Supplementary appendix

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Appendix 1. Standards for Reporting Implementation Studies (StaRI) checklist

Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. *BMJ Open* 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.

The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

		Reported		Reported				
Checklist Item		on page #	Implementation Strategy	on page #	Intervention			
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.			
Title and abs	strac	t						
Title	1	1	Identification as an implementation study, and d	Identification as an implementation study, and description of the methodology in the title and/or keywords				
Abstract	2	3	Identification as an implementation study, including a des based intervention being implemented, and o	Intification as an implementation study, including a description of the implementation strategy to be tested, the evidence- based intervention being implemented, and defining the key implementation and health outcomes.				
Introduction								
Introduction	3	5-6	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.					
Rationale	4	5-6	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	kground and rationale for the egy (including any underpinning el, how it is expected to achieve its and any pilot work). 5-6 The scientific background and rational intervention being implemented (includin about its effectiveness and how it is ex achieve its effects).				
Aims and objectives	5	5	The aims of the study, differentiating between implementation objectives and any intervention objectives.					
Methods: de	scrip	otion						
Design	6	6	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons					



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Context	7	6	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).						
Targeted 'sites'	8	9	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	8-9	The population targeted by the intervention and any eligibility criteria.				
Description	9	9-11	A description of the implementation strategy	9	A description of the intervention				
Sub-groups	10	9	Any sub-groups recruited for additional re	search tasks,	and/or nested studies are described				
Methods: ev	alua	tion							
Outcomes	11	11	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	t any pre-determined targets					
Process evaluation	12	12	Process evaluation objectives and outcomes related	to the mecha	anism by which the strategy is expected to work				
Economic evaluation	13	N/A	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Methods for resource use, costs, economic outcomes and analysis for the intervention				
Sample size	14	13	Rationale for sample sizes (including sample size calculationale for sample sizes (including sample size calculationale for sample size)	ationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)					
Analysis	15	13-14	Methods of analysis	Methods of analysis (with reasons for that choice)					
Sub-group analyses	16	N/A	Any a priori sub-group analyses (e.g. between differe populations), and sub-groups re	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks					
Results									
Characteris- tics	17	14	Proportion recruited and characteristics of the recipient population for the implementation strategy	14-15	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention				
Outcomes	18	15	Primary and other outcome(s) of the implementation strategy	16 Primary and other outcome(s) of the Intervention assessed)					
Process outcomes	19	16	Process data related to the implementation strategy map	oped to the m	echanism by which the strategy is expected to work				
Economic evaluation	20	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention				
Sub-group analyses	21	N/A	Representativeness and outcomes of subgrou	ups including	those recruited to specific research tasks				
Fidelity/ adaptation	22	16	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	ementation strategy as planned and N/A Fidelity to delivering the core components of intervention (where measured)					
Contextual changes	23	N/A	Contextual changes (if any) which may have affected outcomes						
Harms	24	N/A	All important harms or u	All important harms or unintended effects in each group					

Discussion									
Structured discussion	25	17-20	Summary of findings, strengths and limitations, co	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications					
Implications	26	17-20	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	cussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability) 17-20 Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)					
General									
Statements	27	21-22	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest						





The pilot study was carried out in 11 primary care facilities (either health posts or health centers) in two health districts in the Ministry of Health primary care system in Guatemala. Note that after the pilot trial was planned and had begun to be implemented, the health district in the Sololá region was divided into three separate districts. This administrative change had no bearing on the implementation or evaluation of this project. For the purposes of consistency with our trial protocol and clarity in reporting, we describe the study setting as two health districts in the main manuscript. The map inset depicts the location of Guatemala relative to neighboring countries.

Appendix 3. Diagnostic codes used for patient enrollment in the Ministry of Health

Hypertension diagnostic codes

- 1. Essential (primary) hypertension
- 2. Unspecified secondary hypertension
- 3. Renovascular hypertension
- 4. Hypertensive kidney disease without renal failure

Diabetes diagnostic codes

- 1. Diabetes mellitus specified, with unspecified complications
- 2. Non-insulin-dependent diabetes mellitus, with multiple complications
- 3. Insulin-dependent diabetes mellitus
- 4. Unspecified diabetes mellitus, with neurological complications
- 5. Unspecified diabetes mellitus, with coma
- 6. Unspecified diabetes mellitus, with ketoacidosis
- 7. Unspecified diabetes mellitus, with unspecified complications
- 8. Unspecified diabetes mellitus, without mention of complication

Appendix 4. Figure: Conceptual model guided by the Implementation Research Logic Model

DETERMINANTS

Based on formative research

WHO Building Blocks

- 1. Service delivery: Suboptimal care models, limited emphasis on chronic care, clinical guidelines rarely used
- 2. Human resources: Need for improved teamwork, high staff turnover, limited training on chronic disease care
- 3. Information systems: Limited medical record system, undercounting of medication stockouts, no routine monitoring of disease control
- 4. Medications and technologies: Inconsistent availability of medications and supplies, technologies not disseminated to rural areas
- 5. Financing: Inconsistent funding, misalignment between funding and delivery levels
- 6. Governance & leadership: Shifting political priorities, need for intersectoral collaborations

IMPLEMENTATION STRATEGIES

Based on HEARTS Technical Package

- 1. Training on clinical protocols
- 2. Strengthening access to medications and diagnostics
- 3. Task sharing with nonphysician health workers
 - 4. Monitoring and feedback at the facility level

5. Medical record system at the patient level

MECHANISMS

- Based on formative research
- Catalytic investments in resource provision
- Improved clinician knowledge
- Improved supply chains and logistics for medications/supplies
- Positive feedback loops at health district level
- Increased political capital and awareness

EVIDENCE-BASED INTERVENTION

Clinical guidelines of the Ministry of Health (implementing organization)

- 1. Pharmacological treatment of hypertension in primary care
- 2. Pharmacological treatment of diabetes in primary care

OUTCOMES

Based HEARTS indicators and the IOF

Implementation outcomes:

- Feasibility (primary): FIM questionnaire and enrollment metrics
- Acceptability (primary): AIM questionnaire and follow-up metrics
- Adoption (secondary): Facility-level uptake
- Fidelity (secondary): Degree of fidelity to implementation strategies
- Sustainability (secondary): PSAT and CSAT select items
- Usability (secondary) of electronic data tool: System Usability Scale

Clinical (service) outcomes:

- Uptake or reach (secondary): Monthly treatment rates
- Effectiveness (secondary): Disease control

Appendix 5. Figure: Summary of data collection procedures



Abbreviations: MOH: Ministry of Health. Note that this study reports on the pilot trial's quantitative results; qualitative and mixed methods analyses are ongoing and will be published separately.

Characteristic	Value
Primary health facilities, n	10
Health region, n	
Sololá	5
Chiquimula	5
Type of health facility, n	
Health post	5
Health center	5
General information, n (%)	
Functioning computer	5 (50%)
Functioning mobile phone or table	6 (60%)
Functioning internet	5 (50%)
Patient records retrieved and consulted each time a diabetes and/or hypertension patient visits the facility	6 (60%)
Facilities conducting monthly coordination meetings focusing on hypertension and/or diabetes patients	2 (20%)
Most common type of access to the facility from the municipal center, n (%)	
Walking	0 (0%)
Only by four-wheel drive vehicle	2 (20%)
Only by boat	2 (20%)
Any vehicle	6 (60%)
Physical infrastructure, n (%)	
Physical space to store patient records	8 (80%)
Designated space for pharmacy	9 (90%)
Has ≥2 clinic rooms	6 (60%)
Staffing at the health facility (at least one full-time staff in each role), n (%)	
Physician	3 (30%)
Medical student	5 (50%)
Professional nurse	5 (50%)
Auxiliary nurse	10 (100%)
Laboratory technician	3 (30%)
Nutritionist	2 (20%)
Psychologist	1 (10%)
Availability of core medications	
Overall availability of core medications ^a	60%
Enalapril, n (%)	6 (60%)
Losartan, n (%)	5 (50%)
Hydrochlorothiazide, n (%)	7 (70%)
Metformin, n (%)	6 (60%)

Appendix 6. Table: Baseline characteristics of primary health facilities

Glimepiride, n (%)	6 (60%)
Availability of other medications, n (%)	
Insulin	0 (0%)
Availability of core diagnostics (functioning)	
Overall availability of core diagnostics ^a	87%
Glucometer, n (%)	8 (80%)
Glucometer test strips, n (%)	8 (80%)
Blood pressure apparatus (digital), n (%)	10 (100%)
Availability of supplies, diagnostics, and equipment (functioning), n (%)	
Urine test strips	8 (80%)
Tests for hemoglobin A1c	2 (20%)
Tests for cholesterol	0 (0%)
Tests for serum creatinine	0 (0%)
Adult weight scale	9 (90%)
Measuring tape or stadiometer board	9 (90%)
Stethoscope	8 (80%)
Blood pressure apparatus (manual sphygmomanometer)	5 (50%)
Refrigerator for storage of medicines and supplies	10 (100%)

^aOverall availability is the mean availability of items at each health facility.

Appendix 7. Table: Availability of key medications and d	iagnostics during pilot period
Kov modication (n-10 hoalth facilities)	Availability (0/)a

Key medication (n=10 health facilities)	Availability (%) ^a
Availability of core medications	
Overall availability	81%
Overall availability of antihypertensive medications (enalapril, losartan, hydrochlorothiazide)	82%
Overall availability of glucose-lowering medications (metformin, sulfonylureas)	80%
Enalapril	82%
Losartan	82%
Hydrochlorothiazide	83%
Metformin	82%
Sulfonylureas (glimepiride or glibenclamide)	78%
Availability of core diagnostics (functioning)	
Overall availability	82%
Glucometer	79%
Glucometer test strips	73%
Blood pressure apparatus (digital)	85%

Availability is calculated as the mean monthly availability of each item at each clinic over the 6-month pilot period. Note that Appendix 6 reports on these indicators at baseline as opposed to during the pilot period in this table.

Appendix 8: Output for segmented regression models for treatment rate

Variable	Coefficient	Std. Err.	z-value	P> z	95% Conf. Interval
Pre-intervention intercept (_cons)	108.5	5.1	21.44	<0.001	98.6 to 118.5
Pre-intervention slope (t)	-0.1	1.0	-0.05	0.96	-2.1 to 2.0
Post-intervention change in intercept (x1)	-8.9	9.5	-0.93	0.35	-27.6 to 9.8
Post-intervention change in slope (x_t1)	22.3	3.1	7.20	<0.001	16.2 to 28.4
Postintervention slope (_b[_t]+_b[_x_t1])	22.3	2.8	7.91	<0.001	16.7 to 27.8

Table7a: Segmented regression results for hypertension treatment rate

Table7b: S	eamented	rearession	results i	for	diabetes	treatment	rate
1001010.0	eginemea	regression	100uno i		alabetes	ucaunon	raio

Variable	Coefficient	Std. Err.	z-value	P> z	95% Conf. Interval
Pre-intervention intercept (_cons)	65.9	34.0	16.56	<0.001	58.1 to 73.7
Pre-intervention slope (t)	2.2	1.0	2.29	0.02	0.3 to 4.2
Post-intervention change in intercept (x1)	1.2	13.3	0.09	0.93	-24.9 to 27.4
Post-intervention change in slope (x_t1)	3.5	2.6	1.36	0.17	-1.6 to 8.7
Postintervention slope (_b[_t]+_b[_x_t1])	5.7	2.6	2.20	0.03	0.6 to 10.9

See the methods section for description of models.