Randomised Controlled Trials, Evidence Hierarchies and Smarter Choices

Steve Melia

Introduction

The selection of research methodologies to inform policy is a contested area, amongst researchers policy advisers and policy makers. The debate revolves around two broad questions:

- 1. What are the most appropriate methods to address different research challenges?
- 2. How should the choice of methods (as well as their application) influence the assessment of research findings in meta-studies and literature views intended to inform policy?

The first of these questions primarily concerns researchers but the interventions of policy makers/advisors around the second question have implications for debate around the first one. The spectrum of perspectives on both questions can be characterised as a choice between two ap-The first approach, favoured by most transport researchers and some policy makers/advisors (e.g. Tavistock Institute and AECOM, 2010) seeks to select the most appropriate method based on the nature of the research questions with no generalised preference for one method over others. The second approach favours a methodological hierarchy, usually with Randomised Controlled Trials (RCTs) at the top (the terminology is not always consistent in the literature but 'experimental methods' is often used as a synonym for RCTs). In response to the first question, this approach would recommend a method from the highest possible level in the hierarchy to address each research question. In response to question 2 it would attach greater weight to findings generated by methods at the higher levels of the hierarchy.

Methodological hierarchies (or 'evidence hierarchies' when applied to meta-studies) have become more influential in transport policy and research in recent years as academics and professionals from a health background have engaged more with transport issues (e.g. Graham-Rowe et al., 2011, Rowland et al., 2003). They have been advocated by policy advisors to some

governments in contexts which encompass transport, such as social policy in Australia (Leigh, 2009) and promoting physical activity amongst children in the UK (NICE, 2007). They have also influenced national policy in the UK on Voluntary Travel Behaviour Change programmes (VTBC – or 'smarter choices' in British terminology), as discussed below.

A substantial literature exists on the issues of research design and the choice of methodology for answering different research questions in different contexts: it is not the intention to address the breadth of that issue here. This article will briefly review the debate around one area where methodological hierarchies have been proposed as a solution to perceived shortcomings: the effectiveness of VTBC programmes.

The rest of the article will focus on a principal area of contention in this debate: the circumstances under which experimental methods can and should be used in transport research. Section 5 will propose 5 criteria (Table 4) for the application of experimental methods in circumstances where interventions must change human behaviour to be effective, and where those interventions must be generalisable to wider populations in order to inform policy. It will argue that the advantages of experimental methods, and the breadth of their applicability to transport research are not as great as advocates of methodological hierarchies claim. It will then consider the implications of this for evidence-based transport policy.

Evidence Based Policy and the Spectrum of Research Designs

The principles of evidence-based policy have been central to transport studies since it emerged as distinct discipline, but the focus of evidence-gathering was, until fairly recently, rather narrow. Whilst government-commissioned studies examine issues such as traffic flow and road safety, as recently as 2000 Terry wrote, in a UK context:

In the case of research supported through universities and research councils, little of such work is, nor is intended to be relevant to policy. (Terry, 2000 p. 188)

Several factors have changed that situation since then. In academia, there has been a greater emphasis on achieving external impact, whilst governments have turned to academic and specialist research in pursuit of environmental and (particularly since the recession) macro-economic objectives.

Tavistock Institute and AECOM (2010) was commissioned by the Social Research and Evaluation unit of the UK Department for Transport to give guidance to public bodies evaluating transport interventions. It discusses the advantages and limitations of six different research approaches but does not suggest a hierarchy. It includes several flow charts suggesting the most appropriate approach depending on: the focus of the evaluation, nature of the intervention and feasibility of the approach. It provides a useful starting point for researchers and practitioners, but has some limitations. The study behind the report was written by consultants with input from academics in the field. The guidance draws on a mixture of theory and practical experience: it is not always clear where a recommendation is being made for theoretical, practical or cost reasons. Some of the criteria under the 'nature of intervention' heading are debatable, (Tavistock Institute and AE-COM, 2010 Figure 6). For example, the requirement that causal pathways should be short and straightforward when using experimental methods cannot be demonstrated from first principles.

As discussed in Section 6, many of the bigger questions in transport research could clearly not be addressed by experimental methods. These include the impacts of major infrastructure projects, longer-term changes to the built environment and the impacts of interventions or programmes on national economies. As a result, the debate around methodological hierarchies in transport research has tended to focus around one area: VTBC, where there has been a vigorous debate about the reliability of evaluation studies.

Voluntary Travel Behaviour Change and Problems of Research Bias

The terms VTBC and smarter choices have been used in different ways, but generally refer to interventions which seek to change travel behaviour by 'management and marketing rather than operations and investment' (Sloman et al., 2010), though many VTBC programmes include or accompany elements of infrastructural change (e.g. new cycle routes). A principal aim of these measures is usually to reduce single occupancy vehicle driving. There have been many published evaluations of VTBC programmes, usually based on 'before and after' self-reported travel surveys, which are susceptible to several forms of bias, tending to overstate the effectiveness of interventions. These include: social approval bias (Bonsall, 2009), expectation bias or the 'good subject effect' (Morton and Mees, 2010 following Orne, 1970), non-response bias, where those with a positive story to tell are more likely to complete the 'after' surveys (Chatterjee, 2009). Some of the studies have been conducted by organisations or individuals with an interest in promoting VTBC, creating the risk of reporting or retrieval bias, where greater prominence is given to positive results (Möser and Bamberg, 2008).

Many of these effects have been recognised in other fields for some time and whilst their influence on VTBC programmes is easy to identify in theory, there is little specific evidence of their importance in practice. Morton and Mees (2010) cite the evaluation of the Travelsmart programme in Alamein, Melbourne, as one example where these effects allegedly distorted the results. Ker (2011) defends the original evaluation and rejects Morton and Mees' criticisms. From the evidence presented in both papers (citing local factors, variations in weather etc.) it is not possible to determine whether the reported modal shift was overstated but there are reasons for believing that it might have been. The response rate of the 'after' survey was considerably lower than the 'before' survey and the self-reported travel in the after survey may have been susceptible to the good subject effect.

Although the reasons have not been studied, there are some examples which suggest that, depending on survey design, self-reported travel surveys may substantially distort findings in this area. Following a strategy to increase cycling, using both infrastructure improvements and marketing measures in York, UK, Harrison (2001) reported that cycling as the usual mode of travel to work had risen from 15% of working people in the 1991 Census

to 18.6% in a self-completed household survey conducted in 2000. The 2001 Census, published the following year, showed that the share of cycling had, in fact, fallen to 12% (ONS, 2009: Table CS121). In an evaluation of the UK's Cycling City and Towns programme, a face-to-face survey in 2009 appeared to show a substantial increase in physical inactivity, from 37% to 26% of respondents, compared to a baseline telephone survey, which asked the same question (Chatterjee and Hardin, 2011). The researchers ascribe this difference to respondents' greater honesty in face-to-face interviews than on the telephone. This explanation suggests that social approval bias influenced the baseline telephone survey; it also suggests that social disapproval of dishonesty outweighed any influence of the good subject effect in the final face-to-face survey.

There is an emerging consensus on some of the methodological measures which could help to address – though not entirely eradicate – these concerns. These have focussed particularly on the use of more objective data, such as traffic or pedestrian counts or GPS-based tracking (Bonsall, 2009, Chatterjee, 2009), and clear-

er separation of evaluation studies from the advocates and implementers of VTBC schemes (Morton and Mees, 2010). Passive observation measures such as traffic counts should solve problems of social approval bias, non-response bias and the good subject effect, but they introduce other problems, such as how to ensure that the counting points are representative of the wider area. GPS-based measures avoid reporting biases associated with reporting, but are not immune from the good subject effect, if participants' awareness of the survey purpose exerts an unconscious effect on actual behaviour. Some studies have sought to 'triangulate' self-reported travel data with objective measures of traffic volumes, for example (e.g. Sloman et al., 2010). These studies inevitably rely on interpretive judgements because general traffic levels are influenced by many external unmeasurable factors. Melia (2013) suggested a new method, which could help to provide a more objective basis for such judgements. This would involve trip counters on self-contained networks of residential streets, where all movements in and out can be measured and compared to self-



Fig 1: Network of self-contained streets in Dungarvan, Ireland (© Openstreetmap contributors)

reported data (including visitors and deliveries). Figure 1 shows an example of such a network in Dungarvan, one of the Irish sustainable travel towns.

The residents of these areas may not be typical of the whole study area, so other methods such as travel diaries may still be needed across the wider area. By measuring traffic volumes in circumstances where they can be precisely compared to self-reported data, this method would enable the researchers to quantify the effect of any self-reporting biases.

Three studies have recommended RCTs as the specific solution to these problems, in evaluating VTBC programmes in general (Graham-Rowe et al., 2011, Möser and Bamberg, 2008), and evaluating school travel plans in particular (Rowland et al., 2003). Möser and Bamberg (2008) use a methodological hierarchy in a meta-study assessing the effectiveness of VTBC programmes. They conclude that the mainly "weak quasi-experimental" evaluation studies they reviewed "may underestimate but more probably overestimate the true causal car reduction effect" of VTBC measures.

Graham-Rowe et al. (2011) reviewed 77 evaluations of transport interventions designed to reduce car use, most of which could be described as VTBC interventions. They classify the evaluations into five levels of research quality, which follow a methodological hierarchy rather than any assessment of how effectively the methods were applied. Those evaluations classified as high quality used 'rigorous experimental designs' (only five were RCTs). Those classified as 'low quality' used "weak designs without control groups, from which we cannot draw methodologically valid inferences." The authors recognise that "rigorous experimental designs are challenging in field studies". They suggest that 'weaker' research methods have tended to exaggerate the effectiveness of certain interventions but that valid evidence does support the effectiveness of some interventions. They make a plea for "more robust evaluation methods...and in particular that RCTs are adopted wherever possible" Rowland et al. (2003) conducted a RCT of school travel plans, which found no significant modal shift in travel to schools in London. They go further than others in arguing that positive evidence from RCTs should be a condition for continued public funding of school travel plans.

This debate has directly influenced national policy on VTBC in the UK. The UK Department for Transport (DfT, 2012) cites Möser and Bamberg (2008) in national guidance which had the effect of ascribing only limited potential benefits to VTBC programmes when appraising the cost-benefit ratios of transport projects seeking public funding.

Criteria for the Use of Experimental Methods to Inform Transport Policy

Whatever their advantages and disadvantages, it seems the contribution of RCTs to knowledge in transport studies has been fairly limited, so far. There are two possible explanations for this: that transport researchers have been neglecting a method which could improve the quality of their work, as implied by Graham-Rowe et al., (2011) and Möser and Bamberg (2008) or that RCTs are of limited use in answering 'real world' transport questions. To assess those two possibilities, this section will consider the conditions under which RCTs can be used, with comparisons to other methods.

Table 1 lists five criteria for the application of experimental methods to assess interventions which seek to alter human behaviour, and where the intention is to apply 'successful' interventions more widely. Criterion 1 implies that existing knowledge must be sufficient to construct a hypothesis where the intervention is believed to affect a limited number of known and measurable outcomes. Another criterion from Tavistock Institute and AECOM (2010) suggests that experimental methods should only be used to measure interventions with "a single outcome goal" but there is no reason in principle why a RCT cannot measure more than one outcome. Similar considerations would apply to quantitative analysis of 'real world' data. Where the intention is to test and explain, a combined method, using both quantitative and qualitative methods is likely to be most appropriate.

Two elements of Criterion 2 could affect the generalisability of findings: the representativeness of the sample and the sample size. Similar challenges may affect other survey-based evaluations, but it

- 1. The main focus of the research is to test (but not explain) a hypothesised cause-effect relationship
- 2. A representative study population of a sufficient size can be obtained from the target population to whom the intervention would be applied
- 3. The intervention can be applied selectively to an experimental group within the study population
- 4. No other factors with a significant influence on the outcome would impact the experimental and control groups differently during the experiment
- 5. Wider application of the intervention would replicate the causal relationships which applied during the experiment

Table 1: Criteria for the use of experimental methods to inform policy (all must be satisfied)

may be more difficult to obtain volunteers for an experiment than respondents to a survey about something which was already happening.

Criterion 3 rules out using a RCT to assess something which has already been applied across the country. It effectively rules out measures which are introduced over specific geographic areas, unless the areas themselves become the unit of randomisation in a cluster RCT, in which case the second and fourth criteria would become much more onerous. Cluster trials applied to larger geographical areas, even where practically possible, could violate Criterion 4.

An analogous issue was considered by Sloman et al. (2010) in evaluating the Sustainable Travel Demonstration Towns, a three year VTBC programme in England. Although a RCT would not be possible (the towns were selected based on bids to government) the authors considered and rejected a quasi-experimental approach (comparing the demonstration towns to comparator towns) because the municipal leaders of comparator towns were likely to respond to the programme by making changes of their own. The existence of an experiment might also change the nature of interactions between external bodies, such as the national Department for Transport, and the two groups of towns: experimental and comparator.

Whether criterion No. 4 is satisfied or not would be difficult to prove in most situations: it would require a judgement on each occasion. The criteria proposed by Tavistock Institute and AECOM (2010) such as 'short timescales' and 'political

stability during the trial' may be considered judgements about the likely implications of such factors on this criterion.

As Goodwin (2011) has argued, the relationship between transport interventions and outcomes is generally characterised by synergies between measures, delayed and imperfectly reversible effects and feedback loops, both positive and negative. All of these factors affect Criterion number 5.

Circumstances where social norms or the actions of external bodies influence the behaviour under study would violate Criterion 5. Several studies have shown that perceived social norms do indeed influence modal choice in situations where VTBC might apply (e.g. Bamberg, 2003, Melia, In Press). Cluster trials might address this problem in some circumstances, but not all. To take the issue tested by Rowland et al. (2003) introducing travel plans in a handful of randomly distributed schools is unlikely to have the same effect on social norms around 'the school run' and active travel by children as a city-wide or national programme of school travel plans.

Criterion 5 will be more onerous where the experiment is used to estimate the quantitative impacts of an intervention. If an experiment demonstrates some change in behaviour, then it may be reasonable to draw conclusions about the likely direction of change from introducing similar measures as a wider policy: it would be less reasonable to estimate the magnitude of any change based on such findings.

One issue which illustrates these effects can be found in the literature on cycling

infrastructure. A number of studies of localised improvements in cycling infrastructure have found a limited, or no significant effect on overall cycling numbers, leading some to reject "the hypothesis that cycle use is suppressed by the absence of routes and networks" (Harland, 1993: a quasiexperimental before and after study, see also Brand et al., 2014). A meta-study based on 139 studies of infrastructure and policies designed to increase cycling found that cities which experienced large increases in cycling had all made substantial investments in cycling infrastructure, as well as a range of other policies (Pucher et al., 2010). The study concluded that infrastructure investment is an essential part of a "comprehensive approach", enhanced by synergies. One of these synergies relates to the growth over time of 'cycling cultures'. The relationship between procycling municipal policies, infrastructure improvements and the cycling culture of a city would be possible to investigate but difficult, if not impossible, to accurately quantify. If the synergies are as important as Pucher et al. suggest, then RCTs which attempted to quantify individual effects would yield misleading results. Following the criteria in table 1, they would also be unsuitable for testing the strength of such synergies.

The same argument applies to overall transport policy at national or municipal levels. Several studies – mainly descriptive – have suggested synergies between different policies (e.g. on road network design, parking policy, public transport and cycling) have contributed to the success of cities such as Freiburg in reducing the modal share of driving at a time when it was rising elsewhere (e.g. Melia, 2006). For investigating these types of multi-faceted policy issues, observation studies are likely to be the most appropriate method (discussed further in Tavistock Institute and AECOM 2010).

Jadad and Murray (2007) list over 20 forms of bias that can, and sometimes do, affect RCTs. One of these is 'choice-of-question bias'. Decisions over research objectives and questions may be influenced by vested interests, the personal agendas of researchers and/or constraints related to cost and convenience. This form of bias can affect any research project, but although RCTs are no more or less likely to

be affected, a methodological hierarchy, particularly where it is linked to public funding, is likely to exacerbate the problem. It would incentivise researchers to focus on narrow questions such as 'how does the construction of a few cycle paths in area x affect rates of cycling?' Evidence from such studies would then be given greater weight than the broader longer-term observation studies which suggest that networks of dedicated infrastructure can indeed increase rates of cycling.

Conclusions

Table 1 sets out the criteria for the generation of reliable findings from a RCT. (The word 'reliable' is used here to mean 'evidence which can be relied upon for policy' rather than its more specific definition in research terminology). Where a RCT entirely satisfies all five criteria it can be demonstrated from first principles that it will generate more reliable findings than other research methods. The discussion and examples suggest that such circumstances are likely to be rare in transport research. Whether RCTs which partially satisfy the conditions in Table 1 produce more reliable results than other methods is an empirical question: it cannot be demonstrated from first principles nor deduced by comparing research designs, as required by methodological hierarchies. To test which method more accurately quantified the impact of an intervention would require comparisons between results generated by RCTs and by other methods, in a context where the 'right answer' was known. As it is difficult to conceive of such a circumstance applying to a practical transport question, researchers choosing an appropriate methodology, and policymakers/advisors interpreting research evidence, must fall back on what Flyvbjerg (2001) calls phronesis, or 'practical wisdom'. Although it is not possible to demonstrate from first principles which method would generate more reliable findings, timescales of the cause-effect relationships, the importance of social and cultural influences on the target behaviour and similarities or differences between the experimental and policy target populations, are all relevant when assessing the relative advantages of experimental methods and non-experimental alternatives.

RCTs are likely to be more reliable in test-

ing whether a cause-effect relationship exists. The conditions required for generalising findings about the magnitude of such effects are more onerous. They are unlikely to apply in contexts where social and institutional influences on travel behaviour are significant, as in most VTBC programmes. Although the reasons for its recommendations are not always clear, Tavistock and AECOM (2010) provides a useful starting-point for researchers conducting transport impact assessments. They suggest that experimental methods are best suited to evaluating relatively straightforward small-scale interventions with a short time frame. This cannot be demonstrated from first principles but it is a reasonable response to the uncertainties discussed in this article.

What may seem a rather technical issue for researchers does have potentially important implications for transport policy. The UK national guidance on VTBC programmes in transport appraisals (DfT 2012) chose to follow a methodological hierarchy, giving greater weight to experimental findings. This effectively reduced public support for VTBC in the UK. As VTBC programmes are generally introduced in geographical areas or nationwide, the implication that experimental methods can more accurately quantify the impacts of VTBC programmes is, following the analysis in this article, misplaced.

This article has challenged the arguments in favour of evidence hierarchies and argued that the application of such hierarchies increases the risk of 'choice of guestion bias'. Several of the articles reviewed here assume but do not demonstrate that the RCTs they or others have conducted satisfy the criteria for generalisation. Some reasonable concerns have been expressed about the reliability of VTBC evaluations. Section 4 discussed some of the ways in which such concerns might be overcome, but ultimately all decisions about methodology and the implications of research findings rely on judgements. Evidence hierarchies create an incentive for researchers to make unwarranted assumptions about the generalisability of findings, creating an illusion of quantitative precision, misleading for policymakers.

Author details:

Dr Steve Melia PhD Senior Lecturer Centre for Transport & Society University of the West of England Coldharbour Lane Bristol BS16 1QY

Email:

steve.melia@uwe.ac.uk

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