

Design and feasibility of an implementation strategy to address Chagas guidelines engagement at the primary healthcare level in Argentina: a pilot study

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1 **Title page:**

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4 at the primary healthcare level in Argentina: a pilot study

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14

15 **Abstract**

16 **Background**

17 Chagas is a public health problem, especially in Latin America, exacerbated by migratory movements
18 and increasing urbanization. Argentina has the highest number of cases in the region, with 1,500,000
19 infected people, with mother-to-child as the primary mode of transmission. Vertical transmission has
20 been significantly reduced by treating women of childbearing age; several guidelines in the region
21 recommend treatment as a primary prevention strategy for the child and a secondary prevention
22 strategy for women and their families. Despite recommendations, women of childbearing age are not
23 always treated, and children do not receive timely diagnosis and treatment. The objective of this
24 research was to design an implementation strategy to improve using Chagas guidelines at the primary

25 healthcare level and pilot it to assess its feasibility and the factors that influence its implementation
26 in three primary health care centers in Chaco, Argentina.

27 **Methods**

28 We conducted a pilot feasibility study using the Consolidated Framework for Implementation
29 Research. A qualitative process evaluation was conducted using semi-structured interviews with
30 health care providers and observations in primary health care centers.

31 **Results**

32 We developed a multifaceted implementation strategy including training, flowcharts and reminders,
33 a register of suspected and confirmed Chagas cases, and the selection of a management facilitator.
34 The pilot study took place between September 2019 and May 2020. The implementation level was
35 heterogeneous and varied depending on the components, being the facilitating factors, the simplicity
36 of the intervention, professionals' willingness to expand the indication of serologic tests, and staff
37 commitment to the adoption of intervention components. The main barriers found were the change
38 of authorities at the local level, some professionals' reluctance to administer etiologic treatment,
39 staff shortages, lack of diagnostic supplies (linked to contextual factors), and the health emergency
40 caused by the COVID-19 pandemic.

41 **Conclusions**

42 Behavioral change strategies should be applied to improve implementation to address some of the
43 main barriers, including support actions offered by opinion leaders, medical experts, and local health
44 authorities. Rapid diagnostic tests should be readily available to maintain behavior changes. We
45 suggest further refinement of the strategy and its implementation in more centers to assess outcomes
46 prospectively with a hybrid implementation research design.

47

48 **Keywords**

49 Chagas, primary health care, implementation strategy, feasibility, guideline, effective intervention.

50

51 **Contributions to the literature**

- 52 • Chagas is a neglected disease and a public health problem, especially in Latin America.
- 53 • Several barriers affect access to timely diagnosis and treatment for infected people at the
54 primary care level.
- 55 • There is a lack of evidence about effective interventions to improve diagnosis and treatment.
- 56 • We designed, piloted, and evaluated the feasibility of an implementation strategy to improve
57 the management of Chagas at the primary care level.

58

59 **Background**

60 Chagas is a public health problem worldwide, especially in Latin America (1), exacerbated by migratory
61 movements and increasing urbanization (2, 3). Argentina has the highest number of cases in the
62 region, with 1,500,000 infected people, over 370,000 people affected by heart disease of Chagasic
63 origin (1), with mother-to-child as the primary mode of transmission (4, 5). Vertical transmission has
64 been significantly reduced by treating women of childbearing age (6-8); several guidelines in the
65 region recommend treatment as a primary prevention strategy for the child and a secondary
66 prevention strategy for women and their families (9, 10). Treating children has also proven to be
67 effective and safe (11, 12).

68 Despite recommendations, women of childbearing age are not always treated, and children are not
69 diagnosed in time because of several barriers at different levels: lack of access to diagnosis tests,
70 complex diagnosis and treatment processes, inadequate medical training, inaccessible specialized
71 care, drug toxicity, insufficient patient and healthcare provider awareness, and shortages of
72 medication (13-16). To promote healthcare providers' adherence to national recommendations for a

73 comprehensive approach in the management of Chagas diseases in Argentina (9), a multicomponent
74 implementation strategy was designed based on elements with proven effectiveness in behaviour
75 change (17-20). This strategy was adapted after a formative research evaluation aimed at assessing
76 stakeholders' perspectives on the acceptability and feasibility of the proposed implementation (14).

77 The objective of this research was twofold: we designed an implementation strategy for the use of
78 Chagas guidelines at the primary healthcare level, piloted it and assessed feasibility and factors that
79 influenced implementation.

80

81 **Methods**

82 **Study design**

83 We conducted a pilot feasibility study based on the implementation research approach (21) and using
84 the Consolidated Framework for Implementation Research (CFIR)(22). The intervention was piloted
85 for nine months in three primary health care centers (PHCs) in northern Argentina.

86 A process evaluation was performed using qualitative methods (23, 24), collecting data through semi-
87 structured interviews (developed by the research team and not previously published) and
88 observations at the PHCs. The findings are reported in accordance with relevant reporting guidelines
89 (25), see additional file 7.

90 **Setting**

91 This study was performed in Resistencia, capital city of Chaco Province, Argentina. Resistencia is a
92 metropolitan area with a population of approximately 400,000 inhabitants. The city receives a
93 constant flow of migrant population from rural endemic areas in the province. The National Chagas
94 Program categorizes Chaco as a high-risk area (4). Resistencia has 31 PHCs and three hospitals where
95 Chagas cases are referred to. Three PHCs process samples at their own laboratories, whereas the other
96 PHCs send samples to a central laboratory in Chaco Province weekly or refer patients to this laboratory
97 for testing. The Provincial Chagas Program, part of the Chaco Provincial Epidemiology Department,

98 provides the etiological treatment of Chagas disease to all users of the public health system in the
99 province. The program also registers and monitors all cases treated.

100 Sites and population

101 PHCs were selected if they were in areas with interrupted vector transmission, had no Chagas-related
102 active projects that could interfere with the intervention, and had at least one professional defined as
103 a direct user of the implementation strategy (pediatricians, general practitioners, gynecologists or
104 obstetricians). PHCs also had to serve a varied population, including, for example, indigenous people
105 among their users. The final selection of centers was agreed upon with provincial and city health
106 authorities. PHC health care teams, including managers, general practitioners, gynecologists,
107 obstetricians, obstetrics, pediatricians, and nurses, participated in this study.

108 Description of the implementation strategy

109 We developed a multifaceted implementation strategy including training, the use of flowcharts and
110 reminders, a register of suspected and confirmed Chagas cases, and the selection of a management
111 facilitator in each PHC (see Table 1). The theoretical basis for the development of the strategy included
112 a systematic review of effective strategies for implementing clinical practice guidelines (26), the
113 Platform for the comprehensive care of adults with Chagas disease that improved access to diagnosis
114 and treatment in Bolivia (17), and the Patient-Centred Care Model from Colombia (27). In addition,
115 the strategy was tailored and adapted through formative research(14).

116 The training was directed to the health care providers in charge of the target population (pregnant
117 women, children, adolescents, women of childbearing age). It covered the use of the national
118 guidelines for the management of Chagas disease (early detection of cases and those living with them,
119 diagnosis, treatment and follow-up, and resource utilization) (9). The training comprised a four-hour,
120 face-to-face session. Flowcharts were distributed among healthcare staff; distributed material
121 included risk screening tools, a description of procedures for managing people at risk and cases of
122 Chagas disease, and printed reminders to show diagnostic tests and follow-up cases (see Additional
123 files 1 to 6). The team's researchers developed the design of the flowcharts and other support

124 materials based on the national guidelines and adapted them according to the findings obtained in
125 the formative research (14). PHCs were encouraged to identify medical records of patients at risk and
126 to register positive cases and their cohabitants. Posters and leaflets describing the national Chagas
127 program were also made available to PHC users. Finally, an opinion leader (named the management
128 facilitator) was appointed in each PHC to allocate resources and communicate with the research team.
129 A frequently asked question sheet with information on the management of positive cases at the first
130 level of care supported the role of opinion leaders.

131 **Outcomes: process evaluation**

132 The implementation process evaluation was based on implementation outcomes (28) and the CFIR
133 (22). This framework describes a list of dimensions and constructs that influence implementation, such
134 as intervention characteristics, context, external factors, and the people involved. The implementation
135 outcomes evaluated were adoption, fidelity, acceptability, appropriateness, and feasibility. Findings
136 obtained in qualitative semi-structured interviews (24, 29) were triangulated with data collected from
137 observations and telephone interviews. To assess users' adoption of components, we took each PHC
138 as the unit of analysis. We assessed fidelity by comparing how the component was used against the
139 proposed utilization. We also evaluated acceptability, appropriateness, and feasibility through
140 participants' perceptions.

141 **Data collection**

142 Once a month, the research team conducted telephone interviews with facilitators at PHCs and
143 collected information on the availability of materials. Additionally, a researcher visited each PHC twice
144 during the study period, one month after the intervention started and halfway through the
145 intervention. A planned third visit to each PHC had to be canceled because of social isolation measures
146 during the COVID-19 pandemic, and data collection was performed remotely. Twenty-two semi-
147 structured interviews with PHC directors, facilitators, and healthcare staff were performed. A guide
148 was developed to cover the acceptability, implementation of components, and barriers and
149 facilitators. Additionally, during the visits, observations were made to register the use and availability

150 of printed materials and the use of the recording systems. Data collected during these observations
151 were recorded on specially designed forms. Data collected through telephone interviews and
152 observation were entered into the Research Electronic Data Capture (REDCap) system.

153 Data analysis

154 Interviews were recorded, transcribed verbatim, and entered into Atlas. ti v8 (Berlin, Germany).
155 Thematic analysis was performed based on CFIR (30). To compare the implementation process in each
156 PHC, matrices were used with information on adoption, fidelity, acceptability, feasibility, barriers, and
157 facilitators.

158

159 Results

160 Implementation process outcomes

161 The pilot study took place between September 2019 and May 2020. Overall, the implementation level
162 of the intervention was heterogeneous across PHCs and varied depending on components (see Table
163 2).

164 The training component of the intervention was implemented in the three participating PHCs.
165 Although healthcare staff positively described training, it did not reach all professionals, and there was
166 no internal or cascade training. Health care providers who had not attended the training session did
167 not know the intervention well enough. Participants at all sites mentioned having implemented the
168 flowcharts, as confirmed by observations. Risk screening was only implemented partially,
169 unsystematically, and differently from what had been proposed (low fidelity). Some respondents used
170 the screening questions as a guide to prescribing serologic tests. In two PHCs, the Chagas serologic
171 test was prescribed for all women of childbearing age without risk screening.

172 Participants thought reminders were helpful and implemented their use, especially posters. However,
173 cards with frequently asked questions were rarely used because no treatments were carried out.

174 Despite participants' willingness to implement the register of positive and at-risk cases early, uptake
175 was low. When components were implemented, the implementation did not conform to proposed

176 indications (low fidelity). In fact, at one PHC, staff developed a register for patients receiving
177 treatment, but it was not used because patients were not treated. In another PHC, registration of
178 positive cases was abandoned after a few entries. All PHCs used labels to signal positive case records
179 but not for at-risk patients. Management facilitators were appointed in the three PHCs, but their
180 performance had mixed results. Often, facilitators did not fulfill the proposed role; indeed, many
181 health care providers were unaware of this component. Replacement of facilitators during the study
182 due to leave of absence or transfers affected the performance of this role.

183 The health care teams well received the intervention. Participants regarded the components of the
184 intervention as acceptable and relevant but pointed out critical aspects of the feasibility of the
185 intervention. Participants perceived that the implementation strategy had a low impact and that the
186 main positive effect was the increased diagnostic tests. Although more tests of women of childbearing
187 age were prescribed, the risk was not screened. This increase in tests was only seen during the first
188 months of the intervention. Limiting factors were blood samples not sent to the central laboratory
189 due to summer recess, work overload of the laboratory that had to process COVID-19 tests, and the
190 interruption of healthcare services at PHCs because of the pandemic. Significantly, some participants'
191 unwillingness to start treatment undermined the proactive search for positive cases.

192 Despite the increased testing, few new cases were detected, and no treatment was started. Reasons
193 provided by participating health providers included patients' comorbidities, patients who were
194 outside the recommended age range for treatment, and health providers' reluctance to administer
195 treatment at the first level of care. Several professionals expressed concerns, and one physician
196 refused to indicate treatment altogether, as they thought adverse effects outweighed benefits and
197 feared legal actions from patients and their families.

198 **Barriers and facilitators**

199 The facilitating factors were the simplicity of the intervention, professionals' willingness to extend the
200 indication of serologic tests to other populations, and staff commitment to the adoption of
201 intervention components. Participants identified barriers to the implementation at different levels,

202 such as internal factors, contextual factors, and individual-level attitudes of the intervention's target
203 population (see Table 3). At the individual level, the most significant barrier was professionals'
204 reluctance to treat Chagas at the first level of care due to fear of adverse effects. Sometimes, this
205 refusal was associated with a lack of knowledge and negative experiences in the past, a lack of
206 experience in treating the condition, and fear of medication supply shortages. Disagreement between
207 healthcare staff on the need to treat Chagas at the PHC led to some professionals perceiving that the
208 intervention was pointless.

209 Inner setting

210 Insufficient human resources to carry out intervention activities at the PHCs was one barrier identified
211 by professionals. The lack of human resources resulting from annual leave, the annual summer recess
212 and other priorities, such as dengue epidemic containment and other health programs, negatively
213 affected the capacity to implement the intervention. Informants highlighted the lack of time to cope
214 with the demand for care.

215 PHC directors' and facilitators' low commitment disrupted the implementation. Staff turnover and
216 frequent leaves of absence were obstacles to promoting implementation components. Limited
217 understanding of the intervention, because some staff had not taken part in the training sessions, was
218 a barrier to adopting the components; additionally, internal communication and training among staff
219 did not work.

220 Outer setting

221 External factors, such as lack of resources for sampling at the central laboratory and the COVID-19
222 pandemic, were critical aspects that negatively affected the implementation and continuity of the
223 intervention. A limited sampling at the central laboratory resulted from the summer recess and the
224 COVID-19 pandemic. During the summer months, serologic tests were only performed in emergencies,
225 which did not include Chagas tests. Additionally, there was a shortage of reagents for other
226 pathologies, which contributed to an interruption of sampling at PHCs. Resistencia city was a hotspot
227 during the pandemic, and the central laboratory that processed Chagas tests was the only one in the

228 province that processed COVID-19 tests. The pandemic and the associated social isolation measures
229 led to a disruption of healthcare activities at PHCs. Since the pandemic, healthcare staff numbers have
230 been reduced, and some staff has been reassigned to tasks related to pandemic control.

231

232 **Discussion**

233 This research designed an implementation strategy to improve using Chagas guidelines at the primary
234 healthcare level and piloted it to assess its feasibility and the factors that influence its implementation.
235 Implementing the intervention at the first level of care was uneven across PHCs. The pilot study took
236 place between September 2019 and May 2020. During the last months of the intervention, the COVID-
237 19 pandemic and associated measures affected the organization of the health system, the regular
238 operation of PHCs, and the implementation study. Some components have been fully or partially
239 implemented, such as flowcharts and the role of the facilitator. In contrast, the implementation of
240 other components, such as registries of positive cases and people at risk, has been low. Although the
241 target population perceived the intervention as relevant and acceptable, it had a limited impact.
242 Positively, according to interviewed professionals, the population indicated for serological testing
243 increased in the first months of the intervention but then discontinued because of contextual barriers.
244 A few new positive cases were registered during the study, and no treatment was started in the
245 participating centers. Although the intervention proposed that women of childbearing age, and
246 children and adolescents at risk, and all pregnant women had to be tested, the decision was based
247 only on medical criteria.

248 The main factors that affected implementation were the lack of diagnostic supplies (linked to
249 contextual barriers), the change of authorities, staff shortages, and, in recent months, the health
250 emergency caused by the COVID-19 pandemic, which interrupted the normal functioning of health
251 care activities. The reluctance of some professionals to carry out etiological treatment of positive cases

252 of Chagas disease at the first level of care was a considerable barrier to the adoption of the
253 intervention.

254 Lessons learned to improve design and implementation are highlighted, following the dimensions of
255 the CFIR model (31). Concerning the characteristics of the intervention, training needs to be improved
256 to strengthen health personnel's confidence in the quality and strength of the evidence, particularly
257 regarding aetiological treatment. In addition, training should be conducted regularly, aiming to train
258 the entire target population and include barriers or difficulties identified in process evaluations. It is
259 critical to work on health providers' knowledge and perception of the disease, its impact, and
260 treatment possibilities. Producing changes in beliefs, attitudes, and behaviors on both medical staff
261 and patients is one of the significant challenges faced when dealing with Chagas disease (15). The
262 reluctance of health care providers to indicate etiological treatment at the first level of care, a barrier
263 identified in previous studies and formative research (13-15), persisted despite training.

264 The main lessons learned in this study were that behavioral change strategies must be implemented,
265 including support from opinion leaders, medical experts, and local health authorities. This coincides
266 with findings from a study in another city in Argentina, recommending the inclusion of a senior
267 physician from a specialized Chagas organization for medical queries (32). The role of facilitator, taken
268 by someone external to the PHCs, should be strengthened. These points align with regional research
269 (15), which highlighted the identification of interested health workers and the specific training on
270 disease management. The facilitator should also be included in the planning, implementation, and
271 evaluation phases, supported by financial and/or academic incentives.

272 On the other hand, rapid diagnostic tests should be provided (33) in response to the identified barrier,
273 describing that the laboratories lacked the resources to respond to the increased demand for serology.
274 This implementation strategy would be an optimal scenario for testing "Test&Treat" models, with
275 innovations such as the use of two rapid diagnostic tests (2 PDTs) to confirm infection (33, 34) and
276 new antiparasitic regimens to deliver treatments with a better safety profile – BENDITA (35); BETTY

277 (36), TESEO (37); NuestroBen (38). Alonso-Padilla et al. 2019 (15) proposed innovative, simpler and
278 faster diagnostic strategies, LAMPs for antigens and rapid serological tests (T. cruzi-specific IgGs, rapid
279 diagnostic tests), and new therapeutic regimens.

280 It is essential to actively involve the local Chagas program referents and other local authorities and
281 serology laboratories to support and sustain the intervention. As stated by Alonso-Padilla et al. (15),
282 based on the experience in Bolivia, a vertical-to-horizontal healthcare model transition is needed to
283 improve access for people at risk, coordinating with local authorities to adopt the strategy and
284 promote intersectoral policies. The Chagas program implemented in another city in Argentina also
285 refers to the importance of the participation of local authorities in generating trust in the intervention
286 (31). Regarding the inner setting, supplies such as laboratory and electrocardiogram equipment and
287 human resources should be guaranteed, as shown in previous studies (31). It is necessary to improve
288 networking and communication within the centers. However, it is also essential to assess the
289 implementation climate, the ability to make changes, and the participants' willingness beforehand and
290 then incorporate this aspect into the training.

291

292 **Conclusions**

293 In this study, we evaluated the feasibility of an implementation strategy to improve the adoption of
294 national guidelines for managing Chagas disease at the primary care level. The process evaluation
295 showed that the components of the implementation strategy were acceptable to the primary
296 healthcare providers, but their adoption was uneven across PHCs. Training, flowcharts, and reminders
297 were partial to fully adopted, but the fidelity of their implementation was low. Contextual and health
298 care center-related barriers, such as staff shortages, lack of diagnostic supplies, and COVID-19
299 pandemic, limited the impact of the intervention. Professionals' reluctance to administer etiological
300 treatment at the PHCs hindered the intervention. These findings show the necessity to improve the
301 implementation strategy using behavioral change strategies to address some of the main barriers

302 identified in the pilot, including support actions offered by opinion leaders, medical experts, and local
303 health authorities. Rapid diagnostic tests should be readily available to maintain behavior changes.
304 We do not know the sustainability and scalability of the strategy. We suggest further refinement of
305 the strategy and its implementation in more centers to assess outcomes prospectively with a hybrid
306 implementation research design.

307

308 **List of abbreviations**

309 CFIR: Consolidated Framework for Implementation Research

310 PHCs: Primary healthcare centres

311 REDCap: Research Electronic Data Capture

312

313 **Declarations**

314 **Ethics approval and consent to participate**

315 The study was approved by the Health Sciences Research Bioethics Committee of the Faculty of
316 Medicine of the Universidad Nacional del Nordeste (Resolution 37/18). Informants' participation was
317 voluntary, and all and all participating health professionals signed an informed consent form.
318 Researchers maintained the confidentiality of collected information, under National Act 25.326, on
319 Personal Data Protection of the Argentine Republic.

320 **Consent for publication**

321 Not applicable

322 **Availability of data and materials**

323 Data sharing is not applicable to this article as no datasets were generated or analysed during the
324 current study.

325 **Competing interests**

326 The authors declare that they have no competing interests

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329 **Authors' contributions**

330 KK led the conception and design of the study, was closely involved in data analysis and interpretation,
331 and wrote the manuscript. JPA was involved in the design of the study, was closely involved in data
332 analysis and interpretation and wrote the manuscript with KK. JR participated in data interpretation,
333 revised the manuscript critically and translate it into English. MR conducted the interviews, the
334 observations and the secondary data collection. MB, MLC and AMB were involved in the design of the
335 study, participated in data interpretation, and revised the manuscript critically for important
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461

462 **Supplementary Information**

463 All additional files are in the original language (spanish).

464 **Additional file 1:**

465 Flowchart pregnant women.

466 **Additional file 2:**

467 Flowchart women of childbearing age.

468 **Additional file 3:**

469 Flowchart children and adolescents.

470 **Additional file 4:**

471 Reminder: Poster women of childbearing age.

472 **Additional file 5:**

473 Reminder: Poster children and adolescents.

474 **Additional file 6:**

475 Reminder: stickers.

476 **Additional file 7:**

477 Completed Standards for Reporting Implementation Studies (StaRI) checklist.

Supplementary Files

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