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**Economic performance and cost-effectiveness of using a  
DEC-salt social enterprise for eliminating the major  
neglected tropical disease, lymphatic filariasis**

Swarnali Sharma<sup>1</sup>, Morgan E. Smith<sup>1</sup>, James Reimer<sup>2</sup>, David B. O’Brien<sup>3</sup>, Jean M. Brissau<sup>4</sup>,  
Marie C. Donahue<sup>5</sup>, Clarence E. Carter<sup>6</sup>, Edwin Michael<sup>1\*</sup>

<sup>1</sup>Department of Biological Sciences, University of Notre Dame, Galvin Life Science Center,  
Notre Dame, IN 46556, USA

<sup>2</sup>1071 Devonshire Road, Grosse Pointe Park, MI 48230, USA

<sup>3</sup>10720 Serenbe Lane, Chattahoochee Hills, GA 30268, USA

<sup>4</sup>College of Science, University of Notre Dame, Notre Dame, IN 46556, USA

<sup>5</sup>Eck Institute of Global Health, University of Notre Dame, 305 Brownson Hall, Notre Dame, IN  
46556, USA

<sup>6</sup>College of Science, 215 Jordon Hall of Science, University of Notre Dame, Notre Dame, IN  
46556, USA

\*Corresponding author

E-mail: [Edwin.Michael.18@nd.edu](mailto:Edwin.Michael.18@nd.edu) (EM)

## 27 **Abstract**

## 28 **Background**

29 Salt fortified with the drug, diethylcarbamazine (DEC), and introduced into a competitive  
30 market has the potential to overcome the obstacles associated with tablet-based Lymphatic  
31 Filariasis (LF) elimination programs. Questions remain, however, regarding the economic  
32 viability, production capacity, and effectiveness of this strategy as a sustainable means to bring  
33 about LF elimination in resource poor settings.

## 34 **Methodology and Principal Findings**

35 We evaluated the performance and effectiveness of a novel social enterprise-based  
36 approach developed and tested in Léogâne, Haiti, as a strategy to sustainably and cost-efficiently  
37 distribute DEC-medicated salt into a competitive market at quantities sufficient to bring about  
38 the elimination of LF. We undertook a cost-revenue analysis to evaluate the production  
39 capability and financial feasibility of the developed DEC salt social enterprise, and a modeling  
40 study centered on applying a dynamic mathematical model localized to reflect local LF  
41 transmission dynamics to evaluate the cost-effectiveness of using this intervention versus  
42 standard annual Mass Drug Administration (MDA) for eliminating LF in Léogâne. We show that  
43 the salt enterprise because of its mixed product business strategy may have already reached the  
44 production capacity for delivering sufficient quantities of edible DEC-medicated salt to bring  
45 about LF transmission in the Léogâne study setting. Due to increasing revenues obtained from  
46 the sale of DEC salt over time, expansion of its delivery in the population, and greater  
47 cumulative impact on the survival of worms, this strategy could also represent a significantly

48 more cost-effective option than annual DEC tablet-based MDA for accomplishing LF  
49 elimination.

50 **Significance**

51 A social enterprise approach can offer an innovative market-based strategy by which  
52 edible salt fortified with DEC could be distributed to communities both on a financially  
53 sustainable basis and at sufficient quantity to eliminate LF. Deployment of similarly fashioned  
54 intervention strategies would improve current efforts to successfully accomplish the goal of LF  
55 elimination, particularly in difficult-to-control settings.

## 56 **Author summary**

57           With less than three years remaining for meeting the 2020 target set by WHO for  
58 accomplishing the global elimination of Lymphatic Filariasis (LF), concerns are emerging  
59 regarding the feasibility of meeting this goal using the current tablet-based Mass Drug  
60 Administration strategy. Salt fortified with the antifilarial drug, diethylcarbamazine (DEC),  
61 could offer an intervention that avoids many of the barriers connected with tablet-based  
62 elimination programs. We analyzed the economic performance and cost-effectiveness of a novel  
63 DEC-salt social enterprise developed and tested in Léogâne arrondissement, Haiti, as a  
64 particularly significant strategy for accomplishing sustainable LF elimination in such complex  
65 settings. We show that because of increasing revenue from the sale of the DEC salt over time,  
66 expansion of its delivery in the population, and the adverse effect of continuous consumption  
67 of the drug on worms, the delivery of DEC through a salt enterprise can represent a  
68 significantly more cost-effective option than annual DEC tablet-based MDA for  
69 accomplishing LF elimination in settings, like Léogâne. We indicate that development of  
70 policy and research into how to deploy similarly-fashioned interventions, or work with the salt  
71 industry to increase population use of medicated salt, would improve present efforts to  
72 successfully accomplish the elimination of LF.

## 75 **Introduction**

76           Lymphatic filariasis (LF), a mosquito-borne neglected tropical disease (NTD), commonly  
77 known as elephantiasis, is one of only parasitic six diseases currently targeted for potential  
78 global eradication by 2020 using preventive mass chemotherapy [1-3]. Despite the impressive  
79 expansion of a WHO-led elimination program aimed toward the meeting of this goal in all  
80 endemic countries since 2000, stakeholders committed to global LF elimination have recognized  
81 that the current tablet-based mass drug intervention is resource-intensive, can face significant  
82 compliance issues with time, and may be difficult to implement in remote or socio-ecologically  
83 complex areas, such as urban and socio-politically unstable settings, hampering foreseen  
84 elimination goals [4-8]. These difficulties have heightened interest in investigating the impacts of  
85 either approaches aimed at scaling-up treatment strategies or inclusion of preventive activities  
86 into drug programs (such as supplemental vector control), or evaluation of novel intervention  
87 technologies, that can effectively overcome current barriers in order to accelerate parasite  
88 elimination [9-11].

89           Salt fortified with the anti-filarial drug, diethylcarbamazine (DEC), could offer an  
90 intervention that avoids many of the above issues connected with tablet-based elimination  
91 programs [18]. Indeed, DEC-salt has played a major role in the elimination of LF in a number of  
92 pilot and region-wide settings in Africa, Central America, and Asia [5,12-17]. The low dose of  
93 DEC (0.1-0.6% [w/w]) used in these studies and programs was well tolerated and rarely  
94 associated with adverse reactions. It also has the potential to be more effective than tablet-based  
95 Mass Drug Administration (MDA) programs via reduction of the durations of intervention  
96 required to interrupt parasite transmission [18]. Moreover, fortified salt can also be provided to a

97 population without developing a dedicated public distribution system, overcoming the need for  
98 developing an effective health infrastructure capable of distributing anti-filarial drugs at the high  
99 coverages needed for achieving elimination [5,7,8].

100 Haiti is one of only four countries remaining in the Americas where LF is still endemic  
101 [8,19]. MDA using DEC first started in the country under the National Program to Eliminate LF  
102 (NPELF) in 2000, and following funding, sociopolitical and natural disaster-based challenges to  
103 scaling up, the program realized full national coverage by 2012 [5,7,8,20]. This delay together  
104 with the technical challenge of interrupting transmission in areas of highest prevalence even with  
105 good levels of coverage using the suggested five successive years of annual MDA [5,7,8,20],  
106 indicate that it is unlikely that NPELF will meet the goal of accomplishing LF elimination in the  
107 country by the target year of 2020. In 2006, partly to overcome the above issues, a project was  
108 initiated with the collaboration of Congregation de Sainte Croix, the Notre Dame Haiti Program,  
109 and the Ministry of Public Health and the Population (MSPP), focused on the local processing  
110 and marketing of DEC-mediated salt co-fortified with potassium iodate as an alternative means  
111 to facilitate the elimination of LF (and prevention of iodine deficiency disorders) in Haiti [8].  
112 Based on the principle of employing a social enterprise framework for providing goods and  
113 services in an entrepreneurial and innovative fashion to solve social problems [21-23], this  
114 project has since upgraded its salt production facility to facilitate a transition to the production  
115 and sale of processed food-grade co-fortified salt, raising the potential of using DEC-medicated  
116 salt as a long-term sustainable means to accomplish LF elimination in settings, such as Haiti.

117 Here, our major aim was to examine the economic performance and effectiveness of  
118 using the Haitian social enterprise-based framework for producing and marketing DEC-fortified

119 salt as a sustainable, cost-effective, model for achieving the long-term elimination of LF,  
120 focusing on Léogâne arrondissement, Haiti. A cost-revenue analysis combined with a  
121 mathematical modeling-based evaluation of the cost-effectiveness of the DEC salt social  
122 enterprise compared to standard MDA was carried out to undertake this analysis. Specifically,  
123 we evaluated the economic performance and social value of the enterprise by assessing: 1) the  
124 growth in salt production, costs of resources consumed, and revenues from sales gained to  
125 determine break-even points, 2) the impact of the product-mix used for realizing the socially-  
126 relevant sale price of the salt, and 3) its cost-effectiveness compared to tablet-based MDA for  
127 accomplishing LF elimination in the study setting of Léogâne arrondissement, Haiti. We discuss  
128 the results in terms of how using a social enterprise can offer a sustainable and innovative  
129 strategy for accomplishing LF elimination in Haiti, and similarly resource-constrained settings,  
130 that face both programmatic and social difficulties in delivering long-term tablet-based LF  
131 MDAs.

## 132 **Methods**

### 133 **Overview**

134 We carried out a cost-revenue analysis to evaluate the production capability and financial  
135 feasibility of the developed DEC salt social enterprise via assessment of the relationship between  
136 fixed and variable costs versus the revenue received [24,27] and a modeling study centered on  
137 applying a dynamic transmission model to evaluate the cost-effectiveness of using this  
138 intervention versus standard annual MDA for eliminating LF in Léogâne arrondissement, where  
139 the salt enterprise operates [28-31]. The cost-revenue analysis was based on costs and revenue  
140 data contained in financial accounts during the production phase of the salt enterprise from 2013

141 to 2018, while the break-even analysis was carried out over a time horizon that ranged between  
142 2013 to the year when the break-even point was attained. The predicted timelines to LF  
143 elimination along with the costs of annual MDA versus the net cost of supplying DEC-fortified  
144 salt until elimination was achieved were used to carry out the cost-effectiveness modeling study.

## 145 **Cost-revenue and break-even analyses**

### 146 **Cost estimation**

147 From the operational perspective, these included periodic financial investments primarily  
148 used for purchasing large equipment; fixed costs (administrative, marketing, maintenance, and  
149 leasing costs) and variable costs (costs of raw salt, salt packaging, custom fees, labor,  
150 transportation, and drug supplies). As the salt enterprise used a product-mix business strategy of  
151 producing three different types of salt to meet demands and application in different market  
152 segments, viz. industrial – untreated salt processed to meet the requirements of various industrial  
153 applications, coarse and fine single-fortified salt (treated with 40 ppm of potassium iodate only)  
154 and double-fortified salt (treated with both 40 ppm of potassium iodate and 0.32% DEC [w/w]),  
155 to assure price competitiveness of the double-fortified salt with the local table salt in the market  
156 and to meet customer preference for either coarse or fine edible salt, we additionally estimated  
157 the variable costs of the two fortified salt types. At the project level, we multiplied the unit cost  
158 with the unit quantity of each cost item consumed on a yearly basis to obtain the annual total cost  
159 of producing all three types of salt.

### 160 **Revenue estimation**

161           The unit sale price was multiplied by the unit quantity sold per year to quantify the  
162   annual revenue obtained by the sale of each salt type. Total revenue was simply the sum of  
163   revenues obtained from the sale of each salt type.

#### 164   **Forecasting break-even time points**

165           This was conducted by projecting forward the total costs (investment + fixed + variable  
166   costs) and total revenues from the sale of all three types of salt estimated for different periods  
167   between 2013 to 2018 until the point at which cash flow from the project (total revenue – total  
168   cost) becomes zero or the break-even for the enterprise is attained [24-27]. Simple linear forward  
169   projections were used to make these calculations. Costs and revenues (both in US\$) were used  
170   undiscounted in this study.

#### 171   **Cost-effectiveness modeling**

##### 172   **Overview of the LF transmission model**

173           We extended the data-driven Monte Carlo population-based EPIFIL model for predicting  
174   local LF infections [32-36] to include comparative costs and simulations of the effectiveness of  
175   the standard two-drug (DEC plus Albendazole (ALB)) tablet-based MDA used in Haiti versus  
176   consumption of double-fortified salt sold by the salt enterprise to perform this analysis. We used  
177   a data-model assimilation technique based on the Bayesian Melding (BM) algorithm to calibrate  
178   the LF model to the microfilariae (mf) prevalence data observed in our Léogâne endemic setting  
179   [28-31], and used the localized model to simulate the impact of either intervention on timelines  
180   required to the decrease the community-level mf prevalence below the WHO-mandated  
181   elimination threshold of 1% mf [1,2]. The economic cost for carrying out annual MDA was fixed

182 conservatively at US\$0.64 per person inclusive of drug cost, given the finding that this  
183 represented the average cost of treating an individual in Haiti once initial costs stabilized [29,37],  
184 while the cost of delivering DEC-medicated salt per person per year was estimated from the  
185 difference between the costs of production and the revenues gained from sales of the salt.  
186 Simulations of cost-effectiveness were carried out by fixing the Léogâne arrondissement  
187 population at 500,000 [38]. Modeling of the impacts of MDA using DEC+ALB and DEC-  
188 medicated salt followed our previous methods published in detail in Smith et al [18]. Outcomes  
189 were compared at coverages of 65% and 80%, while effectiveness of DEC-medicated salt was  
190 also investigated at population coverages that could be obtained as salt production increased over  
191 time.

## 192 **Input epidemiological data**

193 The data sources used for calibrating the LF model were collected from Léogâne  
194 commune, Haiti [28-31]. The epidemiological data inputs encompassed information on baseline  
195 community-level mf prevalence (15.5%), the annual biting rate (ABR) estimated inversely by  
196 model fitting to mf prevalence data [39], and details regarding the dominant mosquito genus  
197 (*Culex quinquefasciatus*). Published details of the MDA interventions, including the relevant  
198 drug regimen, carried out in this setting during 2000-2008 were also assembled and used as  
199 required [20,28-31]. All model parameters, functions, and fitting procedures specific to this work  
200 are given in detail in S1 Supporting Information.

## 201 **Results**

### 202 **Costs and production of salt**

203           Table 1 summarizes the investment, fixed and variable costs incurred in establishing and  
204   operating the Léogâne DEC salt enterprise. These costs are presented for the years between  
205   2013-2018 when production of food-grade fortified salt began (following an experimental phase  
206   which addressed technical issues in the fortifying of salt with DEC) along with corresponding  
207   data on the quantity of the three different types of salt (industrial, coarse and fine single-fortified,  
208   coarse and fine double-fortified) produced and sold. Note that investments occurred periodically  
209   during different expansion phases (2013, 2014, and 2017), and were primarily used to acquire  
210   capital items either from the US or from within Haiti. These were recorded as fixed assets, and  
211   comprised factory items, such as different types of pumps, screens, control systems, hoppers,  
212   sealers, storage tanks, generators, and office equipment. Fixed costs, i.e., costs that remain the  
213   same whatever the level of output produced or products sold included operating expenses, while  
214   variable costs comprised costs of items which scaled with production volume [24,25]. Examples  
215   of components of the latter two cost types incurred are given in Methods.

216 **Table 1. Cost (investment, fixed cost and variable cost (in US\$)) and summary of all types of salt (industrial salt, coarse and**  
 217 **fine single-fortified salt, and coarse and fine double-fortified salt) produced (tons) from 2013-2018.**

Year	Cost (US\$)			Salt Production (Tons)				
	Investment	Fixed Cost	Variable Cost	Industrial	Single-fortified		Double-fortified	
					Coarse	Fine	Coarse	Fine
2013 (Jan-Dec)	98,418	36,612	75,176	10	0	0	230	0
2014 (Jan-Dec)	397,249	180,589	120,296	272	1	5	470	0
2015 (Jan-Dec)	0	275,495	225,367	557	146	33	334	7
2016 (Jan-Dec)	0	275,495	392,882	2140	452	206	479	61
2017 (Jan-Dec)	49,280	558,904	601,308	2811	648	308	979	91
2018 (Jan-Dec)	23,000	352,000	800,000	2431	1013	527	1841	33

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220 The data on salt production show that initial output was low (e.g., 10 metric tons of  
221 industrial salt and 230 tons of coarse double-fortified salt in 2013, compared to 272, 6, and 470  
222 tons of industrial, single-fortified, and double-fortified salt respectively in 2014). To increase  
223 production, a three phase expansion of the project was introduced beginning in the year 2013.  
224 Phase 1 focused on installing higher capacity processing equipment (January 2013-March 2014),  
225 while Phase 2 aimed to expand processing capacity by adding bulk storage and extension of the  
226 brine-washing system (May 2014-March 2015), and Phase 3 further expanded these washing,  
227 processing and storage capacities (January 2017-June 2018). These expansion phases meant that  
228 both the fixed and variable costs of salt production varied over time (Table 1), but in general, and  
229 as expected, as production expanded the variable costs increased proportionately while the fixed  
230 costs simply reflected increases in capital investments. By contrast, the production figures show  
231 that the manufacture and sale of each type of salt increased steadily, with industrial salt  
232 dominating production particularly toward the later years followed by double-fortified (i.e., DEC  
233 and iodine medicated) and single-fortified (iodine-medicated only) coarse salts. Given the  
234 population preference for coarse edible salt in Léogâne (and Haiti in general), fine salt  
235 production and sale lagged behind in volume (Table 1). The figures, however, demonstrate that  
236 with expansion in capacity the enterprise was able to achieve significant production volumes for  
237 the double-fortified salt by year 2018 (1841 metric tons recorded for the coarse variety).

### 238 **Net cash flow and break-even forecasting**

239 The total annual costs of salt production (= Investment + Fixed Costs + Variable Costs)  
240 and revenues attained from the sale of all three types of salt are given in Table 2. Total annual  
241 costs increased as production expanded (Table 1) from US\$210,206 in 2013 to US\$1,175,000 in

242 2018 – i.e., approximately five times – but the figures show that revenue increased even faster,  
243 up to 17 times that obtained initially in 2013 (US\$61,636) to close to cost of production by 2018  
244 (US\$1,064,000). The net cash flow [24-27] figures in the Table, which represent the difference  
245 between total production cost and total revenue, although being negative for all the years from  
246 2013-2018, capture this increasing revenue returns (as reflected by the declining negative trend  
247 in the net cash flow) towards the later years, suggesting that the project is close to achieving  
248 break-even or profitability in the near future. To estimate the exact time point when the  
249 enterprise is likely to break-even (i.e., the time point when the total program cost is equal to the  
250 total revenue), we employed a simple linear model to project forward the total project costs and  
251 revenues calculated for 2013-2018. Fig 1(a) shows that if we use the full data on annual costs  
252 and revenues obtained for the whole 2013-2018 period, the project will break-even in 2027.  
253 However, if we use the data from 2016-2018, when total salt production had reached significant  
254 levels (Table 1), to predict the time point at which the break-even point will be achieved, this  
255 will occur earlier by year 2022 (Fig 1(b)).

256 **Table 2. Year wise details of total cost, total revenue and net cash flow attained by the Haiti**  
257 **salt enterprise between 2013 to 2018.** The total costs shown are calculated using the cost data  
258 for the production of all three types of salt, while total revenue is calculated using the revenue  
259 data from the sale of all three types of salt for each year.

Year	Total Cost (US\$)	Total Revenue (US\$)	Net Cash Flow
2013	210,206	61,636	-148,570
2014	698,134	118,583	-579,551
2015	448,168	175,629	-272,539
2016	721,070	512,588	-208,482
2017	1,209,492	832,285	-377,207
2018	1,175,000	1,064,000	-111,000

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261 **Fig 1. Forecasts of the break-even years of the salt enterprise.** Results are shown from using a  
262 simple linear model to project forward the total project costs and revenues (in US\$). **(a)** Forecast  
263 of break-even year using total cost and total revenue data calculated for 2013-2018 given in  
264 Table 2. **(b)** Forecast of break-even year using total cost and total revenue data calculated for  
265 2016-2018 given in Table 2. The red dotted line indicates the break-even point for each scenario.

266 Fig 2 depicts the per ton revenues from sales and costs of producing the three different  
267 types of salts for the years 2013-2018. The results show that for all salt types, while initially  
268 there was a large difference between the production cost and revenue per ton (i.e., a large  
269 negative cash-flow), this difference decreased for each salt category with time. This occurred  
270 faster, however, in the case of the industrial and single-fortified salt, such that break-even was  
271 achieved by 2018. By contrast, the cash-flow from the production and sale of the double-fortified  
272 salt was still negative (lower revenue compared to production costs) at the end of the present  
273 study period of 2018. This result shows, first, that the overall break-even estimated in this study  
274 (Fig 1) for the project is due to the delay in reaching the break-even year for double-fortified salt.  
275 Second, it also highlights how the mixed product strategy of producing different types of salt  
276 targeting different market sectors can allow the more profitable products (industrial, single-

277 fortified salt) to subsidize the sale of a product (double-fortified salt) whose cost (approximately  
278 US\$200 per ton (Fig 2)) needs to be kept competitive with other edible salt sold (retailed at  
279 \$US265 per ton in Haiti (James Reimer, personal communication)) in the local market.

280 **Fig 2. Revenue and production cost for industrial, single-fortified and double-fortified salt.**  
281 Both revenue and production cost (in US\$) for each salt are shown per ton.

## 282 **Marginal cost of manufacturing DEC-medicated salt**

283 This was evaluated by analysis of the difference in the variable costs of producing the  
284 single-fortified (which included only potassium iodate) versus the double-fortified (both  
285 potassium iodate and DEC included) salt types, given that the investment and fixed costs going  
286 into manufacturing all salt types were shared equally between each type. The variable costs per  
287 ton for producing the single-fortified (coarse and fine) and double-fortified (coarse and fine) salt  
288 for two types of bags/bales (25.0-kg bags and 12.5-kg bales) are provided in Table 3 for the  
289 years 2014-2018 when both salt products were produced (note that production of single-fortified  
290 salt began only in 2014 (Table 1)). Analysis of the difference in the variable costs for producing  
291 the single-fortified versus the double-fortified salt indicate that this was consistently about  
292 US\$70 per metric ton, irrespective of which type - coarse or fine variety - or types of bags/bales  
293 were produced (Table 3). Given that the cost of DEC, as delivered by Syntholab Chemicals to  
294 the project was US\$21.60 per kg (James Reimer, personal communication), and DEC salt in this  
295 project was fortified with 0.32% DEC by weight or with 3.2kg of DEC/ton, it can be seen that  
296 the cost of producing one metric ton of DEC salt works to be US\$ 69.12/ton (i.e., 3.2 kg DEC x  
297 US\$21.60 per kg). This result indicates that the marginal cost, or difference in the variable cost,  
298 of adding DEC to single-fortified salt (US\$70; Table 3) was simply due to the purchase cost of  
299 DEC.

302 **Table 3. Marginal cost of manufacturing DEC-medicated salt.** This was evaluated by  
 303 analysis of the difference in the variable costs of producing the single-fortified (which included  
 304 only potassium iodate) versus the double-fortified (both potassium iodate and DEC included) salt  
 305 types, given that the investment and fixed costs going into manufacturing all salt types were  
 306 shared equally between each type.

Year	Types of Bags/Bales	Variable cost of Coarse Salt (US\$/Ton)			Variable cost of Fine Salt (US\$/Ton)		
		Single-fortified	Double-fortified	Difference	Single-fortified	Double-fortified	Difference
2014	25.0-kg Bags	150	220	70	160	230	70
	12.5-kg Bales	190	260	70	200	270	70
2015	25.0-kg Bags	145	215	70	155	225	70
	12.5-kg Bales	185	255	70	195	265	70
2016	25.0-kg Bags	145	215	70	155	225	70
	12.5-kg Bales	185	255	70	195	165	70
2017	25.0-kg Bags	135	205	70	145	215	70
	12.5-kg Bales	175	245	70	185	255	70
2018	25.0-kg Bags	135	205	70	145	215	70
	12.5-kg Bales	175	245	70	185	255	70

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### 309 **Population coverage attained by the DEC salt enterprise**

310 Table 4 shows the potential increase in demand for salt in the Léogâne arrondissement  
 311 calculated as a function of changes in population size from 2013 to 2018. It also presents the  
 312 potential DEC-fortified salt coverage which may be achieved in the setting by increasing sale of  
 313 the double-fortified salt produced over this period. The annual population size estimates from  
 314 2013 onwards were predicted using a growth rate of 1.28% [38], whereas the yearly population  
 315 demand for edible salt was calculated by assuming that the daily salt consumption per person is  
 316 15gm (average of the reported daily per-capita consumption in Haiti of 10gm and 19gm [5,40]).

317 Assuming that the sale of double-fortified salt is widespread in the community (i.e., not targeted  
318 towards one segment of the population), coverage of DEC salt in Léogâne can then be roughly  
319 estimated simply by dividing the quantity of salt produced over the estimated demand. The  
320 results from this calculation, listed in the last column of Table 4, shows that as production  
321 increased rapidly from 2013 to 2018, this could increase potential population coverage achieved  
322 by sales of the DEC-medicated salt from as low as 8.45% in 2013 to approximately 65% in 2018.

323 **Table 4. Details of production of double-fortified (DEC-medicated) salt (tons), its potential demand/year, and coverage in**  
 324 **Léogâne Arrondissement.**

<b>Year</b>	<b>Quantity of double-fortified (DEC-medicated) salt (Tons)</b>	<b>Population of Léogâne Arrondissement*</b>	<b>Potential Demand of salt/year (Tons)**</b>	<b>Coverage (%)</b>
<b>2013</b>	230	497,274	2,723	8.45
<b>2014</b>	470	503,241	2,755	17.06
<b>2015</b>	341	509,280	2,788	12.23
<b>2016</b>	540	515,799	2,824	19.12
<b>2017</b>	1070	522,401	2,860	37.41
<b>2018</b>	1874	529,088	2,897	64.69

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327 \*Population growth rate of Haiti is 1.28% [38]

328 \*\*Assuming that the salt consumption rate per person per day is 15gm [5,40]

329

## 330 **Cost-effectiveness modeling**

331 This was carried out by comparing the costs and effectiveness achieved by the production  
332 and sale of DEC-fortified salt versus implementation of the annual tablet-based DEC/ALB MDA  
333 for accomplishing LF elimination in Léogâne (as measured by the times by which the initially  
334 observed baseline pre-control mf prevalence in this setting reach below the WHO-recommended  
335 1% mf prevalence threshold [1,2]). Timelines taken by each intervention to reduce the initial  
336 prevalence to below the 1% mf threshold were quantified by simulating trends in infection  
337 prevalence due to these interventions using the Monte Carlo-based EPIFIL model localized to  
338 reflect LF transmission in Léogâne [32-36]. The impact of the annual tablet-based MDAs was  
339 studied by running the model at 65% and 80% population coverages, while we simulated the  
340 effect of the produced DEC salt using 65%, 80% and the actual population coverages given in  
341 Table 4. EPIFIL was calibrated to the pre-control mf prevalence data observed in Léogâne  
342 (15.5% [28]) so that it could reproduce the baseline age-infection prevalence for carrying out this  
343 analysis.

344 Fig 3 portrays the predicted timelines to LF elimination in Léogâne under each of the  
345 MDA and salt interventions investigated. For MDA, the depicted simulations indicate that it  
346 would take up to 7 years at 65% coverage, and 5 years at 80% coverage, respectively, to reach  
347 the 1% mf threshold. By contrast, the model predictions show that it will take just 1 year at 65%  
348 coverage, 5 months at 80% coverage, and 3 years if actual population coverage (Table 4) are  
349 used to reduce the pre-control prevalence to below this threshold (Fig 3). This highlights the  
350 dramatic effect that daily consumption of DEC-medicated salt even at low dosages (0.32% w/w)  
351 would have compared to annual intake of a higher dosages of DEC (and ALB) as provided by

352 tablet-based MDA for eliminating LF infection in an endemic setting [12,15-18]. Note that the  
353 actual DEC salt population coverages (Table 4) used in this analysis assume that salt supply  
354 occurred uniformly and sale was restricted to Léogâne arrondissement only. Any changes in  
355 these parameters would mean attaining lower annual population coverages than shown in Table  
356 4; however, a sensitivity analysis using coverage values 15-20% lower than those depicted in the  
357 Table did not affect the above timelines significantly (data not shown).

358 **Fig 3. Timelines to reach the WHO recommended 1% mf threshold for MDA implanted at**  
359 **65% and 80% coverage and DEC-medicated salt at 65%, 80%, and actual population**  
360 **coverages.** The median model predicted trajectory is shown for each intervention strategy. The  
361 black dotted horizontal line indicates WHO recommended 1% mf prevalence threshold. The  
362 blue, red, orange, purple and green dotted vertical lines indicate the time points to reach 1% mf  
363 threshold using either MDA at 65% and 80% coverages or DEC Salt at 65%, 80%, and actual  
364 coverage respectively.

365 The comparative costs of carrying out annual MDA versus supplying DEC-medicated  
366 salt are shown in Table 5. These show that while the total cost of delivering annual MDA (here  
367 fixed at US\$0.64 per person, inclusive of the cost of the drug [29,37]), simply scaled with  
368 population growth, and will continue to be substantial on a yearly basis until LF elimination is  
369 achieved, the net cost of supplying DEC-fortified salt through the social business model will  
370 decline dramatically with time as production costs decrease and revenues begin to increase over  
371 time (Fig 2). Indeed, projection forward of the net or revenue - production cost data collected  
372 during the years 2013-2018 indicates that the total and per capita net costs of DEC salt provided  
373 through the present social enterprise could potentially even become zero at the time point (2027)  
374 when the project breaks even (Fig 1(a)).

375 **Table 5. Forecast of the population of Léogâne, annual cost of supplying double- fortified**  
 376 **(DEC-medicated) salt per person per year, and total costs of treatment with DEC-**  
 377 **medicated salt and MDA respectively for the years 2013-2027.** The population growth rate for  
 378 Haiti estimated in year 2015 (1.28%) was used in making the population size estimations shown  
 379 in the Table, whereas a simple linear model based on the cost and revenue data connected with  
 380 DEC-medicated salt production and sale (both fine- and coarse salt types) for the years 2013-  
 381 2018 (Fig 2) was used to forecast the annual cost of salt-based DEC treatments per person and  
 382 for the total population between 2019-2027.

Year	Population of Léogâne*	Annual Cost for Double fortified (DEC-medicated) salt per person (US\$)	Total cost for treating with DEC-medicated salt (US\$)	Total cost for MDA (US\$)**
2013	497,274	3.38	1,680,786	318,255
2014	503,241	4.27	2,148,839	322,074
2015	509,280	0.94	478,723	325,939
2016	515,799	0.97	500,325	330,111
2017	522,401	1.01	527,625	334,337
2018	529,088	0.58	306,871	338,616
2019	535,860	0.61	329,018	342,950
2020	542,719	0.51	276,787	347,340
2021	549,666	0.41	223,164	351,786
2022	556,702	0.30	168,124	356,289
2023	563,827	0.20	111,638	360,849
2024	571,044	0.09	53,678	365,468
2025	578,353	0.01	5,783	370,146
2026	585,757	0.001	586	374,884
2027	593,254	0	0	379,683

383

384 \*Population growth rate of Haiti is 1.28% [38]

385 \*\*Using cost for annual MDA as US\$0.64 per person/year [37]

386

387 We used the total costs of implementing each strategy until LF elimination (crossing  
 388 below the 1% mf threshold) is achieved to investigate the cost effectiveness of either strategy.  
 389 The total costs and effectiveness of using MDA at 65% and 80% coverages and supplying DEC  
 390 salt at 65%, 80% and the actual coverages given in Table 4, were evaluated and compared via  
 391 calculations of the average cost effectiveness ratio [10,41-47]. With respect to DEC salt, we also  
 392 conducted the analysis using three different net costs of salt production per person per year as

393 recorded in Table 5: (i) average of the net cost of salt produced per person calculated for the  
394 years 2018-2020, i.e., US\$0.57 per person/year, (ii) average of the net cost of salt per person for  
395 the years 2021-2023, i.e., US\$0.3 per person/year, and (iii) average of the net cost of salt per  
396 person for the years 2025-2027, i.e., US\$0.025 per person/year. This was performed to assess the  
397 sensitivity of the present results to changes in the steeply declining net cost of salt production  
398 over time observed in this study.

399 The results from this exercise are shown in Table 6, and indicate, principally, that  
400 irrespective of coverage, the costs of using MDA are significantly greater than those arising from  
401 using the salt strategies, primarily because of its lesser effectiveness as well as higher and  
402 stationary unit cost. Among the three salt scenarios, costs for eliminating LF, as expected,  
403 declined with decreasing net cost of production over time with scenario three showing the lowest  
404 costs. However, for all strategies, while the most effective strategy is to deliver MDA or salt at  
405 80% coverage, the most cost-effective option (in terms of minimizing the cost-effectiveness  
406 ratio) occurred at either 65% drug coverage for MDA or at the lower actual coverages recorded  
407 for DEC salt (Table 6). This suggests the existence of a trade-off between cost and effectiveness  
408 (in terms of duration of interventions required to achieve elimination) in the case of these  
409 strategies, i.e., obtaining a higher coverage for accomplishing earlier LF elimination comes with  
410 heightened costs. Overall, however, the results indicate that because of: 1) decreasing net cost of  
411 DEC salt production over time, and 2) expansion of its coverage in the population leading to  
412 significantly reduced elimination timelines, the delivery of DEC through a salt enterprise may be  
413 significantly more cost-effective than annual DEC tablet-based MDA for accomplishing LF  
414 elimination in the Léogâne arrondissement setting. It is also to be appreciated that we used a  
415 conservative treatment cost of \$0.64 per person for modeling the cost-effectiveness of the tablet-

416 based MDA program in this study. This represented a best-case scenario for the MDA program  
417 implemented in Léogâne given that the actual economic costs, i.e., inclusive of the cost of  
418 donated drugs, started out higher (US\$1.84 over the first 3 MDAs) before approaching the  
419 stabilized value used in our analysis as the program became more efficient [29,37]. Indeed, a  
420 recent systematic review indicated that MDA program costs can vary substantially between  
421 settings, with an average economic cost that could reach as high as US\$1.32 [48]. Use of such  
422 values or inclusion of the actual change observed in the per person treatment cost over time in  
423 Léogâne in the present analysis would clearly further increase the cost of MDA over that  
424 presented in Table 5, which in turn would lead to an even higher cost-effectiveness ratio for  
425 MDA compared to those estimated for DEC salt in this study (Table 6).

426 **Table 6. Comparison of total costs and CE ratios of population treatment using MDA**  
 427 **versus supply of DEC-medicated salt for different drug coverages and DEC salt costs.**

<b>Treatment Method</b>	<b>Coverage</b>	<b>No. of years to reach 1% mf threshold</b>	<b>Total Cost (US\$)</b>	<b>CE ratio</b>
<b>Annual MDA*</b>	65%	7.00	1,456,000	208,000
	80%	5.00	1,280,000	256,000
<b>DEC salt<sup>1</sup></b>	65%	1.00	185,250	185,250
	80%	0.42	95,760	228,000
	Actual <sup>†</sup>	3.00	105,450	35,150
<b>DEC salt<sup>2</sup></b>	65%	1.00	97,500	97,500
	80%	0.42	50,400	120,000
	Actual <sup>†</sup>	3.00	55,500	18,500
<b>DEC salt<sup>3</sup></b>	65%	1.00	8,125	8,125
	80%	0.42	4,200	10,000
	Actual <sup>†</sup>	3.00	4,625	1,542

428

429 \*Using cost for annual MDA as US\$0.64 per person/year [37], and total population of Léogâne  
 430 arrondissement 500,000 (fixed).

431 †Actual coverage of DEC-medicated salt given in Table 4.

432 <sup>1</sup>Average of the net cost of DEC salt produced per person calculated for the years 2018-2020  
 433 given in Table 5, i.e., US\$0.57 per person/year.

434 <sup>2</sup>Average of the net cost of DEC salt produced per person calculated for the years 2021-2023 given  
 435 in Table 5, i.e., US\$0.3 per person/year.

436 <sup>3</sup>Average of the net cost of DEC salt produced per person calculated for the years 2025-2027 given  
 437 in Table 5, i.e., US\$0.025 per person/year.

438

## 439 **Discussion**

440           In this study, we have undertaken a performance assessment of a novel social enterprise  
441 developed through a collaboration between Haitian and international partners engaged with LF  
442 control in the country, as a means to enhance the delivery of anti-filarial drugs to populations  
443 through the trading of salt co-fortified with DEC. Although DEC-fortified salt has been used  
444 previously in both pilot and region-wide LF intervention programs in a variety of global regions,  
445 ranging from Brazil, Tanzania, India and China to effectively control or eliminate LF [5,12-17],  
446 it is to be noted that the developed Haiti salt enterprise is the first attempt anywhere in the world  
447 to apply the principles of social entrepreneurship for delivering such an intervention. Recent  
448 work has highlighted how such social enterprises – that is, a social mission-driven organization  
449 that trades in goods or services for a social purpose – are emerging as a potentially effective  
450 supply side solution to the provision of cost-efficient public services in response to government  
451 failures, business that seek to extract maximal returns on investment, and unstable non-profit  
452 organizations [21-23]. In particular, this work has shown how these business entities can solve  
453 social problems via their potential to deliver greater responsiveness, efficiency and cost-  
454 effectiveness, through an explicit focus on meeting specific social goals while operating with the  
455 financial discipline and innovation of a private-sector business [21-23,49,50].

456           Although there is continuing debate as to how best to evaluate the performance of social  
457 enterprises, it is clear that at least two basic components related to the bottom line of these  
458 entities require assessment [21,23]. These primarily include: the economic-financial component  
459 for measuring overall organizational efficiency, profitability and hence sustainability, and the  
460 social effectiveness of the enterprise [21-23]. Here, we have combined the tools of financial

461 accounting and modeling of cost-effectiveness to measure these components in order to present a  
462 first analysis of the utility of using the developed Haitian DEC salt enterprise as a sustainable  
463 and economically efficient strategy to bring about LF elimination in programmatically difficult-  
464 to-control settings, like the arrondissement of Léogâne, Haiti [10,41-47].

465 Our analysis of the performance of the present salt enterprise for creating social value  
466 first focused on the question of capacity to economically produce sufficient amounts of DEC-  
467 fortified salt for significantly affecting the elimination of LF in the study setting. The production  
468 figures shown in Table 1 indicate, firstly, that while initial production of all types of salt were  
469 low during the initial years of operation, by 2018, and just 5 years after processing began in  
470 2013, the enterprise had reached high levels of both total (5,845 metric tons) and DEC-fortified  
471 salt (1,841 metric tons) production, respectively (Table 1). Our analysis of the population  
472 coverage that the sale of DEC salt could provide demonstrate that the amounts produced could  
473 have potentially resulted in a coverage rate of 65% by 2018 (Table 4), which our previous  
474 modeling study [18] and the present cost-effectiveness exercise (Fig 3 and Table 6) indicate is  
475 sufficient to accelerate the achievement of LF elimination in the Léogâne setting. These findings  
476 suggest that as the result of the expansion phases carried out through new capital investments  
477 (Table 1), the current DEC salt project may have reached the production capacity required to  
478 achieve its stated social mission of using a market-based approach for delivering sufficient edible  
479 DEC-medicated salt as a means to bring about efficient LF transmission interruption in the  
480 present study setting.

481 Assessment of the economic and financial performance of the salt enterprise carried out  
482 in this study using cost-revenue analysis and financial forecasting has provided further insights

483 regarding the organization efforts used to reach economic equilibrium and hence trading  
484 viability. This is an important consideration for evaluating the performance of social enterprises  
485 because first and foremost these entities are enterprises, and therefore their social goals can be  
486 pursued only by ensuring economic and financial fidelity [21-23]. Our major result in this area is  
487 providing clarity regarding how the enterprise's achieved outputs in salt production and sale may  
488 affect its potential to reach break-even points (Fig 1). Specifically, we show that given the  
489 observed trends in production costs and revenue to 2018 (Table 2), the present salt enterprise  
490 may either break-even by 2027 (if we forecast linearly using all the data from 2013 to 2018), or  
491 as early as by 2022 (if we use data collected during 2016-2018 after the project had significantly  
492 expanded capacity). This result is clearly dependent on assuming that capacity to produce the  
493 increased amount of salt to meet either break-even points is available within the enterprise  
494 without any further expansion, and demand for the produced salt in all sectors (industrial to  
495 edible salt markets) will also expand commensurately. Nonetheless, the finding that it might be  
496 possible to reach the break-even point by 2022 (i.e., over the next 4 years) is encouraging, and  
497 suggests that the enterprise is likely to be self-sustaining and could become profitable in the very  
498 near future. Indeed, analysis of trends in costs of production and revenues gained per ton of each  
499 category of salt (Fig 2) indicate that both the industrial and single-fortified salt categories may  
500 already have reached their individual break-even points in 2018, and that the delay for achieving  
501 break-even status by the social enterprise is primarily due to the lag experienced by the  
502 production and sale of the double-fortified salt. Although the per ton production cost of the latter  
503 salt declined as significantly over time as the other two salt categories (Fig 2), indicating the  
504 achievement of considerable economics of scale, the need to keep the price of the DEC salt  
505 below the marginal cost of adding the drug (\$70/metric ton (see Table 3)) to compete with

506 untreated local edible salt in the market means that either: 1) the current market price needs to be  
507 revised upwards, or 2) further economies of scale need to be found to bring down production  
508 costs, or 3) cross-subsidy from the more profitable categories of salt produced will be required in  
509 order to continue with the processing of DEC salt in this setting. While on the one hand, such a  
510 capacity to use a product mix strategy innovatively as a means to subsidize the marketing of a  
511 product for meeting a social need is a feature of using an enterprise model, note that this may be  
512 a particular effect of developing markets in settings, such as Léogâne and Haiti in general, where  
513 a strong market-based economy is only just evolving. For other LF endemic settings with  
514 stronger market economies and established salt industries, the need for such subsidies may be  
515 significantly lower meaning that the sale of DEC salt could occur at nearer the true marginal cost  
516 of production, i.e., at the actual cost of purchasing the drug itself. Note also that our present  
517 forecasts do not fully consider the likely impacts of key swing factors that may significantly  
518 affect the profitability of the salt social enterprise, such as enforcement of the 2017 law requiring  
519 all food salt in Haiti to be fortified, further progress on market segmentation and the resulting  
520 product mix, and significant weather events similar to Hurricane Michael in 2016. Positive  
521 changes in the first two factors will clearly enhance the enterprise's ability to break-even faster  
522 and hence attain profitability sooner than predicted in this work.

523         The cost-effectiveness modeling exercise carried out in this study showed that apart from  
524 the efficiency of the business model used for achieving economic and financial sustainability, the  
525 salt enterprise may also be more cost-effective than the standard tablet-based annual MDA  
526 program for accomplishing LF elimination in Léogâne (Table 6). This is because not only will  
527 the population coverage that can be potentially attained by sale of the DEC salt (Table 4) be  
528 sufficient to make this strategy more effective than annual MDA in reducing the number of years

529 (3 versus 7 years) required for achieving LF elimination (as defined by reducing mf prevalence  
530 below the WHO threshold of 1% [2]), the total overall costs involved - due to both decreasing  
531 net cost of production and the need for shorter durations of control - for using the salt approach  
532 are also significantly lower than those which will be incurred in running the MDA program.  
533 Indeed, this greater social impact of using the present social salt enterprise compared to annual  
534 MDA was found to be a general outcome, irrespective of the other intervention coverages  
535 investigated (i.e., at 65% coverage – the often normal coverage obtained by MDA programs - or  
536 at the recommended optimal coverage of 80% [2]) (Table 6). These results add to our recent  
537 modeling work, which highlighted how the continuous consumption of the drug, even at low  
538 daily per capita dosages, by resulting in a cumulative impact on the survival of worms and mf  
539 which is significantly higher than that afforded by the higher-dosed annual MDA treatment,  
540 make DEC medicated interventions, even when delivered at moderate population coverages, a  
541 markedly potent strategy for interrupting LF transmission [18]. Finally, an intriguing  
542 possibility highlighted by the break-even analysis and the cost forecasting results shown in  
543 Fig 1 and Table 5 is that using a social enterprise strategy for delivering DEC through  
544 marketing of medicated salt could in principle also lead to zero disease elimination cost for  
545 the community once the social business attains profitability (i.e., return a positive cash-flow).  
546 This is an important result, and demonstrates how using a social enterprise that pursues a  
547 social goal by production of services and goods whilst respecting economic efficiency may  
548 offer an effective, financially sustainable, intervention strategy in settings facing major fiscal,  
549 infrastructural and logistical barriers to carrying out tablet-based programs aiming to control  
550 or eliminate parasitic infections.

551           The present performance evaluation primarily focused on internal (labor, capital,  
552 income and taxes) and external (goods and services bought outside the company)  
553 expenses/resources related to the economic viability of the salt enterprise [21]. However,  
554 estimation of the full social value of a sustainable health social enterprise must also consider,  
555 apart from the social benefits accruing from reducing disease only, the wider consequences  
556 for a community [21]. Benefits here could be via the choice and use of resources that further  
557 address the community interest, such as choosing local salt suppliers to favor short supply  
558 chains, choosing socially certified suppliers, adopting a regime of decent work conditions and  
559 even giving employment to workers coming from disadvantaged backgrounds [21]. Such  
560 analysis must also include calculation of the larger social benefit associated with the potential  
561 for the double-fortified salt to additionally and simultaneously reduce the impacts of iodine  
562 deficiency in the population [5]. Note, additionally, that the present salt enterprise represents  
563 the first attempt to build industrial-scale capacity on the island for processing large volumes  
564 of salt to meet various local needs, which apart from providing a market for local raw salt  
565 producers can also act as means to significantly stabilize the price of salt sold in the local  
566 markets. These benefits, however, must be contrasted against potential adverse effects, such  
567 as domination of the market by the growing enterprise, requiring an analysis of how best to  
568 compensate for such losses. Recent developments in applying Social Returns on Investment  
569 (SROI) approaches for comparing the full monetized social costs of a program with the full  
570 monetized social benefits of achieving a health outcome (or set of outcomes) may offer a  
571 means for undertaking this fuller analysis [22,51].

572           We have also used rough first calculations of the population coverages that could be  
573 obtained with the expansion of salt production in the present cost-effectiveness modelling

574 study. Field studies to assess the actual household coverage achieved through the enterprise  
575 will be critical for not only more realistically quantifying its effectiveness for accomplishing  
576 LF transmission interruption in a community, but also for identifying better marketing  
577 strategies to achieve good population coverage.

578 In conclusion, we have presented an economic and financial analysis of the Haitian  
579 salt social enterprise, which indicates that it may present a sustainable and socially-  
580 responsible strategy for aiding the elimination of LF via the marketing of DEC-medicated salt  
581 in settings facing fiscal, infrastructural and logistical challenges for delivering tablet-based  
582 elimination programs. Results from the break-even projections carried out in this study  
583 indicate that the strategy may even have the potential to achieve zero societal costs once it  
584 attains profitability (i.e., results in a positive cash-flow). This study further has shown that the  
585 Haitian salt enterprise may have already reached production and sales levels that could result  
586 in the coverage of the Léogâne study population at proportions sufficient enough to break LF  
587 transmission. Finally, our simulation-based cost-effectiveness study has indicated that because  
588 of: 1) increasing revenue from the sale of the DEC salt obtained over time, 2) expansion of its  
589 delivery in the population, and 3) the effect of continuous consumption of the drug, even at  
590 low daily per capita dosages, leading to a cumulative impact on the survival of worms and mf  
591 higher than that afforded by the higher-dosed annual MDA treatment [18], the delivery of  
592 DEC through the present Haiti salt enterprise may represent a significantly more cost-  
593 effective option than annual DEC tablet-based MDA for accomplishing LF elimination. While  
594 these are encouraging first results and highlight both the economic viability and social  
595 effectiveness of using a salt enterprise in the fight against LF, it is clear that efforts to more  
596 fully quantify the social value and strategies for developing similar salt social enterprises

597 elsewhere in other endemic settings with different market structures than those of Haiti are  
598 now required if the comparative or joint utility of the approach among the current arsenal of  
599 LF intervention strategies is to be fully appraised and understood. We note that the means by  
600 which the global iodization of edible salt has been accomplished successfully over the past  
601 two decades may offer a particularly apt model for building and sustaining the present  
602 intervention globally, and suggest that similar tactics used in that program based on  
603 introducing DEC medication into prevailing salt production and distribution systems,  
604 collaboration with the national and regional salt industries, and engagement with the  
605 government sector, civic society and the general public [52], could also make the universal  
606 deployment of DEC-medicated salt eminently possible. With less than three years remaining  
607 for meeting the 2020 target set by WHO for accomplishing the global elimination of LF, the  
608 present results indicate that these appraisals and development of policies and strategies for  
609 delivery of DEC-salt, either via deployment of similarly-fashioned salt enterprises, such as the  
610 present, or through mobilization of existing salt industries, perhaps along with health system-  
611 led MDA and vector-control programs, in socially-challenging environments, like Haiti,  
612 would improve our current efforts for meeting this laudable but exacting goal successfully.

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812 **Supporting Information**

813 **S1 Supporting Information. Lymphatic Filariasis model descriptions.**

814

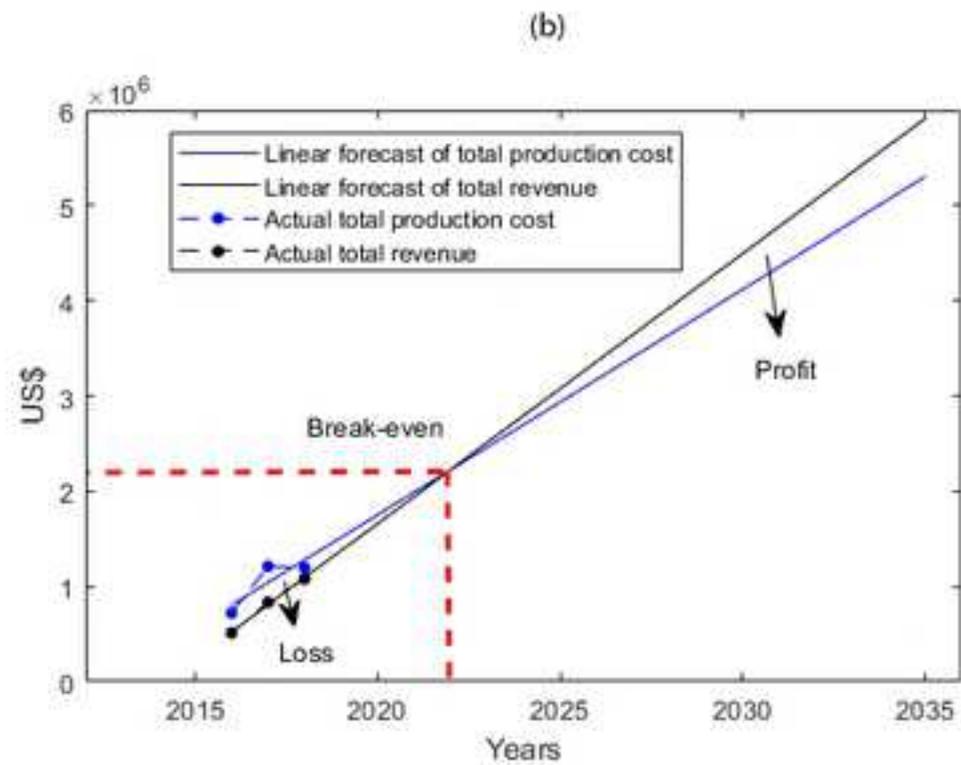
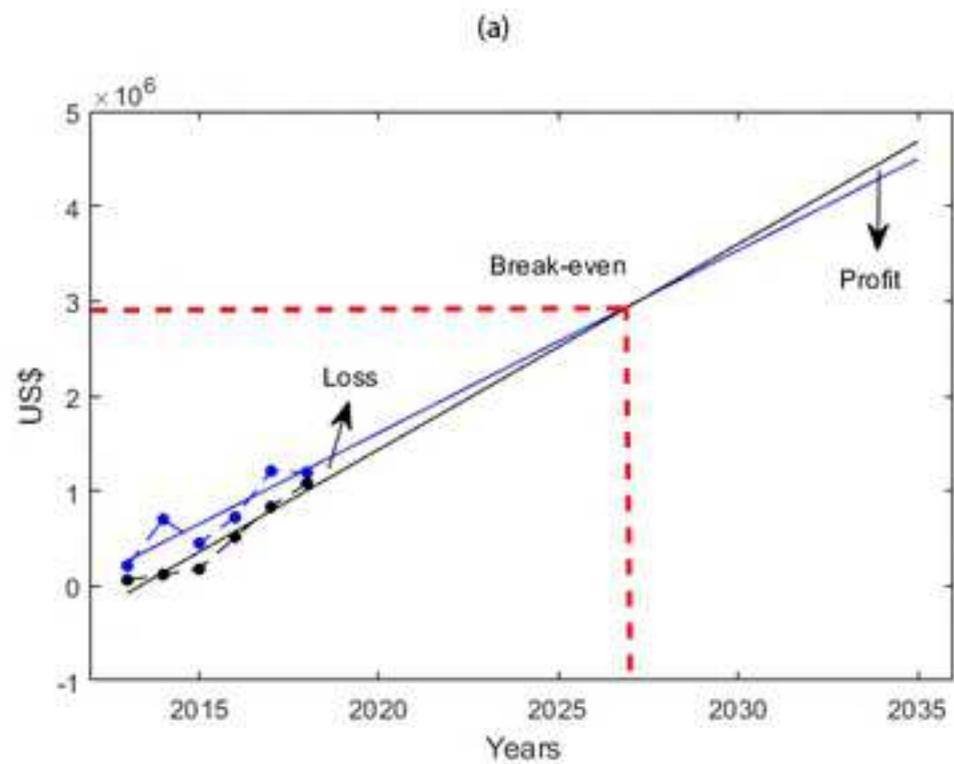
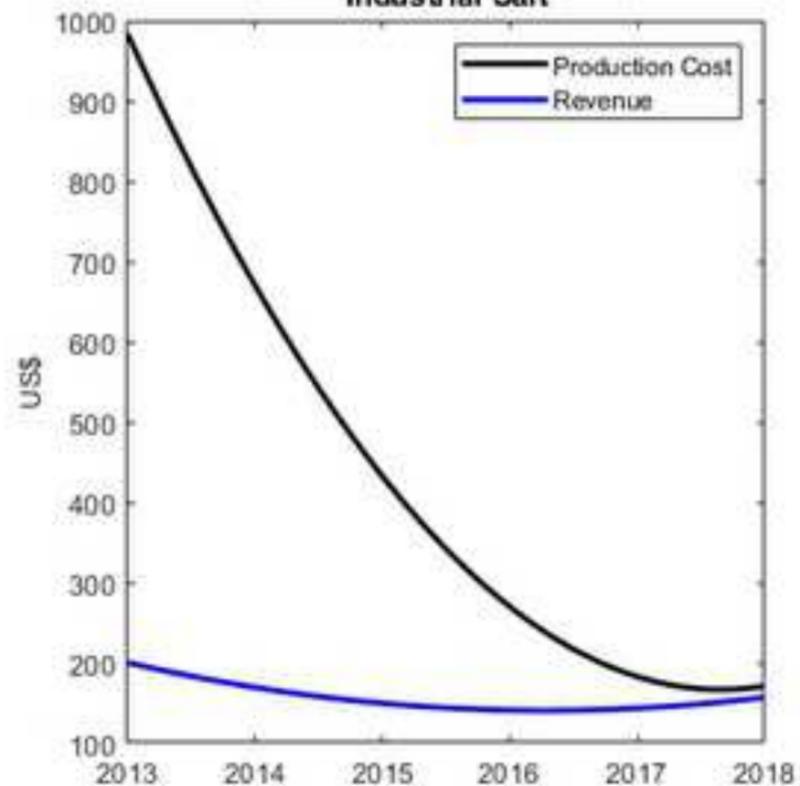
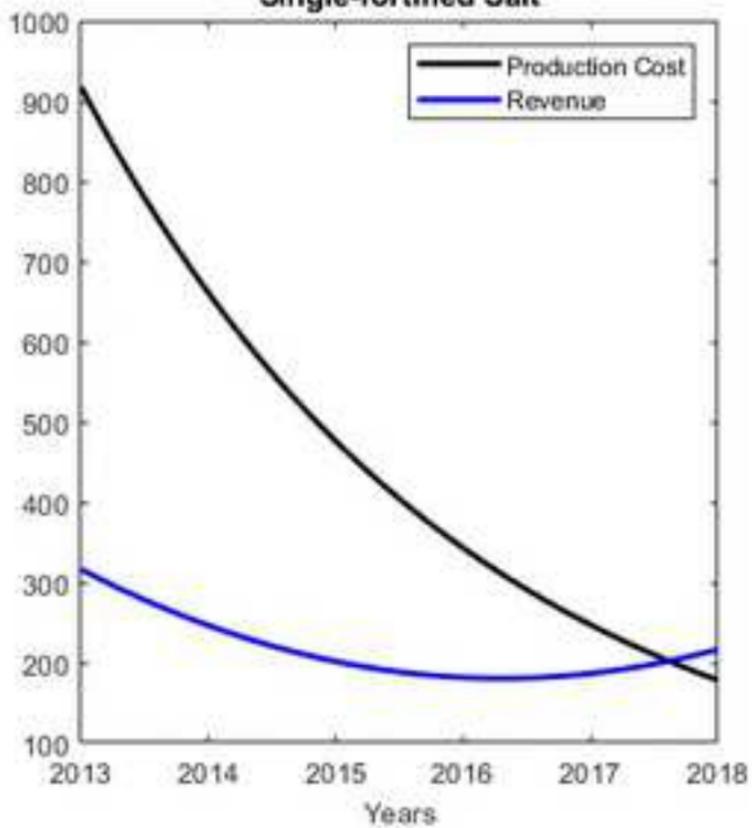
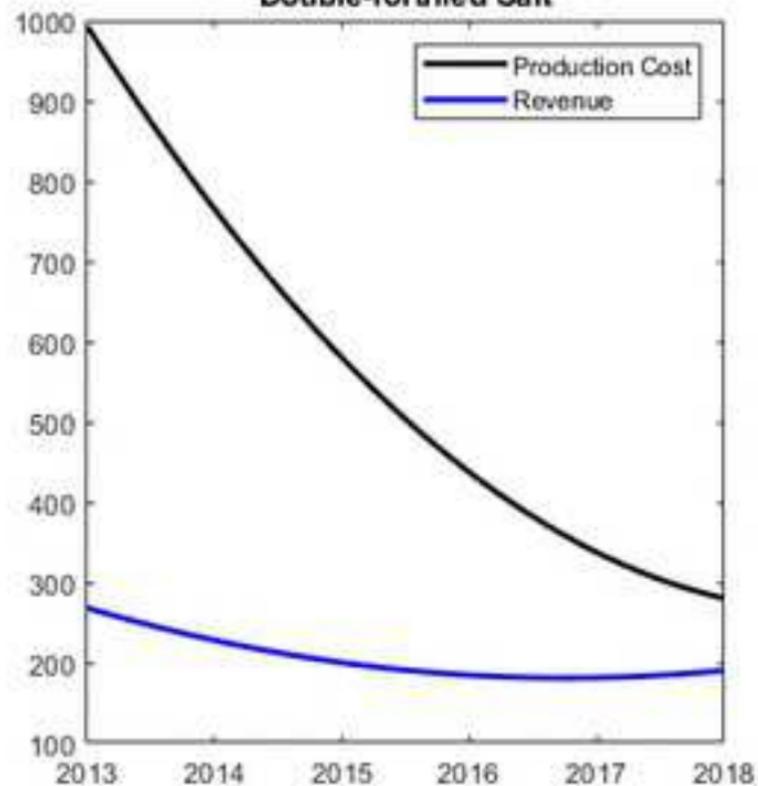


Figure 1

**Industrial Salt****Single-fortified Salt****Double-fortified Salt****Figure 2**

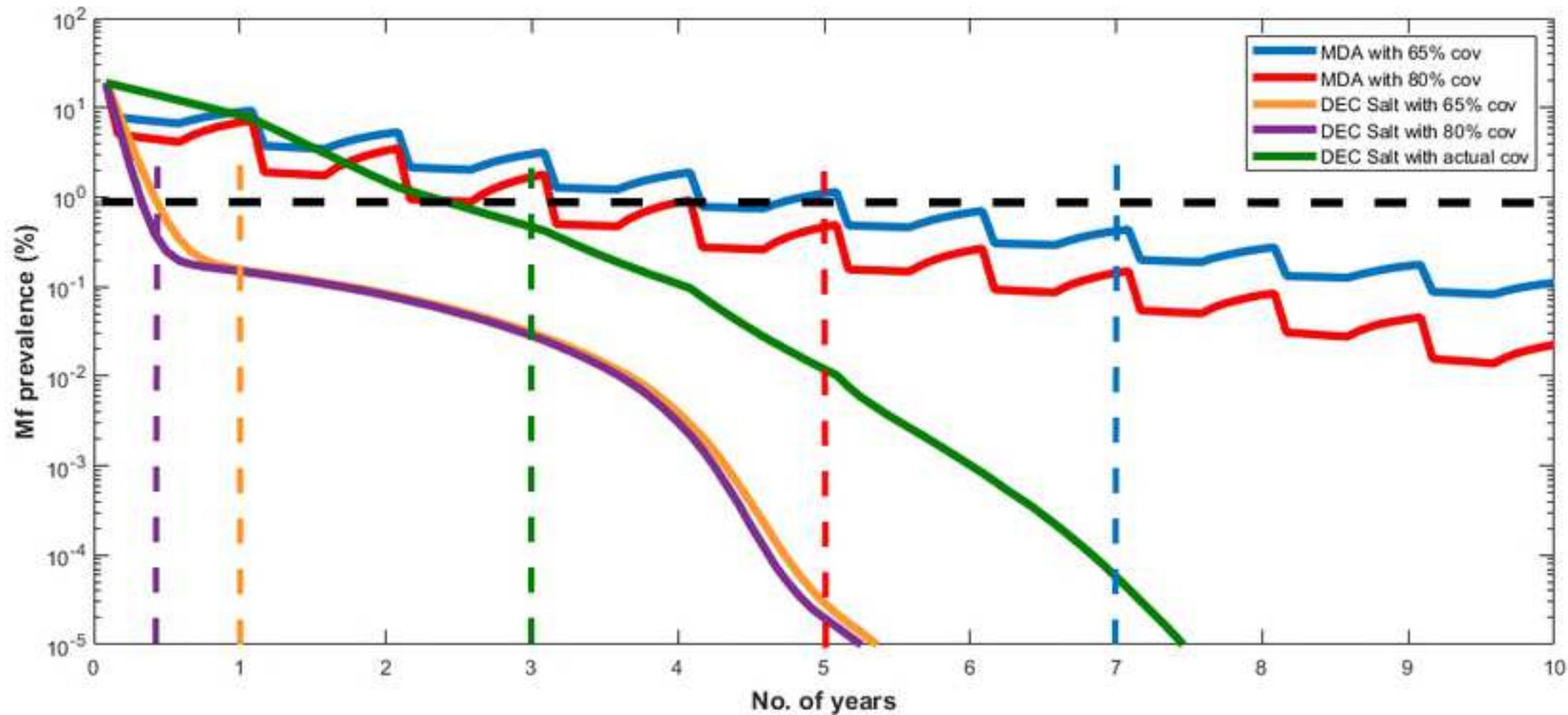


Figure 3