DISCUSSION
Chapter 10

Discussion

The word complexity and public health interventions go hand-in-hand. They are multi-faceted interventions which seek a grass root delivery to a vast heterogeneous population and comprise a bundle of activities, where it may not be possible to separately study the influence of individual components. The details of complexity in public health interventions has been expatiated in section 1.7. Complexity is an important aspect which renders the results of a public health intervention not generalizable.\textsuperscript{16} Systematic reviews and meta-analysis mark the current vogue in health care evidence synthesis. The evidence generated by them is considered to be superior to that of any other study design.\textsuperscript{370} Systematic reviews and meta-analysis cater to the evidence needs of all major health care decisions including health care policies and programmes. The complexity is more likely to mask the true effect in meta-analysis of public health interventions and thus behaves as a barrier for the meta-analysis of such interventions.\textsuperscript{17} Several international organizations like Cochrane collaboration (www.cochrane.org), Medical Research Council (MRC), UK (www.mrc-bsu.cam.ac.uk) and others have been engaged in extensive research activities to develop appropriate methods to handle the complexity in systematic reviews of public health importance. The present investigation demon-
strates an alternate approach for pooling the results of public health interventions, which comprises measuring the complexity in public health interventions by a tool and incorporating the measurement in meta-analysis to obtain the pooled estimate which is adjusted for complexity.

A qualitative study “Complexity in Public Health Interventions - Stakeholders’ Perspective: A Qualitative Analysis” provided a deeper understanding of the concept of complexity in public health interventions. Views of stakeholders about complexity are diverse and all of them consider it to be a serious concern. Population characteristics, multi-component intervention, numerous outcomes and contextual factors jointly contribute complexity. One of the important responses about context is that it hinders the applicability of findings of a public health intervention study in other contexts or populations. This tallies with the observation made by Belinda et al in their article “Assessing the applicability of findings in systematic reviews of complex interventions can enhance the utility of reviews for decision making”. The major consequence of complexity is that, it causes difficulties in assessing whether the intervention is really acting in the way that it was supposed to. Other consequences include lack of generalizability of intervention and failure to obtain desired data leading to the conclusion of poor effectiveness of intervention programme. Noyes et al and Anderson et al also have a similar observation. Petticrew et al agree to the research question being complex and Squires et al recommend a strong logical frame work for its formulation.

Tool to measure complexity in public health interventions was developed focusing four primary domains of complexity namely population, intervention, context and outcome. Items included in the tool were derived from three sources namely (1) Theories deduced from qualitative study (2) Meticulous examination of published public health interventions and (3) Expert opinion. The scoring pattern was set for each item based on its importance and number of options such that a higher
score reflects a higher complexity. Scores of all items of the domain were added to obtain domain specific complexity scores and addition of complexity scores of all four domains presented the total complexity score for the study. Guidelines for assessing complexity and allocated scores for each domain have been illustrated in section 6.2. There is no upper limit for the total score. The domains of population and outcome had good reliability (ICC with 95% CI) of 0.85 (0.71, 0.93) and 0.81 (0.66, 0.91) respectively, whereas the intervention domain had a moderate reliability of 0.74 (0.55, 0.88). This moderate reliability is because some of the authors of primary studies did not mention clearly about the number of components in the intervention. This resulted in discrepancy among the raters in deciding the components and subcomponents. Context domain had least reliability amongst the four domains, which is 0.43 (0.17, 0.69). This is due to the fact that most of the authors did not disclose adequate information about the contextual factors in their publications leading to subjective assessment of the context. This resulted in a moderate overall reliability of the tool, which was 0.69 (0.47, 0.85). Spreckelsen in his article on “Additional requirements for complex interventions” appeals for the authors to report the details of delivery of intervention, participant compliance and context of implementation in addition to the intervention design in their primary studies involving complex interventions. Streiner et al state that for a scale that is meant to measure a heterogeneous characteristic, it is conceivable to have a low reliability provided it is valid in terms of its content.

Using the developed tool domain specific and overall complexity of 259 public health interventions were measured and these scores are presented in table 7.1. The tool has the flexibility to measure new studies and incorporate diverse interventions. Overall score increases as the complexity increases. The tool is fairly sensitive to all domains of the study. The minimum and maximum total score obtained from these studies were 16 and 88. Intervention domain is the major
contributor for the overall score. Complexity scores of context domain were found to be low in all studies.

Table 7.2 shows the details of the systematic reviews from which the studies were retrieved. It can be noted from the table that for different studies addressing same question have varying complexity. For instance, the studies with sl.no 1 - 17 are from the systematic review “Behavioural interventions to reduce risk for sexual transmission of HIV among men who have sex with men”.339 Even though studies focussed on the same objective, their complexity scores vary from 22 to 88. Hence pooling these studies without considering complexity measure could be misleading. Similarly the complexity score among studies in the systematic review “Interventions to prevent obesity in children” ranges from 20 to 73 and so on.102 This substantiates the fact that if complexity is measured and adjusted in meta-analysis, it will provide a more reliable pooled estimate of effect size.

From the distribution fitting exercise, lognormal distribution was found to be the best fit for total complexity score. Squires et al30 claim that complexity is created by “nonlinear causal pathways between intervention and outcome”. This can happen when the components of the intervention interact in a multiplicative manner. Lognormal distribution is an ideal fit for a situation when a large number of factors influence the characteristic in a multiplicative manner.371

A composite dynamic index was constructed as a weighted linear combination of standardized complexity scores to rank the studies according to their complexity status. Each of the domains received a weightage which varied inversely as the standard deviation of their scores. This prevents large variation in any one of the domains from undermining the contribution of other domains. The indices and their ranks speak about the relative position of different studies in terms of their complexity. An attempt was made to classify the studies into four classes namely of complexity namely very highly complex, highly complex, moderately complex
and least complex based on their complexity score in order to enable easy inter-
pretation. The fundamental idea was that, as the scoring pattern of the tool was
set in direct proportion to complexity (higher the score, higher the complexity),
the studies may be classified into four classes of complexity on the basis of quartile
classification points of the distribution of total complexity score as; the studies
with total complexity score lesser than first quartile belong to least complex class,
studies with total complexity score between first and second quartile belong to
moderately complex class, those with scores lying between second and third quar-
tile may be classified as highly complex and finally studies with total complexity
score greater than the third quartile may be referred to as being very highly com-
plex. However, classifying the studies on the magnitude of total complexity score
would be misleading as the relative contribution of the four domains towards the
total complexity score is not equal. Therefore analogously, beta distribution which
is positively skewed and assumes the values in the range 0 to 1 was fitted to the
values of the index and studies were classified into four classes on the basis of corre-
sponding fractile classification points. From table 8.2, it is interesting to note that
the context domain received least weightage amongst the four domains (19.31%),
indicating that it is the most variable domain.
Meta-regression technique was employed to adjust the measured complexity in
meta-analysis. Borenstein et al quote that “meta-regression follows the same ap-
proach as simple/multiple linear regression except that the dependent and inde-
pendent variables are measured at the unit of study rather than at the level of
subject”.\textsuperscript{8} It is one of the effective approaches to determine the relationship be-
tween study level covariates and the effect estimates of studies included under
meta-analysis. In the present study, the pooled estimate adjusted for complexity
was obtained as the estimate of intercept after centering the complexity score at its
median (subtracting the median complexity score of all studies from the complex-

ity score of each study included under meta-analysis). It was observed that meta-
regression changed the estimates and complexity adjusted estimates had wider
95% CI than unadjusted estimates (Table 9.16). In addition, both the I-squared
statistic and Tau-squared of the adjusted estimates were higher than that of the
unadjusted estimates in almost all of the 15 analyses (Table 9.17). For instance, in
case of the outcome “Self reported physical activity at 12 months (dichotomous)”,
the unadjusted estimate with 95% CI from meta-analysis was found to be 1.37
(1.05, 1.79), $I^2 = 68\%$ and $\tau^2 = 0.11$, whereas from meta-regression, the adjusted
estimate was found to be 1.41 (0.94, 2.13), $I^2 = 70.72\%$ and $\tau^2 = 0.15$. Simi-
larly, for the outcome “Glycaemic Control”, unadjusted estimate was -0.16 (-0.50,
0.18), $I^2 = 66.70\%$, $\tau^2 = 0.17$ whereas, adjusted estimate was -0.04 (-0.50, 0.42),
$I^2 = 67.84\%$, $\tau^2 = 0.20$. Sensitivity analysis was executed by computing adjusted
and unadjusted estimates sans the study with extreme (maximum/minimum) com-
plexity score. It was observed that the adjusted estimates are not sensitive to the
extreme scores (Table 9.18). This can be attributed to the fact that the indepen-
dent variable i.e., the complexity score is being centered at median, which is not
sensitive to extreme observations. However, the estimates adjusted for complexity
are highly sensitive to the median complexity score, which is most likely to belong
to either highly complex or moderately complex class.

## 10.1 Comparison with other approaches to deal
with complexity in public health interven-
tions

Other tools to deal with complexity in systematic reviews of public health inter-
ventions are iCAT - SR, CerQual and TiDier. Intervention Complexity Assessment
Tool in Systematic Reviews (iCAT - SR) is an initiative of Methodological Investigation of Cochrane Reviews of Complex Interventions (MICCI) project, funded by Cochrane Collaboration Methods Innovation Fund (MIF). Main aim of the tool is to aid in disaggregating intervention components and their delivery. It also involves rating interventions across a set of 10 ‘dimensions’ that are identified as pertinent in assessing complexity and mapping the dimensions to understand the complex framework to (1) Systematize data extraction on the key components of the complex interventions to inform analysis, interpretation and reporting, (2) Group interventions in reviews according to their complexity (3) Explore and understand heterogeneity and to inform subgroup analysis and (4) Facilitate the development of logic models within reviews. CerQual - Certainty of the Qualitative Evidence was also initiated under MICCI project. This approach finds its utility in reviews which encompass qualitative evidence synthesis. It evaluates the strength of evidence in systematic reviews of complex interventions which involve qualitative synthesis in terms of four levels of certainty or confidence namely high confidence, moderate confidence, low confidence and very low confidence. Ti-Dier - Template for Intervention Description and Replication serves as a checklist and guide to facilitate better reporting and replicability of complex interventions. The 12 item checklist was developed by TiDier steering committee comprising an international panel of experts and stakeholders established in collaboration with CONSORT steering group. However, none of the above mentioned three tools offer a numerical measurement as PHESA complexity tool.

10.2 Importance of the study

Advancement of policies/programmes in health system particularly involving public health dimensions is an iterative process. It involves gathering evidence, im-
implementing the programme and then evaluating once again to see its impact to inform what the design of fresh intervention needs to be. It requires strong evidence to decide on the correct type of policy to be adopted. Systematic reviews and meta-analysis are known to produce highest level of evidence. However complexity of public health interventions adds difficulty in pooling results and creating the summary evidence. The present study demonstrates a new mechanism of pooling the quantitative results of public health interventions, which involves measuring the complexity in public health interventions and incorporating the measured complexity score in meta-analysis. This is likely to open up a new dimension of meta-analysis for complex community level interventions and provide more refined evidence. It will serve as a platform to make use of available literature to identify and consolidate the most effective intervention.

10.3 Strengths of the study

1. The present study which involves measuring the complexity and incorporating the measured complexity in meta-analysis is unique and first of its kind.

2. Tool to measure complexity in public health interventions is based on a strong theoretical framework with theories deduced from a qualitative study. In addition, the items of the tool were also derived from observation of studies and expert opinion. Feedback was collected from seven experts for content validation and reliability of the tool was determined by applying it to assess complexity of large number of studies independently by three raters.

3. The tool was applied to assess complexity of a very large number of studies included in a range of diverse public health systematic reviews and the statistical properties of the complexity score were explored.
10.4 Limitations of the study

Limitations of the study are listed below;

1. Even though, the PHESA complexity tool includes most of the items to capture complexity in four major domains, it lacks items to account for the duration of intervention, type of intervention and intensity of intervention.

2. The overall reliability of the PHESA complexity tool was found to be moderate. Context domain had low reliability.

3. The tool was validated only for its content. It was not subjected to criterion validation and construct validation.

10.5 Recommendation for further research

Following are some recommendations for future research;

1. Tool has a good potential for improvement. Adequate modifications could be brought about to the tool to ensure that it has high overall reliability. Specifically, the context domain should be subjected to a major amendment.

2. Sophisticated statistical techniques such as non-linear meta-regression could be employed to adjust the complexity score in meta-analysis.

3. A statistical package could be developed which on entering the data for meta-analysis and corresponding complexity score, directly provides the estimate adjusted for complexity.