







Implementation of a salt substitute intervention using social marketing in resourced-limited communities in Peru: A process evaluation study

Maria Lazo-Porras, MD, MSc

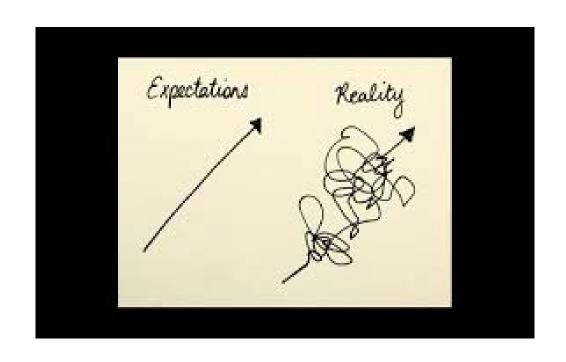
CRONICAS Centre of Excellence in Chronic Diseases, UPCH, Peru Division of Tropical and Humanitarian Medicine, UNIGE & HUG, Switzerland

Outline

- Process Evaluation
- Medical Research Council Framework for Process Evaluation
- Salt Project
- Conclusions

 Once a complex intervention is developed and implemented in the field; it needs to be evaluated. How this evaluation is done varies according to the study design and its objectives. However, some types of studies prioritize the measurements of health outcomes and others prioritize the implementation outcomes.

• In order to close the implementation gap, it is important to identify what is working and what needs to be adjusted for achieve the maximum impact to reduce the diseases burden and improve the quality of life of people with these conditions.







PE is necessary for different reasons:

- Understand how context impact efficacy outcomes
- To determine implementation fidelity, and interpret trial outcomes.
- Distinguish between 'active' components of the intervention
- To study the way outcomes vary in subgroups.
- Spell out the key causal assumptions or the underline theory

Century J, Rudnick M, Freeman C. A framework for measuring fidelity of implementation: a foundation for shared language and accumulation of knowledge. Am J Eval 2010;31:199-218.

Harachi TW, Abbott RD, Catalano RF, Haggerty KP, Fleming CB. Opening the black box: using process evaluation measures to assess implementation and theory building. Am J Community Psychol. 1999;27(5):711-31.

Within the field of implementation science, theories, theoretical frameworks and models (TFM) can help facilitate the description, explanation and systematic evaluation of program implementation.

Nilsen et al described theoretical approaches and organized them in:

- (i) process models to guide the process to translate research in practice
- (ii) evaluation frameworks to evaluate implementation
- (iii) classic and implementation theories as well as determinant frameworks to describe or explain influences on implementation outcomes

McIntyre SA, Francis JJ, Gould NJ, Lorencatto F. The use of theory in process evaluations conducted alongside randomized trials of implementation interventions: A systematic review. Transl Behav Med. 2020;10(1):168-78.

Nilsen P. Making sense of implementation theories, models and frameworks. Implement Sci. 2015;10:53.

Fynn JF, Hardeman W, Milton K, Jones AP. A scoping review of evaluation frameworks and their applicability to real-world physical activity and dietary change programme evaluation. BMC public health. 2020;20(1):1-1000.

- Realist Evaluation
- Normalization Process Theory
- Theoretical Domains Framework (TDF)
- Consolidated Framework for Implementation Research (CFIR)
- RE-AIM

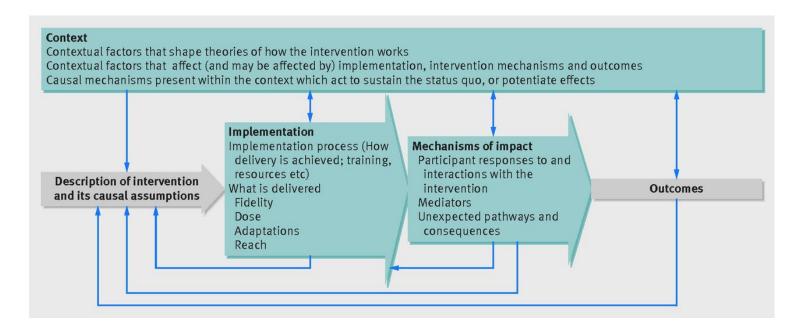
Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. BMC Med. 2010;8(1):63-.

Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. Implement Sci. 2017;12(1):77.

Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50.

Medical Research Framework for Process Evaluation

Context (how does context affect implementation and outcomes?); Mechanisms of impact (how does the delivered intervention produce change?); Implementation (what is delivered and how?)

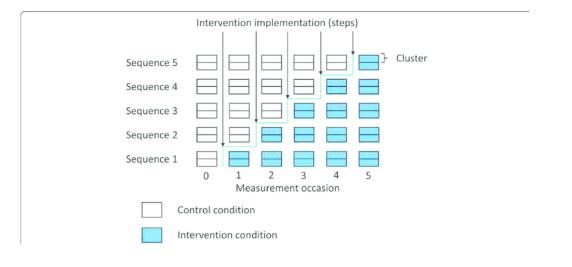


Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ. 2015;350:h1258.

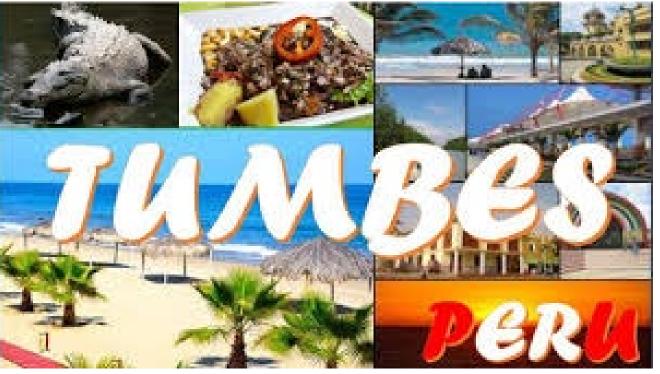
SALT study

The SALT project is a populationwide implementation of a potassium-enriched substitute (75% NaCl and 25% KCl) to reduce blood pressure. A stepped-wedge, cluster, randomized controlled trial was conducted, in which the six participating villages crossed over from the control to the intervention phase during the study.













SALT study: Preliminary Phase

- The salt substitute project had a preliminary phase that included a formative phase with a choice experiment and a qualitative study. Also, during this phase, the intervention was developed.
- <u>Triangule Taste Test</u>: The first one aimed to identify the proportion of sodium and potassium to be used in the salt substitute without altering significantly the taste of food.
- The second was a *qualitative study*. The themes of the interview were about hypertension, its relationship with salt consumption, and whether or not the local population was willing to adopt a salt substitute.

SALT study: Intervention

- The intervention consisted in the use of a social marketing campaign targeting women responsible for food preparation at home.
- The purpose of the marketing campaign was to introduce the salt substitute as a new product in the intervention villages, and enhance its acceptance.
- The components of this intervention were: the salt substitute (now branded as salt Liz), "Amigas de Liz", salt Liz spoon and entertainment educational activities.











SALT study: Intervention

- The time for provision of a salt replacement was planned to happen over a period of 5 months.
- The intervention considered delivering the salt to families, as well as to owners of small shops, bakeries and community kitchens, and food vendors including street vendors and restaurants.
- The social marketing campaign included entertainment educational activities and the "Amigas de Liz" that were members from the communities that support the research team.
- Also the salt was provided with a spoon (salt Liz spoon) to introduce the right amount of salt that should be used.





 Among participants without hypertension at baseline, the use of the salt substitute was associated with a 51% (95% confidence interval, 29% -66%) reduced risk of developing hypertension compared with the control group.

 Also, in the overall population, there was an average reduction of 1.29 mmHg in systolic and 0.76 mmHg in diastolic blood pressure.

Bernabe-Ortiz A, Sal YRVG, Ponce-Lucero V, Cardenas MK, Carrillo-Larco RM, Diez-Canseco F, et al. Effect of salt substitution on community-wide blood pressure and hypertension incidence. Nat Med. 2020.

SALT study: PE Objectives

- To understand the components and processes that resulted in the success of the trial, we used the Medical Research Council (MRC) framework to report process evaluation findings of the study.
 - (i) Identify contextual factors that play a role in the implementation of the salt substitute
 - (ii) Identify the mechanisms of action by which participants incorporate the salt substitute in daily life
 - (iii) Describe the acceptability of the salt substitute and identify their associated factors
 - (iv) Evaluate the fidelity of the intervention components
 - (v) Explore the perceptions of the participants surrounding social marketing campaign components.
 - (vi) Collect the feedback from the participants to improve the intervention and informits future

SALT study: PE Methods

- This is a qualitative study that included interviews of 60 women from the community during the trial.
- These participants were from four intervention villages.
- The intervention was delivered and the health outcomes evaluated between April 2014 (village 1) and March 2017 (village 6). The interviews for the PE were conducted in March 2016.
- The women were between 18-34 years old and >=35 years old, and also women with hypertension were recruited.

SALT study: PE Methods

	Definition
Context	Identification of contextual factors that impact the implementation of the Salt Liz
Mechanism of action	Explore and understand how the Salt Liz was incorporate in the daily lifes of community members and achieved the change that it was expected
Implementation outcomes	
Acceptability	Satisfaction with salt substitute and which factors play a role to improve the acceptability of the product
Fidelity	Degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers. Measure to the fidelity of the exclusive use of the salt-substitute by community members, to the use of the Salt Liz spoon and the "right" measurement of salt and the amount of the salt substitute distributed was considered
Perceptions	Intervened groups perceptions towards the intervention components such as the "Amigas de Liz" and the education entertainment activities
Feedback	Intervened groups provide feedback to improve the intervention implementation

Sociodemographic characteristics:

- Sixty women, 20 with hypertension and 40 without hypertension including 20 women between 18 and 34 years old and 20 were >=35 years. Five women from each village in each group were included. Nine participants reported to have a family member with hypertension.
- Most of them were housewifes or with a part time job.
- The education level were mostly more tan 7 years of studies



CONTEXT

• Context:

- Food preparation
- Decision about the menu
- Special diet
- Use of seasonings
- Other uses of salt: salt for meat and fish preservation (27/60) and "aliño" preparation



- Mechanism of impact
 - Process of incorporating Salt Liz into the day-to-day: initial impressions about taste (pleasant and tasty; others "bland", "bitter" or "sweet")
 - Adjusting to Salt Liz (one month)
 - Factors influencing use of salt-substitute
 - Everyone in their village uses Salt Liz and are used to it
 - Some participants mentioned not finding common salt
 - There is no need to buy it since they are given free



Implementation outcomes	
	 It is good for their health (hypertension, or other health conditions) High quality in comparison to common salt
Acceptability	 Field staff shared the message of the benefits of salt Liz and solve doubts of the participants
	Prior University projects
	It was provided for free

Implementation outcomes	
Fidelity	 Most participants from all four villages described their household had adopted Salt Liz exclusively.
	 Half of the respondents mentioned using the spoon (30/60) It's too small and that makes it difficult to use
	 Half of the people interviewed consumed more salt than recommended by the project (30/60)
	 The most common amount of salt Liz distributed to households by field staff was 2 kg per month for their personal consumption

Implementation outcomes	
Perceptions	 "Amigas de Liz" are recognized as members from the community, participants perceived different roles of them related to Salt Liz Entertainment Educational Activities Those who go and do not participate said they feel embarrassed Regarding the "Healthy Dish" event, some do not participate because they do not cook well or because they cannot afford to buy the ingredients (fish is expensive). In general they like to participate in the events because they laugh, find it fun, win prizes and relax themself. Salt Liz and health Potassium, sodium and iodine

Implementation outcomes	
Feedback	Participants said they would be willing (56/61) to pay. The average price they would pay would be 2 PEN Participants from their villages shared how ingrained salt Liz was in the community ("everyone is using it" "now they can't do without"). Some participants would ask rhetorically or to the interviewer if (or when) there were plans to stop the program and discontinue the
Feedback	Some participants would ask rhetorically or to the interviewer if (or

Conclusions of the PE SALT study

- Salt Liz was considered healthier than common salt.
- Participants took around one month to get use to the taste of Salt Liz
- Some specific factors from these communities support the high acceptability such as the "high quality" of Salt Liz in comparison to previous salt or the previous experience with a University project
- The fidelity to the use of Salt Liz was high but the use of the Salt Liz spoon ant the right amount of salt was poor
- Participants enjoyed the entertamint activities





Thank you / Muchas gracias