medical research: Lexchin et al (2003) conducted a systematic review of 30 studies, published between 1966 and 2002, that had examined the relationship between conflict of interest and research findings in the medical sciences. Their meta-analysis of meta-analyses suggested an Odds ratio of OR = 4.05 in favour of positive outcomes where pharmaceutical companies had funded the research. Bekelman at al. (2003) conducted a review of reviews on the impact of financial conflict of interest on research findings in the biomedical sciences. This study found an Odds Ratio of OR = 3.6 in favour of pro-industry conclusions if a financial conflict of interest was present. In a recent study, Sismondo (2008) reviewed 19 systematic reviews on the effects of conflict of interest on study findings across a range of fields in medical research. 17 of these systematic reviews found an association

between industry support and research findings, while 2 studies failed to find such an association.

These findings suggest that financial conflict of interest may have an effect size of OR = 3 to 5 in some areas of research. This corresponds to a Cohen's d of 0.60 to 0.90, i.e. a 'medium' to 'strong' effect (Lipsey & Wilson, 2001). In fact, the effects associated with conflict of interest in biomedical research are larger than the mean treatment effects reported in meta-analyses in criminology, which typically range between Cohen's d = 0.20 and 0.40. If, therefore, conflict of interest is present in criminological research and if it is associated with bias similar to that found in medical research, many findings in current criminological meta-analyses of experimental studies could simply be a result of bias.

It is currently impossible to say whether conflict of interest exists in criminological research and whether it is associated with biased results, because no such research has yet been conducted. The study closest to measuring conflict of interest in criminology is the meta-analysis by Petrosino and Soydan (2005), which examined the effects of developers-as-evaluators on reported prevention effects. It analysed 300 distinct randomized field trials relevant to individually-focused crime reduction. Overall, this meta-analysis showed a small positive effect size of Cohen's d = 0.11. Yet, in studies in which the evaluator was the program developer, the reported effect size was d = 0.47, by far the largest mean effect for all subcategories. In contrast, in the studies in which the evaluation team was external to the program delivery, the mean effect size was exactly zero. The authors conclude that "studies in which evaluators were greatly influential in the design and implementation of treatment report consistently and substantially larger effect sizes than other types of evaluators." (Petrosino and Soydan, 2005: 444).

Petrosino and Soydan (2005) also reviewed 12 meta-analyses of offender treatment programs that included measures of the relationship between the programme developer and the investigator. In 11 of the 12 meta-analyses they found that larger mean effect sizes were found when the evaluators were involved or influential in the program setting than when they were not. These differences can be substantial. Beelmann and Lösel (2006), for example, conducted a meta-analysis of social skills programs. They found that programs delivered by teachers or psychosocial professionals yielded an average effect size of d = 0.29 compared to an effect size of d = 0.49 if the program was delivered by the study authors or the research staff (Loesel & Beelmann, 2003).

Petrosino and Soydan (2005) emphasize that their findings can be interpreted in at least two ways: They call the first perspective the *high fidelity view:* It assumes that a high involvement of researchers leads to greater attention to the implementation process and better implementation fidelity, resulting in greater treatment effects. The other perspective is labelled the *cynical view:* It assumes that conflict of interest is associated with problematic decisions at various stages of a study, which in the aggregate lead to biased findings. However, while there is

some experience in measuring implementation fidelity in criminological meta-analyses, no efforts have yet been made to measure potential conflict of interest as a mediator of reported effect sizes. It is therefore impossible to disentangle the two explanations of the empirical patterns.

## Measuring Conflict of Interest

There is considerable evidence that conflict of interest (COI) is significantly associated with reported outcomes in *some* disciplines, but no consensus exists on how COI is best conceptualized and measured so that it can be used in meta-analyses. One way to classify different approaches is to distinguish between *reactive* and *non-reactive* strategies. In reactive approaches the authors of the primary studies are retrospectively asked to disclose information about potential interests they may have in connection with the evaluated product or programme. Non-reactive approaches, in contrast, rely on published information such as disclosures of COI or the professional affiliation of authors to infer the existence of conflict of interest.

An example of the reactive approach is the meta-analysis by Stelfox at al. (1998) on the safety of calcium-channel protagonists in the treatment of cardiovascular diseases, a hotly debated issue in the late 1990s. They examined 70 articles published in 1995 and 1996. To measure COI the authors and co-authors were sent a questionnaire that comprised questions about whether they had received any kind of financial support from one of 40 pertinent pharmaceutical companies including travel expenses, honoraria to speak at a symposium, research support or consulting fees. The study achieved an impressive overall response rate of 80% and found that authors supportive of calcium-channel blockers were more likely to have financial interests related to pharmaceutical firms. The response rate was considerably higher amongst critical authors (91% response rate) as compared to supportive authors (69% response rate), suggesting that non-response is associated with COI.

Friedberg et al (1999) used a mix of reactive and non-reactive approaches in a study on the effects of COI on conclusions about oncological treatments. For academic publications where pertinent explicit information was provided, research was coded by whether it was sponsored by pharmaceutical companies or non-profit organisations. In all cases where no COI was disclosed in the study, the authors were contacted to provide the respective information. The response rate was high (15 out of 17 studies) and predominantly confirmed that no financial conflict of interest was present in these cases.

However, non-reactive approaches are a more common approach to measuring COI in biomedical research. Here one may further distinguish between studies that indirectly infer COI from additional information actively collected by the researchers and studies that directly rely on disclosed COI.

An example of indirect measurement is the pioneering study by Krimsky et al. (1998), who examined COI amongst biomedical researchers located in Massachusetts, USA, whose work was published in one of 14 leading life science and biomedical journals. They conceptualized COI as any study, in which one of the authors meets one of the following conditions: (1) The author has a membership on an advisory board of a company that develops products related to the scientist's expertise; (2) The author is listed as an inventor on a patent or a patent application for a product or process closely related to the scientist's publication under review; (3) the author serves as an officer, director, or major shareholder in a for-profit corporation involved in commercial activity related to the scientist's field of expertise. To measure these constructs the authors developed an extensive data-base based on searches in the *WIPO (World Intellectual Property Organisation)* patent data-base, a comprehensive list of biotechnology firms and publicly available information about the ownership of these firms and their officers and advisory boards. The study found that in 267 articles (34% of the sample) COI was present according to the above criteria, but that none had declared a conflict of interest.

In contrast, Perlis et al. (2005) mainly relied on published disclosures of study sponsorship and financial COI. They defined COI as any report of consulting or speaking fees, stock ownership, or employment by the study sponsor. 34% of all 397 studies disclosed a conflict of interest. However, the authors also inferred COI if no disclosure was made, but the study authors' addresses were pharmaceutical industry offices. This was the case in an additional 16% of the examined studies.

Friedman et al (2004) examined three different operationalisations of COI, examining publications in two leading biomedical journals. They distinguished a broad definition, based on any financial relationship with the company whose product is evaluated, a narrow definition based on the *International Council of Medical Journal Editors*, and an own definition which operationalizes COI as the presence of each of the following four criteria: 1a) one or more authors have financial associations with a private corporation in the form of grants, unspecified funding, consultancy, employment, stock ownership, or honoraria; and/or b) have a personal financial interest in the study because of a patent license in which an author is eligible to receive royalties or from personal investments. 2) The product reviewed by the author/s is manufactured by the funding corporation, or is in the same retail class as a drug manufactured by a sponsoring competitor; 3) The product(s) reviewed by author(s) have a current or near future commercial potential; and 4) the presentation of the main findings support the commercial product, negate competitor's product, advocate cost benefit, and/or show product has a potential commercial value (demand, size, and growth). The coding was exclusively based on disclosed information as both journals request authors to disclose financial relationships with companies whose products are tested. Each of the operationalisations resulted in slightly different estimates of the prevalence of COI. However, the finding that more positive results were reported in studies with COI was robust against all three types of measurement.

## Financial COI in Criminology: A Measurement Instrument

Conflict of interest can arise in different ways in evaluation studies. One important distinction is between financial and non-financial COI. Financial COI means that at least one author has or expects *personal material* gains as a consequence of one particular outcome. By far the most common situation is that an author benefits financially from positive findings, but one can also imagine situations where an author benefits from showing that a competitor's product is ineffective. Non-financial COI relates to situations where an author of an evaluation study may perceive advantages of positive findings in as far as they increase, e.g., the likelihood of further project funding, personal reputation in the academic community, the likelihood of successful publication, or the standing of the author in a governmental organisation. Such indirect benefits are difficult to operationalize and measure empirically. In what follows we therefore propose an instrument that is limited to measuring *financial* COI.

Academics who have direct or indirect financial associations with the distribution of a treatment programme, may reap benefits in a number of different ways: These include, for example, royalties for copyrights, payment for consulting and training services, contributions to research funding and staff costs, stock ownership, compensation of travel expenses, and honoraria for talks (Resnik, 2000). COI arises if at least one member of the research team has a stake in the evaluated product.

However, establishing whether such a relationship exists can be difficult. For example, two of the strategies used in biomedical research to measure conflict of interest are hardly viable in criminology: Direct measurement on the basis of *public disclosures* is impossible because evidence across various subfields of criminological prevention research suggests that disclosure is very rare. Also, even if it were possible, evidence suggests that public disclosures may underestimate true levels of financial interests that conflict with independent research (Perlis et al, 2005). Second, a *re-active measurement on the basis of a survey* amongst study authors is likely to be difficult for two reasons: For one, existing survey-based measurements have been typically based on a recall period of a few years (Stelfox et al, 1998; Friedberg et al. 1999). In contrast, meta-analyses in criminology often include publications over several decades and retrospective information collected over such a long period of time will probably lack reliability. Second, the research community engaged in experimental prevention research is comparatively small. We therefore anticipate – although this would need to be seen empirically – considerable reluctance to disclose information about personal gains from the dissemination of programmes to research fellows.

For this reason, we propose an instrument that relies on the third option, namely to collect manifest information that is related to potential financial conflict of interest. This strategy

is similar to the approaches suggested by, e.g., Krimsky et al.(1998) and Friedman et al. (2004). It is based on the assumption that conflict of interest is more likely if…

- At least one of the authors of an evaluation is the programme developer, the license holder of a programme or a staff member of the institution that distributes the programme….

  *and*

- the programme is distributed commercially or is developed for commercial distribution…

  *and*

- the organisation that disseminates the programme is a for-profit firm rather than a charity or a public service.

Note that these three criteria do not directly measure whether any of the authors effectively personally gains from the successful dissemination of the programme. Rather, they are designed to measure *potential conflict of interest* in the sense that the more conditions are fulfilled the more likely it is that the author effectively benefits from the programme dissemination.

In order to develop and test an instrument that can measure potential conflict of interest we re-examine an existing meta-analysis with published results. The study is the systematic review by Piquero et al. (Piquero, Farrington, Welsh, Tremblay, & Jennings, 2008; Piquero, et al., 2009) on the effectiveness of early family interventions and parent trainings on antisocial behaviour and delinquency. This meta-analysis comprises 55 studies. The authors of that study found substantive evidence in support of a positive effect of early family-based interventions: Depending on weighting procedure an effect size of between 0.23 and 0.45 was found.

We chose this study for several reasons: First, the study is a carefully conducted and extensively documented meta-analysis. It follows *Campbell Collaboration* guidelines on documenting the search process, the criteria for including studies, and the extraction of effect sizes (Farrington & Petrosino, 2001). Second, the reliance on a published meta-analysis had the advantage that the coding of effect sizes (by the authors of the systematic review) and the coding of potential COI (by the authors of this study) was separated. Also, the data on effect sizes were kept in a separate file during the instrument development and coding phase, reducing the risk of potentially biased coding on our side. However, complete blinding was impossible as the data collection necessitated the reading of the underlying primary publications. Third, it seemed important to choose an area of evaluation research that comprises studies with different constellations of COI and that comprises a sufficient number of primary studies for a preliminary quantitative assessment. Initial explorations of various meta-analyses suggested that the meta-analysis by Piquero et al. (2009) comprised a manageable number of primary studies and a diverse mix of different COI constellations. In particular, family and parenting interventions are probably characteristic of the kind of activities that may be associated with

financial benefits in prevention research such as income from the sale of popular books, programme components, the training of programme providers, or consulting fees. This enables us to test and examine the sensitivity of the instrument. Finally, the studies included in this meta-analysis exemplify the lack of disclosed information about possible conflict of interests. Thus, a preliminary examination of the 50 *published* papers comprised in Piquero et al. (2008) suggests that only 5 comprised a conflict of interest statement. Amongst these five three declared no conflict of interest and two declared a potential conflict of interest.[1]

## Developing the Instrument

Based on the previous arguments we developed an instrument to measure potential financial COI. The goal was threefold: The instrument should be short so that it could easily be implemented as part of systematic reviews and meta-analyses in criminology. The instrument should be sensitive to the three components of potential COI mentioned above. The instrument should be based on explicit rules so that it can be reliably replicated across coders and thematic fields. In developing the instrument we went through an exploratory stage that comprised several rounds of revising earlier ideas, identifying new sources of relevant information, and examining discrepancies in our coding. We finally arrived at an instrument that consists of three elements, which could subsequently be combined into one scale.

The first element entails coding whether one of the *study authors is the programme developer or a person directly involved in the dissemination of the evaluated programme.* Measuring this element is comparatively straightforward and can be integrated in a meta-analysis with little additional effort. However, while important, this first element captures only one aspect that may be reflective of financial conflict of interests. Programmes tested in criminological trials can be in vastly different stages of commercial dissemination and their distribution may be based on a variety of different business models. Thus some programmes may be developed and implemented as part of public services and hence be associated with few financial interests, some may be evaluated as a small project without intentions for later dissemination, while others may be comparatively large international enterprises with a significant annual turnover. Such factors are likely to influence the likelihood and extent of financial interests of researchers who have a stake in the evaluated programme.

[1] Both cases of disclosed conflict of interest are related to the Incredible Years programme and may serve as examples of good practice: Thus, the paper by Edwards et al. (2007) comprises a statement that Judy Hutchings "is paid by Incredible Years for running occasional training courses in the delivery of the parent programme and has served as an expert witness for the NICE appraisal on parenting and conduct disorder." Similarly the paper by Reid at al. (Reid, Webster-Stratton, & Hammond, 2007) states that "Carolyn Webster-Stratton has disclosed a potential financial conflict of interest because she disseminates the Incredible Years interventions and stands to gain from a favourable report. Because of this, she has voluntarily agreed to distance herself from certain critical research activities (i.e., recruiting, consenting, primary data handling, and analysis), and the University of Washington has approved these arrangements".

The second element therefore entails a coding of the *level of commercial distribution* of a programme. Here our goal is to establish whether a programme was commercially available on a broader market beyond the study itself at the time of the publication of the study.

Finally, we examined whether it would be possible to measure the *business model* of the programme. This third element was based on the premise that prevention and intervention programmes are disseminated by different bodies including, e.g., private for-profit companies, not-for-profit charities, and university departments or public services. Such different business models are likely to be associated with different probabilities for personal financial benefits, making it desirable to include a corresponding measure.

*Researcher-Programme Developer Relationship*

If disclosures of conflict of interest are not available, a first necessary step towards measuring COI consists in establishing the link between the evaluated product and the study authors. In most biomedical studies this entails determining the relationship between the study authors and usually large corporations outside academia that have developed a treatment and hold the respective patent. In criminological prevention and intervention research such situations are probably rare. The most common situation is that individual researchers develop an intervention as a standardized series of activities (i.e. a 'programme') that is supported by training material, which eventually may become commercially disseminated at a larger scale. Also, in all cases that we are aware of, the developers of a programme retain an interest in and control over the programmes that they have developed, even if parts of the dissemination may be handed over to larger publishers specialized in education and health care topics. We therefore believe that an important precondition for potential conflict of interest is that the authors involved in conducting an outcome evaluation are also programme developers or closely related to the programme dissemination.

Retrieving the respective information entails the identification of the programme developers and of the study authors. In the studies comprised in the Piquero et al. (2008) meta-analysis the programme developers were explicitly acknowledged in most cases. In a few studies, though, we found that the information provided in a study was not sufficient to infer the programme developer and we had to resort to either subsequent publications or conduct additional searches to establish the programme developer.

Based on this information we developed three dummy variables that capture different constellations between the programme developer and the authors of the publication: The first variable measures whether the first author of a publication was one of the programme developers. In the present pilot study this was the case in 41% of the publications.

The second variable measures whether one of the programme developers was a co-author other than the first author of a publication. This was the case in 50% of publications. Combining the first two variables suggests that in 72.6% of the studies considered by the Piquero et al. (2008) review one of the programme developers was amongst the authors of the paper.

A third variable assessed whether the first author was a collaborator of the programme developer. A first author was coded as a collaborator of the programme developer if the first author reported the same institutional affiliation as the programme developer. This was the case in 22.2 % of the studies. Shared institutional affiliation is likely to indicate that the first author's employment is tied to the programme and its evaluation. This is supported by the fact that in all such cases the programme developer was also included as a co-author.

*Table 1* *Author – Programme Developer Relationship*

| Variable | | Prevalence |
|---|---|---|
| One of programme developers is first author | | 40.7 % |
| One of programme developers is co-author | | 50.0 % |
| Collaborator of developer is first author | | 22.2 % |
| *Of which:* | *Developer is not co-author* | *0 %* |
| | *Developer is co-author* | *100 %* |
| None of the above, 'independent' evaluation | | 27.8 % |

*Note: Categories are not mutually exclusive. N = 54; one unpublished study could not be accessed and is not included in the analyses.*

Overall, coding the relationship between the programme developer and the study authors did not pose significant obstacles as it could rely on unambiguous information that is usually made available in the publication itself. Only in a few cases the programme developer was not explicitly referred to in the publication and had to be found through additional literature and internet searches.

An aspect that may require additional attention is the role of license holders. Thus, over the past 20 years several intervention and prevention programmes have been rolled out internationally (e.g. Triple P, Incredible Years, Family-Nurse Partnership, Multisystemic Therapy). This usually requires that a representative in the respective country, often an academic, acquires distribution rights and co-ordinates the dissemination and the training of providers. These academics are likely to also conduct a local evaluation study, meaning that potential COI may extend to license holders. However, such arrangements are probably organised in different ways, resulting in variation of how local license holders participate in financial benefits. Also,

such arrangements are not well documented in publicly available material. Therefore, we have currently not developed a separate code for the involvement of license holders.

*Commercial Distribution and Business Model*

Next we explored whether additional information could be collected on the extent to which a programme was commercially distributed at the time of the study and the business model on which the dissemination was based. Collecting pertinent data proved to entail considerably more work than the coding of the researcher-programme relationship, as it was necessary to compile relevant information from a number of different sources. These include…

- The information provided in the respective studies.
- Electronic queries in the catalogues of National Libraries (e.g. Library of Congress, National Library of Australia) to identify the first year of publication of manuals or general public textbooks.
- Websites related to the respective programmes that provide information about the programme history, its commercial model and its dissemination.
- Specific academic publications on the history and development of the programmes.
- Electronic queries in the *Dun & Bradstreet International Registry of Businesses* to verify whether a business was registered as a commercial entity.
- Electronic queries of trademark registers such as the search facility of the US patent and Trademark Office.

On the basis of these sources we created short profiles of each programme that included information about, e.g. the first year that components of the programme were commercially available, the range of products and services offered by the distributor, any institutional affiliation of the distributor, or whether the distributor was registered as a not-for-profit organisation. These data subsequently served to code for two variables.

The first variable is dummy-coded and measures whether the programme or components of the programme were *commercially distributed* at the time of the publication of the study. By commercial distribution we mean that a programme or treatment is available on a larger market, packaged in a standardized way through handbooks, manualized delivery guidance or professional training programmes, and marketed under a brand name. We operationalized commercial availability as evidence that any of the following criteria was satisfied:

- A general public or practitioner-oriented textbook related to the programme and published before the publication of the study.

- A reference in a historical overview or programme description that explicitly states when the programme or components of the programme became commercially available.

- A registration of the trademark or the name of the disseminating corporation in the respective public databases in the United States, Canada, Australia, New Zealand, or the Netherlands (the countries of origin of all examined programmes).

- The publication refers to the programme with a copyright-protected brand-name such as *Triple P*, *PCIT* or *Incredible Years*.

- The programme is available in different countries.

Establishing the year when an intervention becomes commercially available can be difficult. During their development process therapeutic interventions often evolve from relative small manualized products to complex systems with different components. Each stage in the development of such programmes may entail the testing of newly developed components that are not yet commercially available. However, in the context of measuring potential COI our main interest is not whether a specific component is still in a development phase, but whether the overall programme is commercially available and hence generating income.

In this pilot study, 54 of the 55 studies could be coded for whether at least some components of the programme were commercially distributed at the time of the publication of the study. Result suggest that 72% (N=39) of all publications were coded as testing interventions that were commercially available while 28% (N = 15) of the publications examined interventions that were not available commercially or that were delivered exclusively as part of a local public service.

*Economic Business Model*

The third domain that we tried to measure relates to the economic model on which the dissemination of the programme is based. The prime distinction concerned whether the programme was distributed on the basis of a *for-profit model* or whether its dissemination was managed by *a non-for-profit organisation*. The coding of this variable was derived from the programme profiles collected as part of this pilot study.

Coding of the underlying economic model was only deemed adequate for programmes that were disseminated commercially. Programmes were coded as on a for-profit basis if…

- The organisation that disseminates the programme is explicitly mentioned in a reliable publication as a spin-off company.

- The organisation is a registered company and is *not* registered as a charity in the respective country. For the United States, for example, charity status as described under section 170(c) of the *Internal Revenue Code* can be checked at the IRS website.

- The organisation is registered as an incorporated company or as a company without any links to a public service institution.

- Material related to the programme is distributed by a commercial publisher.

On the other hand, disseminating organisations were coded as not-for profit disseminators if they were mentioned in any of the available sources as a charity or not-for profit organisation.

Amongst the 39 studies that evaluated components of commercially available programmes, 35 (90%) were found to examine programmes whose dissemination is based on a for-profit model. Four studies (10%) examined programmes that are disseminated by non-profit organisations, namely the Nurse Home Visitation Program (two studies, disseminated by *Nurse-Family-Partnership*), the Perry Preschool Programme (disseminated by *HighScope*), and Family Check-Up (disseminated by the *Family Check-Up Institute*).

Two critical issues emerged when we developed and applied the proposed measure for the business model: First, several of the criteria used for establishing whether a programme is distributed on a for-profit or a non-profit basis are only available for the present situation. Thus, relatively good evidence permitted us to classify programme distributors according to whether they were *currently* operating on a 'for-profit' basis. In contrast, it is proved much more difficult, and often impossible, to find out how the dissemination of a programme had been organized one or two decades earlier.

Second, one should note that it is difficult to establish the extent to which the difference between for-profit and non-profit business models has an impact on potential conflict of interest of programme developers. Thus, a closer analysis would have to examine whether and how non-profit organisations compensate programme developers or academic board members with, for example, consulting fees, honoraria for talks, payment for training courses, or compensation for travel expenses.

*A Combined Scale*

In a final step, we developed a tentative scale of potential COI. Based on the elements described in the preceding sections the scale distinguishes three levels of potential COI, namely *"unlikely", "possible"* and *"likely"*. The lowest level *("unlikely")* relates to all studies where none of the study authors is either the programme developer or a collaborator of the programme

developer. The majority of the 15 studies (27.8%) in this category can most probably be regarded as independent evaluations where the evaluating team had no material interests in the outcome of the study. The mean effect size on children's behaviour problems across these studies was Cohen's d = 0.24. On the other hand, situations of potential financial COI were coded as *likely* if one of the study authors is the programme developer or a collaborator of the programme developer and the programme is commercially distributed on a for-profit basis. 25 publications (46.3%) were coded as studies with a likely financial COI. The mean effect size in this group of studies was Cohen's d = 0.61. Finally, we distinguish a third group of studies where the evidence for potential financial COI is ambiguous. We suggest the label "possible financial COI" for this group. It comprises all studies, where the programme developer or a collaborator of the programme developer is one of the study authors, but where the programme is either not commercially distributed or where the programme is disseminated on a not-for-profit basis, for example by a charity. The mean effect size for the 14 studies in this group was Cohen's d = 0.35. Overall, a one-way ANOVA showed that the differences in effect sizes between the three groups marginally failed to be statistically significant with $F(2, 51) = 3.16$, $p = .051$.

*Table 2 Trichotomous Scale for Potential Financial Conflict of Interest*

| Financial COI | Coding Rule | % of Studies (N = 54) | Cohen's d Mean Effect Size (CI in Brackets) |
|---|---|---|---|
| Unlikely | None of the study authors is programme developer, collaborator of programme developer or license holder. | 27.8 % (N = 15) | 0.24 [-0.02; 0.49] |
| Possible | (Programme developer or collaborator of programme developer is study author) AND ((programme is not (yet) commercially available) OR (business model is 'not-for-profit')) | 25.9 % (N = 14) | 0.35 [0.14; 0.57] |
| Likely | (Programme developer or collaborator of programme developer is study author) AND (programme is commercially available) AND (business model is 'for profit') | 46.3 % (N = 25) | 0.61 [0.39;0.84] |

*Note:* Group-wise effect sizes and confidence intervals are based on un-weighted means. One unpublished study (Tulloch, 1997) comprised in the original meta-analysis is not included because the authors could not access the study.

## Discussion

The purpose of this contribution was to propose an instrument, for implementation in criminological meta-analyses, that operationalizes potential conflict of interest, and to learn about the feasibility of the instrument by applying it to studies comprised in an existing meta-analysis. The proposed instrument is based on the notion that potential COI is 'likely' if a study author has a direct stake in the programme (as developer or license holder), the programme is disseminated commercially, and the programme is distributed on a for profit basis. In contrast, the proposed instrument results in studies being coded as 'unlikely' COI if none of the study authors has a known stake in the dissemination of the programme. Finally, we distinguish a third group of 'possible' COI in situations where one of the study authors is the programme developer, but the programme is either not disseminated at the time of the publication or if the programme is disseminated by a no-for-profit organisation.

When testing the practical feasibility of the proposed instrument we found that the difficulty of obtaining valid and reliable information differed between the three elements of the instruments. Establishing whether any of the study authors was also one of the programme developers proved to be comparatively straightforward, and it only rarely required the collection of information other than what is available in the underlying study. In contrast, coding the commercial dissemination and the business model of the programme proved to require substantive additional efforts. Yet the present feasibility study suggests that by systematically collecting publicly available data allows establishing, for most interventions, whether they are disseminated commercially on a wider scale and when the dissemination started. Potentially the most problematic component of the proposed instrument relates to our suggested measure of for-profit versus not-for-profit business models. While the findings of this feasibility study suggest that public data sources can be used, particularly for larger programmes, to establish the current business model, we found it often impossible to establish whether the business model changed over time and exactly on what basis the programme was disseminated at the time of the publication of the study.

Besides these limitations associated with incomplete data, one should note that the approach suggested here is also limited in as far as it does not reveal whether a study author *effectively* benefits financially from the dissemination of a programme, and how large these benefits are. However, such information would probably only become available if relevant journals adopted a consistent policy of public disclosure of conflict of interest. Furthermore, we have intentionally designed the proposed instrument to measure potential *financial* conflict of interest. As mentioned, there may be other sources of conflict of interest such as the potential implications of findings for future research funding, academic reputation, or the ease of academic publication. However, we believe that such conflicts are probably impossible to measure reliably in the context of a meta-analysis.

The preliminary analyses suggest that the differences in effect sizes across the three groups are in line with the view that conflict of interest is associated with higher reported treatment effects. However, further analyses are needed that take other moderators of effect size into account. In particular, a more stringent examination of the two hypotheses proposed by Petrosino and Soydan (2005) – the *high fidelity view* and *the cynical view* - would need to include good measures of implementation quality as an important alternative explanation for the observed empirical patterns. Further research is also needed to establish whether the proposed instrument proves to be useful when applied to meta-analyses in other domains of criminological prevention and intervention research, and whether any of the three proposed elements require refinement.

References


Beelmann, A., & Lösel, F. (2006). Child social skills training in developmental crime prevention: Effects on antisocial behavior and social competence. *Psycothema,* 18(3), 603-610.

Bekelman, J. E., Li, Y., & Gross, C. P. (2003). Scope and impact of financial conflicts of interest in biomedical research. JAMA: *The Journal of the American Medical Association*, 289(4), 454-465.

DuBois, D. L., Holloway, B. E., Valentine, J. C., & Cooper, H. (2002). Effectiveness of mentoring programs for youth: A meta-analytic review. *American Journal of Community Psychology,* 30(2), 157-197.

Edwards, R. T., Céilleachair, A., Bywater, T., Hughes, D. A., & Hutchings, J. (2007). Parenting programme for parents of children at risk of developing conduct disorder: cost effectiveness analysis. *BMJ,* 334(7595), 682.

Eisner, M. (2009). No effects in independent prevention trials: can we reject the cynical view? *Journal of Experimental Criminology,* 5(2), 163-183.

Farrington, D. P., & Petrosino, A. (2001). The Campbell Collaboration Crime and Justice Group. *The ANNALS of the American Academy of Political and Social Science,* 578(1), 35-49.

Farrington, D. P., & Welsh, B. (2003). Family-based prevention of offending: A meta-analysis. *Australian and New Zealand Journal of Criminology,* 36(2), 127-151.

Friedberg, M., Saffran, B., Stinson, T. J., Nelson, W., & Bennett, C. L. (1999). Evaluation of conflict of interest in economic analyses of new drugs used in oncology. *JAMA: The Journal of the American Medical Association,* 282(15), 1453-1457.

Friedman, L. S., & Richter, E. D. (2004). Relationship between conflicts of interest and research results. *Journal of General Internal Medicine,* 19(1), 51-56.

Gandhi, A. G., Murphy-Graham, E., Petrosino, A., Chrismer, S. S., & Weiss, C. H. (2007). The devil is in the details: Examining the evidence for "proven" school-based drug abuse prevention programs. *Evaluation Review,* 31(1), 43-74.

Gorman, D. M. (2005). Drug and violence prevention: Rediscovering the critical rational dimension of evaluation research. *Journal of Experimental Criminology,* 1(1), 39-62.

Krimsky, S., Rothenberg, L. S., Stott, P., & Kyle, G. (1998). Scientific journals and their authors' financial interests: A pilot study. *Psychotherapy and Psychosomatics,* 67(4-5), 194-201.

Lesser, L. I., Ebbeling, C. B., Goozner, M., Wypij, D., & Ludwig, D. S. (2007). Relationship between funding source and conclusion among nutrition-related scientific articles. *PLoS Med*, 4(1), e5.

Lexchin, J., Bero, L. A., Djulbegovic, B., & Clark, O. (2003). Pharmaceutical industry sponsorship and research outcome and quality: systematic review. *BMJ,* 326(7400), 1167-1170.

Lipsey, M. W. (1995). What do we learn from 400 research studies on the effectiveness of treatment with juvenile delinquents? In J. McGuire (Ed.), What Works? Reducing Reoffending (pp. 63-78). New York: John Wiley.

Lipsey, M. W., & Cullen, F. T. (2007). The effectiveness of correctional rehabilitation: A review of systematic reviews. *Annual Review of Law and Social Science,* 3.

Lipsey, M. W., & Wilson, D. B. (2001). Practical Meta-Analysis. Thousand Oaks: Sage.

Littell, J. (2005). Lessons from a systematic review of effects of multisystemic therapy. *Children and Youth Services Review,* 27(4), 445-463.

Lösel, F., & Beelmann, A. (2003). Effects of child skills training in preventing antisocial behavior: A systematic review of randomized evaluations. *The ANNALS of the American Academy of Political and Social Science,* 587(1), 84-109.

Lösel, F., & Schmucker, M. (2005). The effectiveness of treatment for sexual offenders: A comprehensive meta-analysis. *Journal of Experimental Criminology,* 1(1), 117-146.

Perlis, R. H., Perlis, C. S., Wu, Y., Hwang, C., Joseph, M., & Nierenberg, A. A. (2005). Industry sponsorship and financial conflict of interest in the reporting of clinical trials in psychiatry. *Am J Psychiatry,* 162(10), 1957-1960.

Petrosino, A., & Soydan, H. (2005). The impact of program developers as evaluators on criminal recidivism: Results from meta-analyses of experimental and quasi-experimental research. *Journal of Experimental Criminology,* 1(4), 435-450.

Piquero, A., Farrington, D., Welsh, B., Tremblay, R., & Jennings, W. (2008). Effects of early family/parent training programs on antisocial behavior and delinquency: A systematic review. Stockholm: Swedish National Council for Crime Prevention.

Piquero, A., Farrington, D., Welsh, B., Tremblay, R., & Jennings, W. (2009). Effects of early family/parent training programs on antisocial behavior and delinquency. *Journal of Experimental Criminology,* 5(2), 83-120.

Reid, M. J., Webster-Stratton, C., & Hammond, M. (2007). Enhancing a classroom social competence and problem-solving curriculum by offering parent training to families of moderate- to high-risk elementary school children. *Journal of Clinical Child and Adolescent Psychology,* 36(4), 605-620.

Resnik, D. B. (2000). Financial interests and research bias. *Perspectives on Science,* 8(3), 255-285.

Sherman, L. W., Farrington, D. P., Welsh, B. C., & MacKenzie, D. L. (Eds.). (2002). Evidence-Based Crime Prevention. London: Routledge.

Sismondo, S. (2008). Pharmaceutical company funding and its consequences: A qualitative systematic review. *Contemporary Clinical Trials,* 29(2), 109-113.

Stelfox, H. T., Chua, G., O'Rourke, K., & Detsky, A. S. (1998). Conflict of interest in the debate over calcium-channel antagonists. *New England Journal of Medicine,* 338(2), 101-106.

Wilson, S. J., Lipsey, M. W., & Derzon, J., H. (2003). The effects of school-based intervention programs on aggressive behavior: A meta-analysis. *Journal of Consulting and Clinical Psychology,* 71(1), 136-149.

Wilson, S. J., Lipsey, M. W., & Soydan, H. (2003). Are mainstream programs for juvenile delinquency less effective with minority youth than majority youth? A meta-analysis of outcomes research. *Research on Social Work Practice*, 13(1), 2-26.