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Original Article

Pooling of effect estimates obtained from various study designs in systematic reviews of public health interventions: A Bayesian approach to meta-analysis

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ABSTRACT

Background: Randomised controlled trials (RCTs) are gold standard in assessing the effectiveness of a clinical intervention because of their high internal validity. However, the same does not hold true for interventions conducted at the population level like public health interventions. Well-designed RCTs are not easy to conduct at population level. Similarly, well planned, high-quality non-RCTs or observational studies can complement RCTs. Because of this, several systematic reviews of public health interventions are assessed with other study designs, namely non-RCTs and observational studies. In such situations, studies of similar study design are pooled together to obtain an overall effect estimate. This is inevitable, because the principle of meta-analysis does not offer an opportunity for combining effect estimates coming from various study designs. If the meta-analysis performed for each study design provides contrasting results, then this introduces a quandary for the decision makers and public health policy makers to call for a decision.

Objective: The present study aims to integrate the results coming from a variety of study designs in order to obtain a single estimate of effect of intervention.

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Methodology: Bayesian approach to meta-analysis was used by formulating prior distribution from observational studies or non-RCTs and likelihood function from RCTs. Five systematic reviews of public health intervention were used to demonstrate the methodology.

Results/conclusions: By formulating prior distribution from observational studies, the posterior estimates were found to be different than that from the results of RCTs or other study designs. The posterior pooled-estimate was found to be precise and the width of the credible interval narrowed. Inclusion of the relevant observational studies (or non-RCTs) in the systematic review is a potential advantage for evaluating the effectiveness of public health intervention.

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1. Introduction

Interventions, programmes and policies that aim at promoting health and preventing disease to a large number of individuals are defined as public health interventions.¹ These interventions are complex, context dependant and are assessed with a variety of study designs, ranging from observational studies to randomised controlled trials (RCTs). There has been increasing interest in the use of observational studies and non-randomised controlled trials (non-RCTs) in assessing the effectiveness of public health interventions.^{2–4} The strength of observational studies in relation to RCTs has been an ongoing debate in the evaluation methodology of public health among experts.⁵

Observational studies along with RCTs are included in many of the public health systematic reviews of interventions and programmes.^{6–10} For example, a systematic review that examined the effect of interventions that administered in the alcohol server setting for preventing injuries, included five before and after controlled studies, eight RCTs and ten non-randomised controlled trials (Non-RCTs).⁹ Similarly, a systematic review that evaluated the effectiveness of interventions to promote smoke alarms at resident included 17 RCTs and nine non-RCTs.¹⁰ In such situations, most of the systematic review authors have performed meta-analysis separately for each study design. This is true because the principle of meta-analysis does not offer an opportunity for combining effect estimates coming from various study designs.¹¹ Moreover, this results in several pooled effect estimates. What if the meta-analysis performed for each study design provides contrasting results? This introduces a quandary for the decision makers and public health policy makers to call for a decision.

Contrarily, there are a number of public health systematic reviews that have included only RCTs rather than observational studies (or Non-RCTs).^{12–15} This provides only partial evidence in concluding the effectiveness of public health programmes and interventions. It is, therefore, very useful to think of how best we can make use of a wide range of evidences available for answering the public health interventions. In this paper, we propose a method based on Bayesian approach to get a single summary estimate by incorporating effect measures coming from a variety of study designs. The idea is to build a prior distribution using evidence from observational studies or non-RCTs and likelihood function from RCTs.

Several studies have appeared in the recent years documenting the use of Bayesian meta-analysis in the systematic reviews of clinical or drug trials.^{16,17} But, to our knowledge, only one systematic review of clinical intervention was found, where prior distribution was formulated from observational studies,¹⁸ and no study was ever found, where this methodology been applied in evidence consolidation of public health intervention. Because of the inclusion of several study designs in public health interventions, we felt the methodology to be of great importance for evidence consolidation.

2. Methodology

2.1. Introduction to Bayesian meta-analysis

The Bayesian meta-analysis assumes that both the parameters and the data are random variables that follow a distribution. This is the main difference between Bayesian meta-analysis and traditional meta-analysis. The prior distribution and likelihood function are essential to perform Bayesian meta-analysis. The likelihood function is defined as the likelihood of the data given the parameters, that is, the effect estimates obtained from different studies will form the likelihood function.¹⁹ The prior belief that is built external to the observed data is considered to be the prior distribution. There are several ways of building a prior distribution, namely vague, sceptical, reference or subjective priors.¹⁹ The posterior distribution is obtained, by multiplying the likelihood function and prior distribution.²⁰ The resulting posterior distribution is summarised by means of computing posterior estimates and credible intervals. For example, a 95% credible interval (CrI) for relative risk is that region in which we believe that the relative risk lies with probability 0.95. The results of Bayesian meta-analysis will be similar to that of results of traditional meta-analysis, when vague prior distributions are placed on the parameters. Bayesian meta-analysis can be performed either by using Gaussian or exact binomial model. The analysis by Gaussian model can be performed for any outcome measure, as long as the effect size and its associated standard error are available from each study. Whereas, an analysis by the exact binomial model can be performed only when odds ratios are available from each study.¹⁹ In the present study, we used

Bayesian Gaussian random effects model by formulating prior distribution from observational studies (or non-RCTs) and likelihood function from RCTs. Public health interventions are often termed as complex interventions due to the complexity in terms of population, intervention, outcome and context. For this variation, a random effects model was used, because we expected heterogeneity across the included studies. More details of the adopted method are explained below.

2.2. Bayesian approach to meta-analysis using random effects model

The Bayesian random effects model is given by

$$Y_i \sim \text{Normal}(\theta_i, \sigma_i^2); \theta_i \sim \text{Normal}(\mu, \tau^2) \\ \mu \sim \text{Normal}(\mu_0, \sigma_0^2); \tau \sim \text{Uniform}(0, 10)$$

where Y_i is the effect estimates from i th RCT, μ is the pooled effect estimate or common overall population effect, τ_i is the between studies variability of the i th RCT.

The effect estimates Y_i are assumed to follow a normal distribution about their unknown true effects θ_i and the variances σ_i^2 are assumed to be known. These unknown true effects θ_i are assumed to be normally distributed about their common overall population effect μ and unknown between studies variances τ^2 . We assumed that μ follows normal prior distribution with mean and variance formulated from observational studies (or non-RCTs). Uniform vague prior distribution for τ with parameters 0, 10 was used.¹⁹ The posterior distribution was summarised by calculating posterior estimate and 95% credible interval.

The above mentioned methodology was applied to published public health systematic reviews of interventions, which consist of combinations of RCTs and observational studies (or non-RCTs) answering the same question and measuring the same outcome. Systematic reviews that included cross sectional studies were not considered. Effect estimates targeted were mean difference (MD), relative risk (RR), odds ratio (OR) and standardised mean difference (SMD). Electronic databases such as Cochrane Database of Systematic Reviews, Medline and PubMed with a combination of keywords, namely “public health interventions”, “randomised controlled trials”, “non-randomised controlled trials”, “cohort studies”, “systematic reviews” and “meta-analysis” were used. Results of traditional random effects meta-analysis as well as Bayesian approach to meta-analysis are reported. All the analyses were performed in WinBUGS 1.4.3 software using Markov Chain Monte Carlo (MCMC) simulation method.²¹ Convergence was assessed using auto-correlation and Gelman-Rubin convergence plots. Observational studies (or non-RCTs) are often regarded as more biased than that of RCTs; hence, we also reported the risk of bias in the included studies as assessed by the systematic review author of the published article.

3. Results

Five published public health systematic reviews of interventions were included to demonstrate the methodology. Table 1 shows the details of the systematic reviews used for demonstration. Interventions were of a wide variety for

Table 1 – Details of included systematic reviews used for demonstration.

Title of systematic review	Participants	Intervention	Comparison	Outcome (effect size)	Number of studies/study design
Psychosocial and psychological interventions for treating postpartum depression	Women with depression	Psychological and psychosocial interventions	Usual care	Risk of depression (RR)	6 RCTs 2 Non-RCTs
The effect of multivitamin/mineral supplements on age-related cataracts: a systematic review and meta-analysis	Adults	Mineral or multivitamin supplements	No supplementation	Risk of nuclear cataract (RR)	2 RCTs 5 Cohort studies
Parenting interventions for the prevention of unintentional injuries in childhood	Parents of children less than 18 years	Parenting interventions	No parenting intervention	Risk of injuries (RR)	9 RCTs 2 Non-RCTs
Home safety education and provision of safety equipment for injury prevention	Children and young people and their families	Home safety interventions	No home safety interventions	Possession of functional smoke alarm (OR)	13 RCTs 4 Non-RCTs
Food supplementation for improving the physical and psychosocial health of socio-economically disadvantaged children aged three months to five years	Children aged three months to five years	Supplementary feeding	No supplementary feeding	Weight gain (MD)	7 RCTs 6 controlled before after studies

RR: relative risk; OR: odds ratio; MD: mean difference; RCT's: randomized controlled trials; non-RCT's: non-randomized controlled trials.

Table 2 – Results of Bayesian approach to meta-analysis and traditional meta-analysis.

Outcomes	Study design	Sample size	Random effects model			
			Traditional meta-analysis	Bayesian approach to meta-analysis		
				Prior distribution	Posterior distribution	
			Pooled estimate with (95% CI)		Posterior estimate with (95% CrI)	Posterior between study variance with (95% CrI)
Risk of depression (RR)	RCTs	329	0.78 (0.66, 0.93)	$\mu \sim N(-0.71, 0.18)$	0.72 (0.44, 0.93)	0.14 (0.0001, 0.91)
	Non-RCTs	226	0.49 (0.21, 1.13)	$\tau \sim U(0,10)$		
Risk of nuclear cataract (RR)	RCTs	3161	0.76 (0.50, 1.15)	$\mu \sim N(-0.30, 0.04)$	0.74 (0.66, 0.83)	0.86 (0.0003, 5.73)
	Cohort	13,637	0.74 (0.65, 0.83)	$\tau \sim U(0,10)$		
Risk of injuries (RR)	RCTs	5516	0.82 (0.72, 0.93)	$\mu \sim N(-0.21, 0.02)$	0.81 (0.69, 0.92)	0.02 (0.00001, 0.15)
	Non-RCTs	368	0.81 (0.62, 1.04)	$\tau \sim U(0,10)$		
Possession of a functional smoke alarm (OR)	RCTs	4276	2.21 (1.43, 3.41)	$\mu \sim N(0.16, 0.04)$	1.48 (1.04, 2.02)	0.82 (0.06, 2.87)
	Non-RCTs	831	1.17 (0.80, 1.73)	$\tau \sim U(0,10)$		
Weight gain (MD)	RCTs	910	0.11 (0.04, 0.18)	$\mu \sim N(0.18, 0.01)$	0.12 (0.05, 0.21)	0.001 (0.00004, 0.26)
	CBA's	722	0.18 (-0.03, 0.39)	$\tau \sim U(0,10)$		

RR: relative risk; OR: odds ratio; MD: mean difference; μ : overall pooled effect estimate; τ : between study standard deviation; N: normal distribution; CI: confidence interval; CrI: credible interval; RCT: randomized controlled trials; non-RCT's: non-randomized controlled trials; CBA: controlled before after studies.

example, psychosocial and psychological interventions, mineral or multi-vitamin supplements, provision of safety equipment's and home safety education, parenting interventions and food supplementations. Four systematic reviews had included RCTs with non-RCTs^{7,22–24} and one systematic review included RCTs with cohort studies.²⁵ One systematic review reported odds ratio as the summary measure,²³ three systematic reviews reported relative risk^{22,24,25} and one reported mean difference.⁷ RCTs were larger in number and had a larger sample size than that of non-RCTs, except, for the outcome on 'risk of nuclear cataract', for which the cohort studies had four times larger sample size than that of RCTs. In Table 2, we report the results of traditional meta-analysis and Bayesian approach to meta-analysis.

3.1. Risk of depression

Dennis et al.²⁴ included six RCTs and two non-RCTs that assessed the effectiveness of psychological and psychosocial interventions in reducing the risk of postpartum depression as compared to usual care. The pooled results from RCTs concluded that the intervention is effective 0.78 (95% CI 0.66, 0.93), whereas the results of non-RCTs showed no effect 0.49 (95% CI 0.21, 1.13) as shown in Table 2. The posterior pooled RR and 95% credible interval obtained from Bayesian approach to meta-analysis was found to be 0.72 (95% CrI 0.44, 0.93) indicating that psychological and psychosocial interventions reduces the risk of postpartum depression among women as compared to usual care.

3.2. Risk of nuclear cataract

Two RCTs and five cohort studies examined the effectiveness of use of mineral or multivitamin supplementation, with no supplementation in reducing the risk of nuclear cataract among adults.²⁵ Meta-analysis of cohort studies showed that the intervention is effective in reducing the risk

of nuclear cataracts whereas the meta-analysis of RCTs were found to be ineffective (Table 2). When prior distribution was formulated from cohort studies and likelihood function from RCTs the posterior pooled RR was found to be 0.74 (95% CrI 0.66, 0.83).

3.3. Risk of injuries

Kendrik et al.²² included nine RCTs and two non-RCTs that assessed the effectiveness of parenting interventions in reducing the risk of injuries as compared to no parenting intervention among children. A similar conclusion was obtained based on meta-analysis of RCTs and that of non-RCTs (Table 2). The results of Bayesian meta-analysis showed that parenting interventions were effective in reducing the risk of injuries among children [RR = 0.81 (95% CrI 0.69, 0.92)].

3.4. Possession of functional smoke alarm

Kendrick et al.²³ studied the effectiveness of home safety interventions in increasing the number of families with functional smoke alarm. Non-RCTs revealed that there was no effect of home safety interventions 1.17 (95% CI 0.80, 1.73) whereas RCTs were found to be effective 2.21 (95% CI 1.43, 3.41). The Bayesian meta-analysis proposed revealed that home safety interventions are effective in increasing the number of families with functional smoke alarm. The posterior odds ratio was found to be 1.48 (95% CrI 1.04, 2.02).

3.5. Weight Gain (cm)

Effectiveness of food supplementations in increasing weight gain among children was examined by seven RCTs and six controlled before after studies.⁷ Although controlled before after studies were proven to be ineffective 0.18 (95% CI -0.03, 0.39) and RCTs as effective 0.11 (95% CI 0.04, 0.18) while prior distribution was formulated by non-RCTs and included with

RCTs, the overall results were shown to be effective [posterior pooled MD = 0.12 (95% CrI 0.05, 0.21)].

In all the above-demonstrated systematic reviews, even though contradictory results were obtained from each study design, Bayesian approach to meta-analysis was successful in obtaining a single pooled estimate of effect of intervention. This single pooled effect estimate was obtained from the combination of two different study designs. Upon a careful observation, the posterior estimates were dominated by the studies with larger sample size; additionally they were precise.

3.6. Risk of bias in the demonstrated systematic reviews

All the five systematic reviews that included RCTs were assessed using the Cochrane risk of bias tool to assess the risk of bias. Similarly the non-RCTs were assessed with modified Cochrane risk of bias tool. In case of the outcome 'Risk of Nuclear cataract', the cohort studies were assessed using 'Newcastle-Ottawa Scale for Quality Assessment'. We found that all the RCTs included were of unclear or low risk of bias, non-RCTs were of low risk of bias and Cohort studies were of high quality.

When the number of included studies were less we found that convergence was not attained for the heterogeneity parameter but was reached for the posterior pooled estimate. To make sure that convergence was attained for the posterior pooled estimate, we ran two chains along with 20,000 iterations burning the sampler and 10,000 iterations used for estimation.

4. Discussion

Randomised controlled trials are gold standard in assessing the effectiveness of a clinical intervention because of their high internal validity.²⁶ However, the same does not hold true for interventions conducted at the population level like public health interventions. Well-designed RCTs are not easy to conduct at population level. Few of the RCTs published to date conducted at population level have limitations (in terms of risk of bias). Consequently, well planned, high-quality non-RCTs or observational studies can complement RCTs or address some of their limitations.³ Because of this, several public health systematic reviews of interventions are evaluated with other study designs. In such situations, studies of similar study design are pooled together to obtain an overall effect estimate. Suppose, if the meta-analysis performed produces contrasting results, then this introduces a quandary for the decision makers and public health policy makers to call for a decision. The present study aims to integrate the effect estimates coming from a variety of study designs in order to obtain a single estimate of effect of intervention. Two different sources of evidence were combined together with the help of Bayesian principle.

To the best of our knowledge, this is the first attempt to apply the proposed methodology to a set of five different public health systematic reviews of interventions. All the outcomes included had evidence coming from only two study designs, either RCTs with non-RCTs or RCTs with cohort studies. This methodology of building prior distribution from observational or non-RCTs and likelihood function from RCTs was successful

in obtaining a single posterior pooled estimate and more importantly obtained an interval for the between study standard variance. This estimate obtained from the analysis was found to be precise and narrow. In case of two outcomes 'risk of nuclear cataract and odds of having functional smoke alarm', we found that the interval of between study standard variance was upwardly biased. This was observed because of the actual between studies variance was close to zero, and that the MCMC will result in biased interval. In case of the outcome 'risk of age related cataracts', RCTs showed that vitamin supplements were not beneficial for decreasing the risk of age-related cataracts 0.76 (95% CI 0.50, 1.15); however, cohort studies showed a contrasting result 0.74 (95% CI 0.65, 0.83). Bayesian approach to meta-analysis revealed that vitamin supplements decrease the risk of related cataracts among adults 0.74 (95% CrI 0.66, 0.83).²⁵ This shows the importance of including evidence from other study designs rather than concluding based on only RCTs. Suppose the systematic review authors had not included the evidence from cohort studies, they could have concluded that vitamin supplementation does not reduce the risk of cataracts.

The approach of building prior distribution from observational studies was first introduced by Sutton et al. in 2001 and labelled it as 'naïve prior distribution'. The authors suggested that if the evidence from observational studies is as reliable as the RCTs, then one can formulate prior distribution from observational studies and likelihood from RCTs. Later, this methodology was demonstrated to find the association of use of bisphosphonate and occurrence of atrial fibrillation.¹⁹ Similarly, a network meta-analysis was used to integrate non-RCTs with RCTs in the study to assess the effectiveness and safety of medical interventions.²⁷ We found that no study earlier applied the proposed methodology, in public health systematic reviews of interventions. Hence, we felt this methodology have a lot of scope in public health evidence synthesis due to the inclusion of wide variety of study designs.

5. Conclusion

The current study attempts to consolidate all quantitative evidences to derive a single effect estimate in public health interventions using Bayesian approach to meta-analysis. This methodology is unique in the area of public health evidence synthesis. By formulating prior distribution from observational studies, the posterior estimates were found to be different than that from the results of RCTs or other study designs. The posterior pooled estimate was found to be precise and the width of the credible interval narrowed. Inclusion of the relevant observational studies (or non-RCTs) in the systematic review is a potential advantage for evaluating the effectiveness of public health intervention. The proposed methodology is applicable for any systematic review of public health intervention that includes more than one study design for a single outcome.

Conflicts of interest

The authors have none to declare.

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