1 Effect of integrated health system leading-managing-and-governing for

2 results model on institutional delivery: Team-based quasi-experiment

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13 Abstract

14 **Objective:** The objective of this study is to examine, based on theory of change, whether 15 integrated leading-managing-and-governing for results model is plausible cause of improved 16 institutional delivery.

17 Methods: A team-based quasi-experimental study was conducted. One-hundred-thirty-four 18 health facility teams were enrolled in the study. Teams were allocated to intervention and 19 control groups in a 1:1 ratio, non-randomly. End line institutional delivery was the dependent 20 variable while the group (main predictor) and the baseline institutional delivery (covariate) 21 were independent variables. The intervention that was given over six months was integrated 22 leading-managing-and-governing for results model. The institutional deliveries were 23 measured with percentages whilst the group was measured with exposure status (yes or no) to 24 the intervention. Data, from both groups, were collected at baseline and end line. Data were 25 analyzed using analysis of covariance. Statistical significance was determined at (p<.05). The main effect of the intervention was determined by 95% CI, presented in the contrast results. 26

Results: The adjusted mean institutional deliveries with 95% CI were 47.4 (46.2, 48.6) and 33.4 (32.2, 34.6) in the intervention and control groups, respectively. Contrast results showed that having an intervention group, p = .000, 95% CI (12.2, 15.8), of integrated leadingmanaging-and governing for results model significantly increased mean institutional delivery compared to having a control group.

32 **Conclusions:** This study provides some guidance regarding the plausible causation of 33 integrated leading-managing-and-governing for results model on institutional delivery. It 34 would serve as a baseline in identifying true causation using a randomized design.

35 Key Words: Effect, ILMG for Results Model, Institutional Delivery, Quasi-Experiment

37 Introduction

Strong health system is required to address global concerns such as Universal Health Coverage (UHC)[1,2]. To realize this, six critical health system building blocks are identified[3,4]. This includes service delivery, health workforce, medical products, health information systems, healthcare financing, and leadership and governance. But, leadership and governance is remained the most challenging to measure, particularly in Low and Middle-Income Country (LMIC) health systems[5,6]. Perhaps, it might be due to lack of scientifically reliable and empirically scalable practices.

Despite this challenge, Integrated Leading-Managing-and-Governing (ILMG) for results model (**Fig 1**), centered in the leadership development program, has been employed over 50 LMIC health systems including Ethiopia[5,6]. Mainly, this has been implemented as a pilot project through the technical support and budget aid from international organizations like Management Science for Health (MSH), John Snow Inc. (JSI) and United States Agency for

50 International Development (USAID)[3,7].

51 Fig 1. Conceptual model: ILMG for results (Source: MSH, 2015)

52 In fact, in the beginning, the model held only integrated leading and managing practices[7-9].

53 But, a decade later, it holds the current structure (Fig 1) through incorporating governing

54 practices[3,10]. Additionally, using factor analysis technique, the current authors reported

55 four integrated latent factors of the three paths[10]. These are compliance with principles,

56 strategic sensitivity, system building and contextual thoughtfulness. Such findings strengthen

- 57 the challenging characteristics of measuring the leadership and governance building block.
- 58 The model (Fig 1), particularly in Ethiopia, is applied in the USAID transform primary
- 59 health care project health facilities, with a goal of ending preventable maternal mortality.

Away from its enormous expansion, only limited studies report the effect of the model on improved health system performance and sustained health outcomes[6,8,9,11]. The studies done in Kenya, Egypt and Mozambique reported that applying the model increased 10%, 41% and 10% average coverage rate on selected health-service delivery indicators. However, the latter two studies were done retrospectively for evaluating pilot projects[9,11].

65 On the contrary, the study done in Afghanistan reported that there was no statistically 66 significant effect of the intervention on health system performance[12]. Rather, it showed that 67 many indicators worsened in the intervention group.

68 Generally, the previous studies lack either using control group[9,11] or controlling plausible69 confounding factors[8,9,11,12].

70 Thus, researching the effect of any initiative led by Theory of Change (ToC) and using rigorous methodology would be important in generating better evidences[13,14]. ToC refers a 71 72 systematic and cumulative study of the links between input, activities, output, outcome and 73 context of the initiative[14]. There are three identified attributes to achieve the potential of 74 ToC on initiatives: plausibility, doablity and testability [13,15]. Plausibility refers whether 75 activities implemented should lead to desired outcomes; doablity is about availability of all 76 resources to carry out the initiative, and testability explains presence of specific and complete 77 ToC to track its progress in credible and useful ways. Moreover, the research done in Kenya 78 acknowledged that using research outcome of interests that varied from team to team lead the 79 analysis to focus on average coverage or service volume rather than on specific indicators[8]. 80 To avoid this, they recommended focusing on either teams addressing the same indicator or a 81 set of related indicators.

Therefore, this study aims at examining the effect of the ILMG for results model on Institutional Delivery (ID) using a prospective pre–post intervention no-treatment control group team-based[16] quasi-experimental study. Quasi-experiment is an empirical study design used to estimate the plausible causal impact of an intervention on its target population without random assignment[17,18]. The findings of this study would support evidence-based leveraging of the model at all levels that is either scale-up or re-design it; as well as serve as a baseline for future research.

89 Methods

90 Study design and teams

91 A prospective pre-post intervention no-treatment control group team-based quasi-experimental 92 study was conducted. One-hundred-thirty-four health facility teams were enrolled in the study. 93 These teams were allocated to intervention and control groups in a 1:1 ratio, non-randomly. 94 Integrated leading-managing-and-governing for results model was given to the intervention 95 group. Yet, the control group was followed without any intervention. Moreover, teams were 96 intact and worked together over the intervention period.

97 Intervention

98 The ILMG for results model was delivered over six-month period. Based on the intervention

99 protocol (S1 appendix), basic concepts that enable the teams to face challenges, and achieve

100 results were transferred with two consecutive off-site three-day workshops.

101 During the first workshop, the main task that the teams carried out was developing six-month

102 project on ID using a tool called the Challenge Model (CM)[3,9] (*Fig 2*).

Fig 2. The challenge Model (Source: Mansour M et al, 2010)

104 The activities, elements of the CM, that the teams worked step-by-step were: reviewed their

105 respective facility mission; set a shared vision in lined with facility vision; developed six-

month Measurable Result (MR); assembled current situation (baseline); identified obstacles
and root causes[19-21]; developed inspirational challenge statement by combining the MR
and obstacles; and designed priority actions to avert obstacles. Moreover, they identified
potential stakeholders to align and mobilize resources for better result.

110 With all the above activities done, the teams were sent back to their respective working place,

111 taking an assignment of sharing and validating the project with the other staff and key 112 stakeholders. Additionally, teams were encouraged to exercise the ILMG for results model.

After average period of one-month, the teams were called back for the second workshop. It 113 114 was began with presentations and discussion on the validated projects. Furthermore, teams 115 were facilitated to develop action plan and monitoring and evaluation (M&E) plan using 116 respective planning formats (S2 and S3 Appendixes). Moreover, concepts of coaching using 117 Observe, Ask, Listen, Feedback and Agree (OALFA) technique; communication using 118 effective model (S4 Appendix); managing facility resource and health services delivery were 119 presented and discussed. By the end of the third day, the teams were sent back to their 120 respective working place for the actual implementation of their projects.

121 Another-month after, based-on the OALFA technique, the facilitators including the 122 investigators did on-site coaching visit for each team. Facilitators were certified experts for 123 integrated leadership-management-and governance Trainer of Trainees (TOT), from the 124 Ethiopian federal ministry of health. Participatory, enquiry-based and practice-oriented 125 facilitation approaches were employed. In addition, brainstorming ideas, insight-invoking 126 questions, role-plays, group discussion, case studies and work place assignments were also 127 used. Moreover, concise and comprehensive notes, tables and figures were distributed to 128 teams as needed.

129 Variables and measuremnts

The Dependent Variable (DV) was the end line ID while the main independent variable was the group. Another independent variable, the baseline ID that had an influence on the DV was considered as a covariate. Regarding to measurements, both the baseline and end line institutional deliveries were measured with percentage means. The groups were measured with exposure status (yes or no) to the intervention.

135 **Data collection and analysis**

The baseline and end line data were collected from teams of each group. Before getting to the final analysis, five stages of data analyses were conducted. These were done using the statistical package for the social sciences version 20. First, descriptive analysis was done to characterize the ordinary mean ID. Second, assumptions of no presence of significant outliers and approximately normally distributed data for each group were assessed by boxplot and Shapiro-Wilk test.

Third, in the absence of the covariate, the effect of the group on the DV was tested using Analysis of Variance (ANOVA). The output indicated significant result: F (1,132) = 79.0, partial eta squared = .37, and p < .001. Partial eta squared measured the proportion of the total variance (effect size) on the DV that is associated with the membership of different groups defined by a group[22]. For example, the above output showed that the group (intervention and control) accounted for 37% of the variability on the DV.

Fourth, group-covariate interaction effect was checked using custom model of Analysis of Covariance (ANCOVA). It tested differences between group means when we knew that an extraneous variable affected the outcome of interest[23,24]. Observing at the p-value of the analysis output: F (1,130) = 1.6, partial eta squared = .01 and p = .21, it was obvious that the 152 covariate was not significantly predicted the DV. The other important output displayed from 153 this analysis was the result of Levene's test: F (1, 132) = 58.5 and p = 000. It indicated that 154 the group variances were not equal and hence the assumption of homogeneity of variance was 155 violated. This further showed that we failed to reject the null hypothesis in that there was no 156 group by covariate effect on DV. Alternatively, the covariate had the same correlation with 157 the DV for both intervention and control groups; and the correlation between the covariate 158 and DV was while they differ for intervention and control groups. Precisely speaking, there 159 was no Lord's paradox [24-26]. Fifth, the effect of the group on the covariate was also tested 160 using ANOVA. The output presented that the group was not significantly predicted the 161 covariate: F(1,132) = 2.8, partial eta squared = .02, and p = .09.

162 Considered the above outlooks, ANCOVA with full factorial model was conducted to 163 evaluate the main effect of the group on DV. The 95% CI from the contrast results was used 164 in determining the main effect of the intervention. From this output, two things were 165 considered: (1) did significant value less than .05, and (2) did not the CI include zero.

The CI here was the difference between means, the original means adjusted for the covariate that showed the likely value in the population. In reality, if the difference between means is zero, then it tells there is no difference between the groups. If the CI does not contain zero, it means that the effect in population is likely to be bigger or smaller than zero.

170 **Ethical considerations**

The current study was registered at clinical trials.gov with identifier NCT03639961.
Additionally, ethical clearance was secured from Bahir Dar University (BDU) with a protocol
record 090/18-04. Moreover, written consent was obtained from each members of study
teams; and data were protected.

175 **Results**

176 **Ordinary means**

- 177 Table 1 displays the ordinary mean and standard deviation (SD) of the baseline and end line
- 178 ID with 95% CI. The mean difference between the baseline and end line ID was 14.6 ± 7.2 in
- 179 the intervention group, whereas, it was 1.1 ± 2.2 in the control group.
- **Table 1** Ordinary mean (SD) baseline and end line ID (n= 134)

	Institutional Delivery (ID)						
	Baseline			End line			
	Measure	Statistic	95%	CI	Statistic	95%	6 CI
Group		-	Lower	Upper	-	Lower	Upper
Test a mark that	Mean	34.2	30.7	37.5	48.8	46.2	51.9
Intervention	SD	12.8	10.6	14.8	12.6	10.4	14.4
Control	Mean	30.9	28.6	33.2	32.0	29.5	34.6
	SD	9.5	7.1	11.5	9.1	6.9	11.2

181 Estimated means

- 182 Table 2 presents the adjusted mean end line ID for both groups that were the original means
- adjusted for the covariate. The mean values had changed compared to those found in
- 184 the ordinary mean (**Table 1**).
- **Table 2** Adjusted mean end line ID (n= 134)

Mean	Std. Error	95% Confidence Interval		
		Lower Bound	Upper Bound	
47.4	.627	46.2	48.6	
33.4	.627	32.2	34.6	
-			47.4 .627 46.2	

Note: The covariate appearing in the model was evaluated at the following value: baseline ID = 32.6.

186 The main effect of the group on the DV

Table 3 informs that there was an overall statistically significant difference on the DV between the groups once their means had been adjusted for the covariate. As highlighted in the table, there was statistically significant difference between adjusted means: F(1,131) =247.2, partial eta squared =.65 and P<.001. Considered the partial eta squared value, the main

- 191 effect size of the group on DV was 65%. This showed that including the covariate increased
- 192 the group's effect size on the DV from 37% (explained in methods part) to 65%.

Source	Type III Sum of	Df	Mean	F	Sig.	Partial Eta
	Squares		Square			Squared
Corrected Model	21955.8	2	10977.9	421.7	.000	.87
Intercept	2169.6	1	2169.6	83.3	.000	.39
Baseline ID	12460.4	1	12460.4	478.6	.000	.79
Group	6435.3	1	6435.3	247.2	.000	.65
Error	3410.4	131	26.0			
Total	244108.0	134				
Corrected Total	25366.2	133				

193 **Table 3** Outputs of between-subjects effects on end line ID, ANCOVA (n = 134)

- Note: R Squared = .8/, Adjusted R Squared = .86
- 194 Yet, Table 3 also displayed that the covariate had significant effect at (P<.001). Thus, to
- 195 interpret such outputs, double testing using contrast results (K matrix) (Table 4) was used.

196 Table 4 K Matrix

Group			DV	
			End line ID	
	Contrast Estimate	14.0		
Intervention vs. Control	Hypothesized Value	0		
	Difference (Estimate - Hyp	14.0		
	Std. Error	.89		
	Sig.	.000		
	95% CI for Difference	Lower Bound	12.2	
		Upper Bound	15.8	

Note: Reference category = Control group

197 The output indicated significant result (P<.001), and the 95% CI was (12.2, 15.8). This

198 showed that the main effect of the intervention was somewhere between this CI.

199 Discussion

200 The current study findings inform that the ILMG for results model intervention causes 201 statistically significant difference on mean ID between the groups. This plausible causation is 202 supported by a study done in Kenya[8]. Differently, the current study shows the effect size by 203 adjusting the original means for the covariate. This has three-fold purposes[18]. First, it 204 reduces within-group error variance that is the intervention effect bias or specification error.

205 Second, it eliminates potential confounders since there is no preexisted group differences 206 systematically on more than it is. Last, it provides additional evidence of causality.

The current finding is also supported by other previous studies[9,11]. However, unlike these studies, the current study controlled a plausible covariate (noted earlier) and used control group. Using control group helps to identify assumption attributes in trends between the groups that occur at the same time as the intervention to that intervention.

The other distinction of the current study is that it used the model that integrated leadingmanaging-and-governing practices (Fig 1) while the other studies used either leading and managing practices[8,9] or governing practices[12]. Interestingly, the effect of balancing and integrating leading managing and governing practices in improving service-delivery outcome in a turbulent environment is similar to keeping the seat of a three-legged stool horizontal while sitting on rough ground[27] (**Fig 3**).

Fig 3. Illustration of a sit on adjusted three-legged stool with effect of ILMG practices on services outcomes

On the contrary, the study done in Afghanistan reported that there was no statistically significant effect of the intervention on health system performance or health outcomes[12]. Rather, it showed that many indicators worsened in the intervention group. As explained by the authors of the study, the intervention environment was fragile and conflict affected in the study period. This supports the significant influence of the turbulent environment to achieve significant results through interventions.

In the current study, the adjusted mean ID (**Table 2**) compared with the ordinary mean ID (**Table 1**) is less in the intervention group, but greater in the control group. This implies that adjusting the mean by removing error variance in the DV that associates with the covariate provides unbiased or uncontaminated mean.

The current adjusted means in both groups are also greater compared with the 2016 Ethiopian demographic health survey ID report (26%). However, compared with the 2019 demographic health survey ID report (48%): the current adjusted mean ID in the intervention group is similar, but it is less in the control group. These mean institutional deliveries are also by far lower than the target (90%) indicated in the national health sector plan, 2015-2019. Taking into consideration, perhaps, the national survey result includes data from big cities, evidencebased investment on ILMG for results model ought to be important.

235 In spite of the above implications, there were potential limitations in conducting this study. 236 The first limitation identified was non-randomization that is the major weakness of quasi-237 experimental design. This weakness brought another challenge that was whether ANCOVA is 238 used in alike data. Yet, two dimensions support its application. First, if the group have caused 239 the difference on covariate beyond randomization [28]. Second, if the authors are certain that 240 the group could not have affected the covariate [29]. Since there was no preexisted group that 241 affected the covariate in the current study, ANCOVA was applied. In fact, this analysis 242 technique is developed to increase the power of the test of the predictor variable [23,24]. It 243 does this through removing error variance in the DV that is associated with the covariate [24]. 244 The second important threat to establishing causality was the statistical principle of regression 245 to the mean[18]. This widespread statistical phenomenon can result in wrongly concluding 246 that an effect is due to the intervention when in reality it is due to chance. Here, though, the 247 degree of caution was diminished by implementing the intervention on the real-world setting, 248 limiting generalizability of results is unavoidable[5].

The third potential limitation was the short duration of the intervention. Six months may not be enough time to overcome barriers and achieve significant result. Nevertheless, if it was

- 251 more than this with similar study design that lacks isolation and temporal precedence,
- contamination will be a threat on the other way round. Even with this time, though no team
- was recorded as loss to follow up, around 11% of intervention teams reported that at least one
- team member transferred to a new area at the time of intervention.
- 255 The last challenge, to the best of our knowledge, was dearth of available literatures on testing
- 256 ILMG for results model, which of course limited the depth of our discussion.

257 Conclusions

- 258 This study provides some guidance regarding the plausible causation of integrated leading-
- 259 managing-and-governing for results model on institutional delivery. It would support
- 260 evidence-based-leveraging of the model in similar settings. It would also serve as a baseline
- for future research, possibly, considering randomization to identify true causation.

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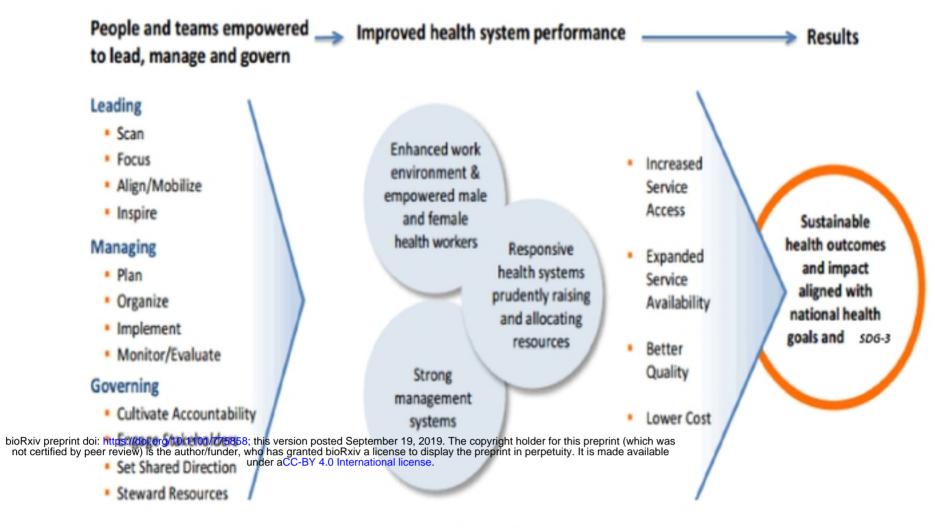
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- **Supporting information**

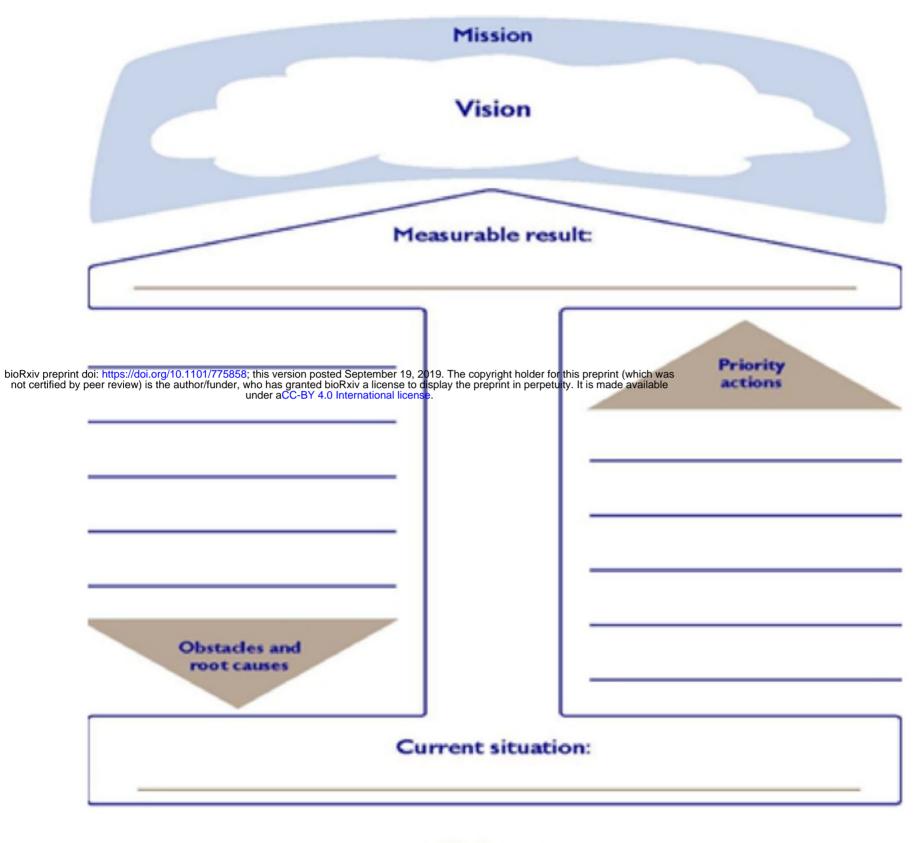
- 335 **S1 Appendix.** Intervention protocol
- 336 S2 Appendix. Action plan planning format
- 337 S3 Appendix. M&E plan planning format
- 338 **S4 Appendix.** Effective communication model







The Challenge Model



Challenge:

(How will we achieve our desired result in light of the obstacles we need to overcome?)







