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The role and interpretation of pilot studies in impact evaluation research

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Motivation

A pilot study is a requisite initial step in exploring a novel intervention or an innovative application of an intervention. Pilot results can inform feasibility and identify modifications needed in the design of a larger, ensuing hypothesis testing study.[1] However, in-depth pilot studies (also referred to as formative studies) that are precursors to larger randomised evaluations of social programs are not as frequently or as intensively conducted as they should be. The contribution of pilot phase that precede the full randomised evaluation study is often times underestimated.

In this presentation, I use the example of a recent pilot study that was designed and conducted as the necessary first step for a planned full-scale randomised evaluation, to highlight how the findings from the pilot informed the theory of change of the intervention and therefore shaped our decision around the full-scale RCT. Additionally the pilot phase also brought to fore some key lessons around measurement and data collection.

Findings from the pilot study have to be cautiously interpreted however. A major challenge when working with implementation partners is to ensure that findings of the pilot are not used to make decisions that involve estimation of effectiveness of an intervention. A pilot study does not provide a meaningful effect size estimate for planning decisions around the effectiveness of intervention per se due to the imprecision inherent in data from small samples. Feasibility results do not necessarily generalize beyond the inclusion and exclusion criteria of the pilot design.[1] However, pilot studies can still be informative to the implementing partner in a more descriptive sense. In this presentation I also touch upon how the finds from the pilot study are communicated to the partner so as to minimise the risk of over-generalisation in policy-

[1] Leon A; Davis L et al. 2012. The role and interpretation of pilot studies in clinical research. *Journal of Psychiatric research*. 45(5):626-629

making. At the same time findings from the pilot study can lead to actionable policy recommendations.

Background

India has made impressive investments to expand the reach of the public health system – but the quality of care in government-run facilities is often still lacking. In collaboration with the Government of Punjab (GoP), J-PAL South Asia planned to conduct a cluster randomized evaluation to test the effectiveness of a range of interventions aimed at increasing the motivation of and making the Auxiliary Nurse Midwives (ANMs) at health sub-centres more attentive to high-quality service provision and patient satisfaction. One important aspect of quality is provider-patient communication which has not been given much attention in evaluation and research in India. The goal of this project titled, 'Improving the Health Worker – Patient Relationship', was to develop and pilot-test interventions to make health workers more accountable to their patients and improve patient satisfaction, health care utilization, and health outcomes. An important focus of this study was to understand whether poor "soft skills" among providers—being disrespectful of patients or lacking a compassionate interpersonal style, for example—may play a central role in inhibiting the exchange of information between providers and patients, and could even drive patients to forgo care or turn to unqualified private providers.

Methods

The overall project was conceived during an in-depth research-policy dialog between J-PAL SA and the Government of Punjab officials, where the state's pressing health policy issues and potential interventions to address them were discussed. The ultimate aim of this project was to identify scalable, cost-effective interventions that improve health worker performance, patient satisfaction, and health. Prior to embarking on the full-scale RCT, the researchers planned an extensive formative phase of 8 months. This pilot was deemed as being an essential precursor to a successful RCT.

The first phase of our pilot, a needs assessment, was conducted in Sangrur district during November and December 2015. The needs assessment aimed at understanding the roles and responsibilities of the ANMs, utilisation of health care services in the state, and community

perception regarding the services provided by an ANM. Here we paid special attention to beneficiaries' opinions of ANM soft skills. The needs assessment was qualitative in nature and included focus group discussions and in-depth interviews with ANMs and their beneficiaries across Sangrur.

During the second phase of the pilot, we field-tested the ‚patient feedback mechanism' – a program whereby we collected beneficiary ratings of ANM soft skills and other skills, aggregated the ratings, and communicated them back to ANMs in the form of report cards. This part of the pilot took place from January to May 2016.

Results and conclusion

Findings from the pilot study were instrumental in initially informing the research questions of our study and later in the decision on whether or not to proceed with the full scale randomised evaluation.

Specifically, the first stage of the pilot, which included a qualitative needs assessment study threw up some interesting findings relating to the perceptions of beneficiaries on the mannerisms and soft skills of the ANMs. The qualitative scoping study found little evidence that a soft skills deficit is a pressing problem with ANM performance. At the same time this phase of the study also highlighted the lack of clarity among ANMs themselves and the beneficiaries regarding the roles and responsibilities of an ANM, as they specifically related to certain important maternal health outcomes. Based on these findings we decided to revise our initial causal hypothesis and decided on not having a soft skills training component. Further, we decided to include a different intervention to address the some other gaps highlighted by our needs assessment study. We decided to include a new '*beneficiary information arm'* into our randomized evaluation in consultation with the GoP.

The second phase of our pilot study field-tested the ‚patient feedback mechanism – a program whereby we collected beneficiary ratings of ANM soft skills and other skills, aggregated the ratings, and communicated them back to ANMs in the form of report cards. The rationale behind this component was that receiving feedback from patients on their strengths and weaknesses might lead to improved performance of the ANMs.

Moreover, one could build upon such a feedback system and provide monetary or non-monetary rewards to ANMs with high feedback scores, which could also incentivize them to improve performance. While the overall intervention was found to be promising based on the pilot, we also encountered some important challenges. Namely, Mother and Child Tracking System (MCTS) data was not very useful for contacting beneficiaries as 42% of the phone numbers recorded were the ANMs' or the ASHA workers'. Therefore, we anticipated that administering the patient feedback intervention at scale would be logistically difficult and costly and given the high frequency of wrong numbers and difficulties in reaching the beneficiaries through phone, we would have faced sample size issues in the full scale RCT. Based on this we decided not to undertake the full scale RCT.

Finally, from a policy influence perspective, the pilot also uncovered some important facets about the functioning of the government health system in Punjab. To our knowledge, the findings of the pilot were perceived as being important and have the future potential for policy actions that can lead to improvements in the system.

This case study highlights the criticality of having extensive pilot studies in informing the causal hypothesis, design of the study, measurement of key variables of interest and ultimately the decision of whether or not to go for a randomised evaluation.