**The Efficacy-Effectiveness Distinction in Trials of Alcohol Brief Interventions.**
**The Inaugural Nick Heather Lecture, 2013.**
**Prof. Nick Heather, Northumbria University**

INEBRIA International Network on Brief Interventions for Alcohol & Other Drugs

Nick firstly reviewed the results of three recent large-scale research projects into screening and brief interventions (SBI) in primary healthcare with null findings (van Beurden; SIPS; PRE-EMPT). These results have been disappointing to those who wish to see significant reductions in alcohol-related harm by means of the widespread implementation of SBI. Commenting on these findings, Richard Saitz has written that "researchers and educators should turn their attention to how to implement alcohol SBI in clinical practice in a way that retains the efficacy seen in clinical trials."

Nick noted that there is considerable inconsistency and confusion in the literature over the meanings of the terms 'efficacy' and 'effectiveness' trials, together with other terms such as 'implementation' and 'pragmatic' trials. He outlined the classic work of Brian Flay, who provided clear definitions of efficacy and effectiveness trials and outlined 8 phases of research for the development of health promotion programmes. Examining these phases, Nick concluded that the history of SBI research had not shown the orderly and logical progression suggested by Flay's and others' recommendations for phases of research. Further, he suggested that most SBI RCTs so far have not been true efficacy trials but more like effectiveness trials in Flay's terms.

Moving on to consider how effectiveness and efficacy were judged in the Kaner et al. Cochrane review of 2007, Nick noted that the scale that had been developed for this purpose showed that most trials in the SBI literature tended towards the effectiveness end of the efficacy-effectiveness dimension. This review concluded there was no difference between effect sizes reported by trials on either side of a median split on the efficacy-effectiveness scale. However, there were psychometric and other deficiencies in the development of this scale and Nick strongly recommended that, in any new meta-analysis of alcohol BI RCTs, these deficiencies should be corrected.

It was also possible that what was measured in the Cochrane review was 'clinical representativeness' which is a related but different concept to efficacy/effectiveness and this possibility too should be examined. However, Nick's guess was that this would not alter the main conclusion that most of the trials so far conducted in the SBI field have tended towards the effectiveness (or clinical representativeness) end of the spectrum.

**Conclusions:**

1. It is a mistake to go straight to effectiveness trials for new forms of SBI intended for different populations in different settings. Such research should begin with foundational research and development studies followed by efficacy trials before large-scale treatment and implementation effectiveness trials are mounted.
2. To properly interpret the findings of effectiveness studies, especially with null findings, it is necessary to ensure that interventions have been delivered as intended and as found to be beneficial in previous research.
3. Clear criteria are available in the literature to guide progress in movement from efficacy research, through effectiveness research, to dissemination in practice.
4. In future meta-analyses of alcohol BI trials, more attention should be paid to the development and application of a scale to measure efficacy-effectiveness.
5. In relation to the 3 'disappointing' findings:
    - The van Beurden et al trial strongly reinforces what we already suspect – that it is extremely difficult to get health professionals to deliver SBI;
    - The null findings of the SIPS trial cannot be attributed to a failure to translate effects from efficacy trials to real world practice because it seems likely that the majority of previous trials included in meta-analyses, upon which the benefits of Bi have been established, tended to be effectiveness trials
    - These null findings and those of the PRE-EMPT trial may be due to the lack of fidelity in the implementation of SBI in large, cluster randomised trials and this hypothesis should be urgently investigated.

Nick intends to publish a full paper on this presentation.

*Summary by Nick Heather based on draft by Niamh Fitzgerald.*