

**Alliance for Health Policy and Systems Research
Flagship Report 2014**

**Medicines in Health Systems: Advancing access, affordability
and appropriate use**

Chapter 5 – Annex 4

**Social Business Interventions to Improve Access to
Medicines**

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**Alliance for Health Policy and Systems Research
Flagship Report on Medicines in Health System**

Case Study on Social Business Interventions to Improve Access to Medicines

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Introduction

Many clinically effective medicines exist to effectively treat diseases, decrease morbidity, and prevent premature deaths. However, many people in low and middle-income countries cannot access quality medicines, risk impoverishment by their spending on health care and medicines, or suffer negative health and wealth consequences of inappropriate medicines use. At the same time, countries and health systems struggle to provide sustainable access to needed medicines for all members of their populations, particularly the poor and near poor—the Bottom of the economic Pyramid (BoP).¹

Several multi-national pharmaceutical companies have begun to engage in innovative public-private partnerships intended to improve medicines access for people at the Bottom of the Pyramid while at the same time generate profit, sometimes termed social business.^{2,3,4} Social business innovations promise to improve affordable access to quality medicines for the poor by targeting health system shortcomings and facilitating efforts to improve access to medicines. At the same time, like any intervention in a complex system, social business interventions have the potential to cause unintended harm.⁵ Furthermore, perceived and real conflicts of interest exist when pharmaceutical companies intervene in systems that may affect current and future markets for their products.

System-focused assessments of social business interventions are crucial to ensure that these approaches achieve their intended outcomes and do not result in an unacceptable degree of unintended side effects such as clinically unnecessary or economically inefficient utilization, discontinuities in patient care, or harmful disruptions in pharmaceutical markets. Such assessments will require explicit conceptual models of complex relationships among actors in health systems, insights into different stakeholders' perspectives and behaviors, and evidence on a range of relevant input, process, and outcome indicators. Practical and valid system frameworks, metrics, and measurement tools are needed to assess social business interventions to improve medicines situations. These metrics and measures should be able to capture direct and indirect intervention effects in dynamics systems <REFER TO CHAPTER ON COMPLEX ADAPTIVE SYSTEMS LENS> using a variety of quantitative and qualitative assessment methods <REFER TO CHAPTER 6, METHODS.

¹Vachani, Sushil, and N. Craig Smith. "Socially responsible distribution: distribution strategies for reaching the bottom of the pyramid." INSEAD Business School Research Paper 2008/21 (2007).

²Peterson K et al. [Competing by saving lives: How pharmaceutical and medical device companies create shared value in global health](#). FSG, 20xx.

³ Haupt S, Kraemer A. [Bringing medicines to low income markets. A guide to creating inclusive business models](#). BMZ 2012

⁴ IFPMA. [Developing World Health Partnerships Directory reflects pharmaceutical industry's and partners' commitment to improving health in developing countries](#). News Release, 11 September 2012.

⁵ Forrester, JW. 1975. Counterintuitive Behavior of Social Systems. Collected Papers of Jay W. Forrester. Cambridge MA: Wright-Allen Press.

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Outline

In this case study, we first describe concepts underlying social business interventions and briefly mention examples targeting medicines access. We then use one example of a social business intervention to lay out hypothesized relationships for a system dynamics model to simulate the interventions' potential mechanisms, identify the main health system actors, and describe their potential responses to the intervention. To refine this hypothetical model and ground it in local reality, we suggest topics and questions to elicit the perceptions of relevant stakeholders and potential sources of data that would help to parameterize and refine the system dynamics model and subsequently to define monitoring and evaluation approaches.

Social business concepts

Professor Muhammad Yunus, 2006 Nobel Peace Prize laureate, suggested that the two extreme types of business models, financial profit-maximizing businesses seeking to create shareholder value and not-for-profit organizations seeking to maximize social profit,⁶ do not suffice to address global concerns. Social businesses apply rules from both models: They seek to maximize social profit, but must make financial profit to cover their full costs and return investment to their owners.⁷ A social business, in Professor Yunus' definition, is "a self-sustaining company that sells goods or services and repays its owners' investments, but whose primary purpose is to serve society and improve the lot of the poor."⁷ pg. 30⁹ Operationally, social businesses function like profit-maximizing businesses; different from non-governmental organizations, social businesses seek to generate profits while pursuing social objectives. They thus are self-sustaining and profit flows to stakeholders who engage in the social mission, rather than shareholders.

CK Prahalad argued that the world's 5 billion poor people have needs and, controversially,⁸ untapped buying power which, if met by appropriate products, would empower customers and generate profits for companies, creating win-win situations, with companies "serving the world's poor, profitably."⁹ According to Professors Porter and Kramer, a "shared value" focus would "generate greater innovation and growth for companies - and also greater benefits for society".¹⁰ Describing failures of BoP-focused business ventures, and acknowledging that people at the very bottom of the economic pyramid are too poor to participate in markets, Professor Rangan and colleagues highlight

⁶ Yunus M. Creating a world without poverty—Social Business and the future of capitalism; and Building Social Business—The new kind of capitalism that serves humanity's most pressing needs

⁷ Yunus M, Moingeon B, Lehmann-Ortega L. Building social business models: Lessons from the Grameen experience. Long Range Planning; 2010:308-325.

⁸ Kirkpatrick D. CNN Money. Muhammad Yunus on tech, profit, and the poor. April 3, 2008. http://money.cnn.com/2008/04/01/technology/muhammed_yunas.fortune/

⁹ Prahalad CK, Hammond A. Serving the world's poor, profitably. Harvard Business Review 2002; 48-57.

¹⁰ Porter ME, Kramer MR. Creating shared value – how to reinvent capitalism and unleash a wave of innovation and growth. Harvard Business Review, 20xx; xx-17.

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three factors for successful approaches: generation of both commercial and social value – differentiated by level of poverty at the BoP - and operations at scale.¹¹

Although an attractive concept, social business innovations guarantee neither social nor business value and thus require careful monitoring and evaluation to realize their potential benefits,^{12,13} arguably even more so when the social goal encompasses health.

Examples of social business initiatives in the pharmaceutical sector

Several pharmaceutical companies have begun social business initiatives.^{14,15,16} For example, to both improve diabetes care in China and increase business value, Novo-Nordisk has invested in physician training, community programs focusing on diabetes prevention, patient education and local production. A Novo-Nordisk-supported National Diabetes Program in China includes public-private initiatives developed and executed in partnership with the World Diabetes Foundation and the Chinese Ministry of Health and includes development of diabetes guidelines, training and health system integration.¹⁷ In only five years, Novartis Pharma AG's Arogya Parivar program is said to have provided access to generic medicines to 42 million people living in 33,000 villages in rural India^{18,19} and serves as an example of pharmaceutical company social business interventions.²⁰

Building on its positive experiences with Arogya Parivar in India, the Novartis AG started the Familia Nawiri (FN) program in Kenya in March 2012. The medicines situation in Kenya is characterized by a lack of availability of generic products in the public sector,²¹ geographic, and economic barriers that prevent access to medicines for the poor; overuse of antibiotics; and underuse of chronic disease treatment. In a 2009 household survey, 57% of respondents in poorest households reported that they cannot usually afford to buy all the medicines they need and 48% of poor households with a chronically ill member had no medicines at home.²²

¹¹Rangan K, Chu M, Petkoski D. Segmenting the base of the pyramid. Harvard Business Review 2011; 113-117.

¹²The Global Compact LEAD Task Force. [Catalyzing transformational partnerships between the United Nations and Business](#). UN Global Compact Office, September 2011.

¹³Pfizer M, Bockstette V, Stamp M. Innovating for shared value. Harvard Business Review 2013 (September):101-107.

¹⁴http://www.sandoz.com/media_center/news/2012/sandoz_around_the_world/2012_08_24_zambia.shtml

¹⁵http://en.sanofi.com/Images/29244_Sanofi_Access_to_Medicine_2011.pdf

¹⁶<http://www.makingmorehealth.org>

¹⁷<http://www.novonordisk.com/images/Sustainability/PDFs/Blueprint%20for%20change%20-%20China.pdf>

¹⁸Novartis AG, [Arogya Parivar](#), <http://www.novartis.com/downloads/corporate-responsibility/arogyafactsheet.pdf>.

¹⁹Pasrija A. Arogya Parivar. Poster presented at the Third International Conference for improving use of medicines. http://www.inrud.org/ICIUM/ConferenceMaterials/385-pasrija_a.pdf#search=%22arogy%22.

²⁰Haupt S, Krämer A. [Bringing medicines to low-income markets](#). GIZ 2012.

²¹Ministry of Medical Services, in collaboration with the World Health Organization. Kenya Pharmaceutical Country Profile. November 2010;

http://www.who.int/medicines/areas/coordination/kenya_pharmaceuticalprofile_december2010.pdf

²²Ministry of Medical Services and Ministry of Public Health & Sanitation. Access to essential medicines in Kenya. A household survey. December 2009; <http://apps.who.int/medicinedocs/documents/s18696en/s18696en.pdf>

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FN pursues social and business goals by interacting with multiple parts of the health care system. Like Arogya Parivar, FN has two arms of operations. The commercial arm seeks to increase the availability of Novartis products to providers who serve the poor countrywide. The social arm of the program targets the 668,821 individuals of the rural population of the country with incomes below \$1 per day, who live in more than 119,000 households.

Activities on the social side focus on raising community members' awareness of basic health, health care, and social issues; and on connecting households with providers to receive care and medicines. Salaried health educators, who are community members with basic education and ideally a diploma in a health field, are hired by FN to serve as community mobilisers. A contracted local health care company provides the health educators with one week of training on target topics (including personal and environmental hygiene; rational use of medicines; symptoms and treatment of respiratory infections, diarrhea, diabetes, and hypertension; de-worming; and health insurance enrollment). Each health educator is responsible for 2-3 wards, equal to about 12,000 households and an average of 66,800 individuals.

Each health educator attends or convenes at least 2 community meetings (representing an average target of about 70 community members) per day to educate members on target topics in sessions of up to one hour each. Meetings are those of organized community groupings linked to churches, clans, "chamas" (i.e., informal gatherings, often of women, who cooperate to pool and invest funds), or other community groups. Each health educator also connects with local networks of community health workers and organizes one health camp per month.

Day-long health camps target 300 community members at a time and are staffed by 3 local diploma medical graduates, 3 nurses, and 3 physicians, 2 community health workers and pharmaceutical technologists who either volunteer their time or are salaried employees of a contracted local private or public health care organization. Nurses triage patients, doctors and clinical officers diagnose, prescribe and are in charge of referrals to local hospitals as needed; and pharmaceutical technologists dispense medicines at health camps. The formulary of products used at the health camps is derived from the 2010 Kenya Essential Medicines list. Products are procured locally from mission hospitals, the Mission for Essential Drugs Supply (MEDS) or private sector distributors. Medicines used are from different manufacturers, meet the quality criteria of MEDS, and are priced according to the MEDS pricing guide. Novartis products used at the health camps are generic products from the company's generic (Sandoz) division and originator brand Coartem. Community members pay a flat KES 200 registration fee (about US \$ 2.30) for each camp visit. The fee covers consultations, laboratory tests, and medicines dispensed during the visit. FN covers the running costs of the health camps through a fixed fee contract with a consultancy firm that manages the health camps, and provides training and quality checks of the social activities of FN. The participating health care providers receive a stipend to cover costs of their transport to the health camp and lunch. Each health educator is mandated to run one health camp per month in their area (cell) of operation, prioritizing locations with problematic access to medicines. The camps are open to all.

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Patients diagnosed with chronic conditions are receive initial treatment and are referred to the nearest qualified provider for follow-up care. The FN plan assumes that community members will continue to seek care outside of health camps preferentially from the private providers who serve in the camps.

On the business side, FN medical representative serves as a territory supervisor. Territory supervisors work with all providers in the counties that they cover and seek to ensure increased availability and prescription of Novartis products to the rural poor target population of FN. Territory supervisors market a basket of products selected from the national essential medicines list to treat the same conditions treated in the health camps. They also facilitate continuing education programs for providers, link providers to health educators and health camps, and ensure a reliable supply of Sandoz products in the market. Each territory supervisor is responsible for about 300-500 clinical officers, nurses, and pharmacists.

In its 2013 expansion to 18 of the 47 counties in three regions of Kenya (Central, Rift Valley, and Nyanza Provinces), FN is engaging in partnerships with a local micro-savings organization. In FN community meetings, representatives will explain micro-savings approaches and facilitate household enrollment in health savings plans using the m-Pesa mobile savings platform.^{23,24} In the future, community meetings will also serve to raise awareness of and facilitate enrollment in the National Hospital Insurance Fund, which covers inpatient care only at government and mission hospitals for a fixed monthly family premium of KES 160 for informal sector workers.²⁵ Future plans also include use of a mobile health platform to provide health education to communities. By 2017, the FN program is expected to have reached 7 million villagers and all private providers in the country, and to have broken even financially.

A conceptual model of social business initiatives

The FN social business initiative interacts with existing community and health system structures, organizations, and processes, with the intent of facilitating access to quality care and medicines for the poor, and ultimately improving health and economic outcomes on the social side. On the business side, FN activities seek to increase sales volumes of a selected portfolio of Sandoz generic products and to generate profits.

Relationships of different stakeholders in the health and pharmaceutical sectors are complex and different actors have competing objectives. For example, increasing access to medicines may improve the health of individuals and increase a company's sales revenue, and also lead to unsustainably high household or government health spending. FN interventions will probably affect multiple connected actors in the Kenyan health system –

²³ Merritt, C. (2011). Mobile money transfer services: The next phase in the evolution of person-to-person payments. *Journal of Payments Strategy & Systems*, 5(2), 143-160.

²⁴ Mas, I., & Radcliffe, D. (2010). Mobile payments go viral: M-PESA in Kenya. The World Bank. <http://papers.ssrn.com/sol3/papers.cfm>, accessed 2013/12/30

²⁵ Center for Health Market Innovations. Kenya National Hospital Insurance Fund. <http://healthmarketinnovations.org/program/national-hospital-insurance-fund-nhif>

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local households, private sector providers, government-run health camps and primary care institutions, mission-run hospitals – in different ways. Its impacts will likely not be isolated and linear (i.e., better access leads only to better health) but rather connected and dynamic (e.g., positive and negative responses in the system will in turn reinforce or counteract other behaviors). A “whole picture” of the system, through a system dynamics lens, is needed to understand FN intervention effects, appreciate interactions in response to the interventions among different actors in the system, to identify leverage points in the system that may account for shifts in outcomes, and to monitor, and measure the impacts of social business programs in the pharmaceutical sector over time.

Broadly speaking, system dynamics is a methodology to represent complex systems and understand how their components interact over time. A computer-based system dynamics model simulates dynamically changing situations – movements of people and things - in complex systems. Models are created in an iterative, step-wise process involving interviews with stakeholders in systems and data from different sources.^{26,27}

We talked with Novartis executives about the company’s social business initiative experiences and plans in India, Vietnam, and Kenya. Based on these conversations, we created an initial conceptual system model of the FN program. Below we describe the initial model and suggest steps to build confidence in it, and to identify data sources and measures of its impacts on health and social structures, processes and outcomes.

The conceptual model of the FN program begins with a single reinforcing feedback loop (R1), which hypothesizes that improving access to needed, quality medicines among the poor improves health status, in turn improving economic activity and household income and increasing the available financial resources to purchase medicines (Figure 1). If the medicines purchased are Sandoz products, this feedback loop will generate profit for the company, which can be invested in expanding the program.²⁸

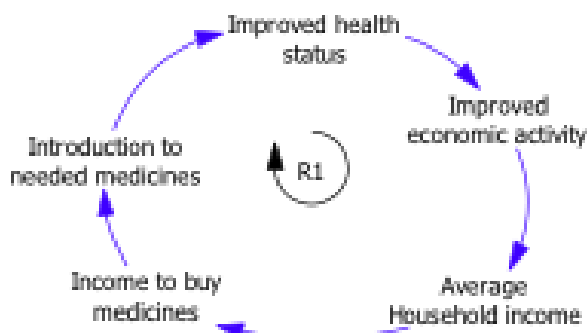


Figure 1. Core loop of FN (R1)

²⁶ See Randers, Jørgen, ed. Elements of the system dynamics method. Cambridge: MIT Press, 1980.

²⁷ Sterman JD. Business Dynamics: Systems thinking and modeling for a complex world. Boston, MA: Irwin/McGraw-Hill;2000.

²⁸ The symbol at the loop center indicates the flow of information is clockwise and is reinforcing or continually growing. The number uniquely identifies this as the first reinforcing loop.

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This core loop exists in every modern healthcare system. What sets the FN program apart from other typical systems is the use of privately-supported health educators and community healthcare workers to raise awareness about health care and financing among the rural poor, combined with privately-run health camps to facilitate their access to care and a strengthened private-sector medicines supply system. Health camps are not new in Kenya; government officials and medical schools offer health camps periodically. The FN initiative regularizes the schedule of health camps and targets care quality at camps through manageable staff to client ratios, availability of laboratory testing at the camps, and selection of medicines from the national essential medicines list, through which the FN target patient population has easier access to initial care. Regular follow-up care may be sought in subsequent health camps and from public and private sector providers. This continuity of attention leads to a second reinforcing loop in the system (Figure 2).

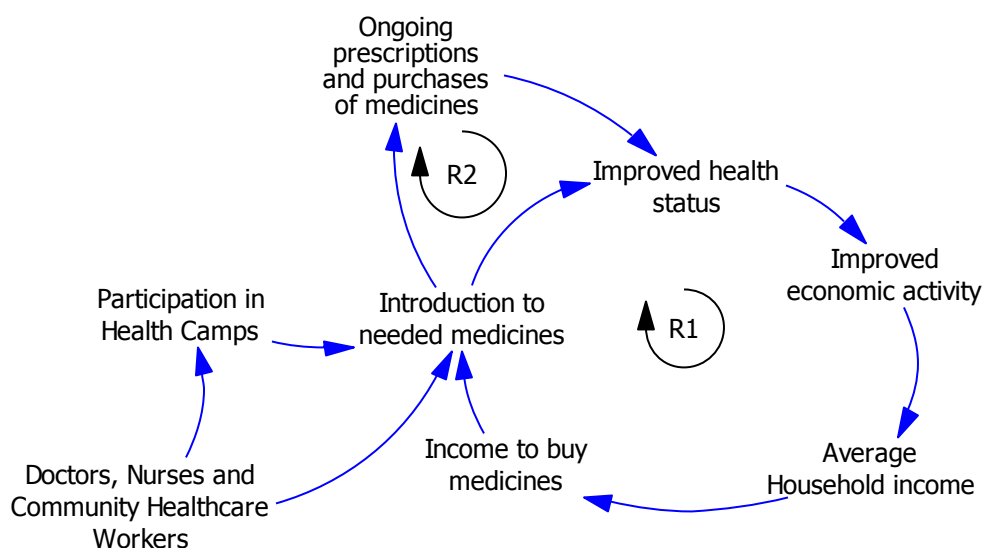


Figure 2. A growth loop representing ongoing purchases of medicines (R2)

Further distinguishing FN from more traditional pharmaceutical marketing programs, coordinated education about and facilitated access to Health Savings Accounts (HSA, for outpatient care coverage), and, in the longer term, enrolment in the National Health Insurance Scheme (for inpatient care coverage), should enable access to financial resources of prospective patients for purchasing needed medicines in the future. In addition, FN may include a microfinance capacity to help prospective purchasers pay when their HSA balances are insufficient. This linked financing capacity provides a third reinforcing feedback loop that may improve the likelihood of consumers accessing services and continually taking prescribed medicines (Figure 3).

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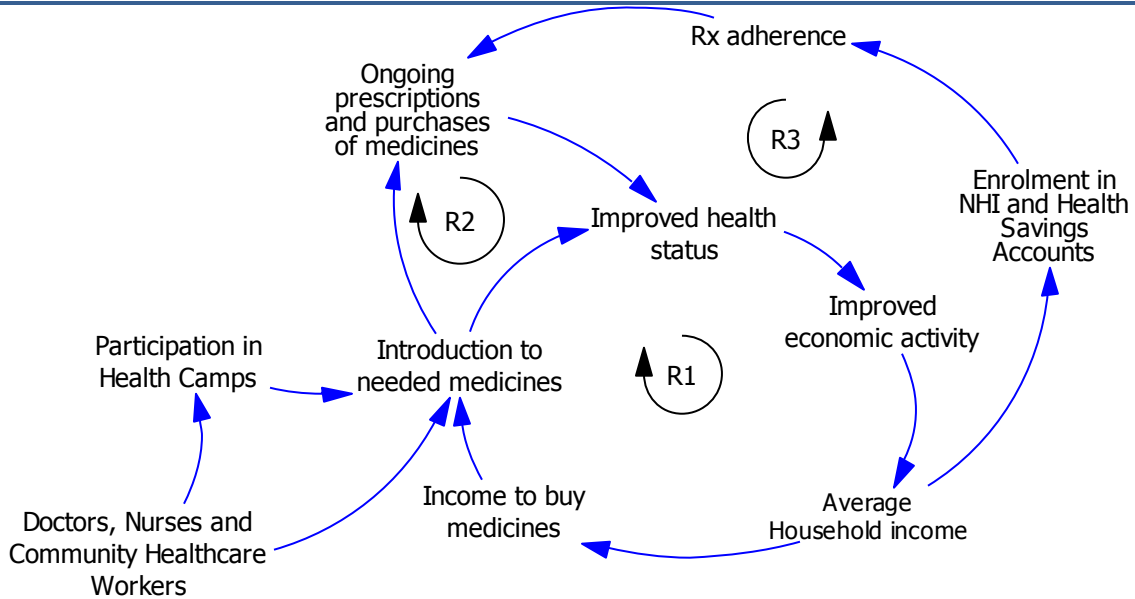


Figure 3. Promoting adherence through health savings accounts and microfinance (R3)

Improving population health status will in the long run improve life expectancy. The inclusion of medicines to treat chronic conditions like dyslipidaemia, diabetes and hypertension, provided that appropriate medicines are taken continuously, would result in better long-term cardiovascular health (Figure 4).

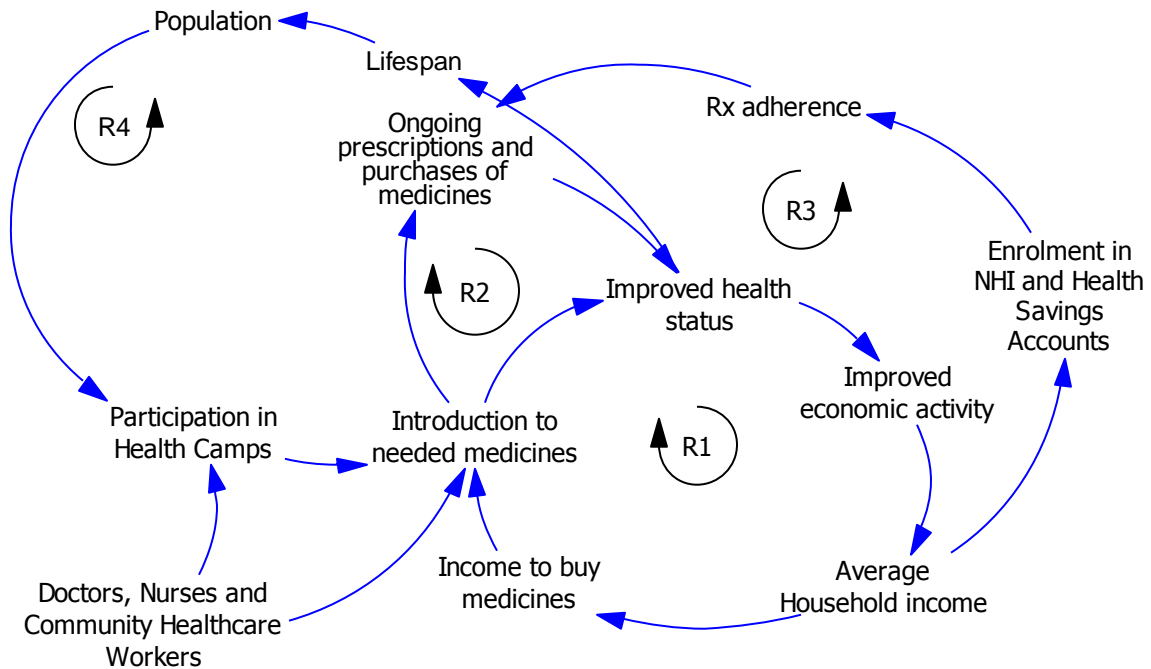


Figure 4. Effect of improved health on lifespan and population (R4)

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The focus of the first four feedback loops is on how FN could work to benefit the target population, that is, to achieve health and social benefits. The fifth feedback loop represents the economic interests of local prescribers, dispensers, and the sponsoring pharmaceutical company (Figure 5), that is, it focuses on the business benefits.

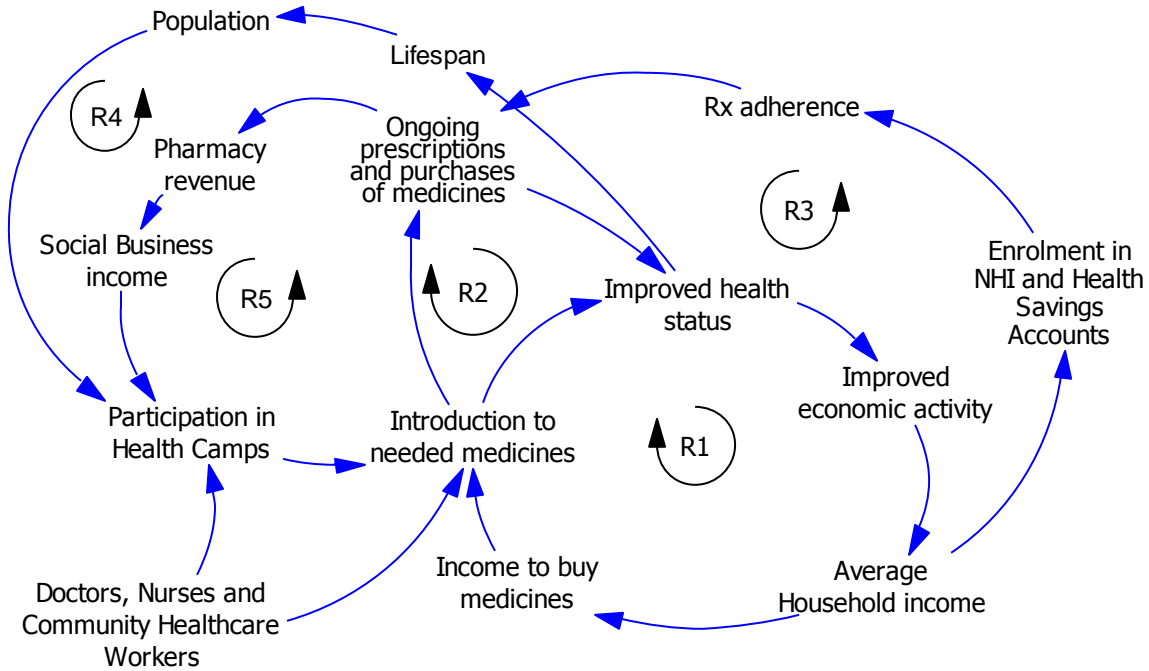


Figure 5. Economic interests of pharmacies and pharmaceutical company (R5)

To close the loop system in the initial conceptual model, a sixth loop connects the population as a potential source of increasing and continuing business for local doctors, nurses and community healthcare workers (Figure 6). However, it should be noted that FN does not rely exclusively on local sources for physicians and nurses.

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Refining the conceptual model

The initial conceptual model hypothesizes a network of relationships intrinsic to the achievement of the FN program's health, social, and business objectives. Refining the model involves developing a greater understanding of how the FN program might achieve its systemic impacts – how care seeking patterns, health systems activities, population health outcomes, and local economies may change with the implementation of FN components. A key step in refining the model is to elicit knowledge and experience of expert system participants: physicians, nurses, pharmacists, health educators, community health workers, hospital administrators, micro-savings and insurance organization staff, sales agents, drug distributors, and—most important—patients and other household members.

In the following sections, we describe observations on each loop in the model and the inputs that we have received from key informant interviews to date. Widening the circle of interviewees will allow triangulation of perspectives, additional modifications to the systems model, and highlight key data sources and variables for measuring impacts of the FN initiative.

Loop R1: Core relationships

In addition to general hygiene, appropriate medicines use, and health financing, FN health education focuses on treatment for respiratory illnesses, diarrhoea, diabetes, and hypertension. The FN medicines portfolio includes products from Sandoz and other manufacturers to treat bacterial and fungal infectious diseases, cardiovascular and gastrointestinal conditions, diabetes, folic acid and iron deficiency, diarrhea, and tuberculosis. One important question is whether these conditions represent the most important untreated health conditions in the target population. Only if that is the case can improved access to care for these conditions lead to improved health and economic benefits for the population. Although UNAIDS estimates that between 5.9% and 6.3% of the population between 15 and 45 years is infected with HIV in Kenya,²⁹ FN does not address HIV/AIDS, presumably because vertical programs provide sufficient access to care and medicines for HIV/AIDS. Aside from HIV/AIDS, FN targets several of the most prevalent causes of death in Kenya overall.³⁰ Key questions include whether national causes of death are representative of those in the local FN target population and whether the FN portfolio of medicines is well-selected for the target population and health conditions.³¹

Improved access to an appropriate basket of medicines can only contribute to improved health status if (1) patients are treated who would otherwise not be treated, and (2)

²⁹ See <http://www.unaids.org/en/regionscountries/countries/kenya/>, accessed 20 December 2013.

³⁰ According to 2006 WHO World Health Statistics, the top 10 causes of death in Kenya are: HIV/AIDS 38%; Lower respiratory infections 10%; Diarrheal disease 7%; Tuberculosis 5%; Malaria 5%; Cerebrovascular disease 4%; Ischaemic heart disease 4%; Perinatal conditions 4%; Road traffic accidents 2%; Chronic obstructive pulmonary disease 2%.

³¹ See <http://www.cdc.gov/globalhealth/countries/kenya/why/>, accessed 20 December 2013, which references WHO World Health Statistics 2006.

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medicines are prescribed and dispensed wisely. Key questions include: Do patients who would otherwise not be treated attend health camps or seek treatment elsewhere due to FN educational efforts? Do doctors and pharmacists in health camps and private practice prescribe and dispense medicines that are appropriate for the patients' conditions (e.g., antibiotics only prescribed for bacterial respiratory infections, diarrhoea treated with oral rehydration salts and zinc)? Do patients obtain quality products and take them as prescribed? How affordable are the medicines purchases to patients and households? Are the frequency and dosage convenient and contribute to adherence?

In the conceptual model, improved health status contributes to improved economic activity, by increasing patients' ability to work. Unless health status is improved by patients' participation in FN activities, local economy will not improve as a second-level effect of the program; however, health and economic gains depend on the health and economic conditions affecting patients and even if health improves, not all treated patients will experience a subsequent increase in economic activity beyond what would have happened in the absence of the FN program.

Improved economic activity may lead to increased household (HH) income, but this is not necessarily so. If local agriculture or other sources of local employment are depressed and unemployment levels are high, improved health may not contribute to increased HH income. Thus, increases in HH resources being allocated to medicines purchases may not automatically follow from improved health status.

Loop R2: Ongoing purchase of medicines

The rate of patient uptake of needed medications depends on more than an initial prescription in health camps. Perceived efficacy of the prescribed medicines relative to alternative treatments (e.g. traditional remedies) must be clearly established in the patient's mind; medication side effects must be understood and acceptable in light of benefits; and medicines must be easily accessible and affordable to households for ongoing purchase. Pharmaceuticals must be relatively more attractive than alternatives, including no treatment. Hypertension, type 2 diabetes and hyperlipidaemia are conditions that generally precede acute medical events but are largely unnoticed by patients. Health camps and clinics may reinforce educational lessons, but consumers will decide whether to continue treatment based on a wide array of influences, including family and neighbour experiences, proximity of medicines outlets, availability of products, relationships with private sector providers, and current affordability.

This raises questions about sources of influence on consumer decisions. Which factors will have the strongest influence on the decision to purchase and continue purchasing medicines, especially when symptoms of disease are not yet apparent to the consumer? Will the FN activities be sufficient to overcome other system barriers to medication use?

Loop R3: Promoting adherence with health savings accounts and microfinance

With an improved local economy, HH incomes will increase. As mentioned previously, greater financial resources may increase the likelihood that patients will adhere to prescribed medicines, contributing to improved health status. Additional resources may

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also be used to help fund NHI premiums and HSAs and improve prospects that microfinance loans will be repaid. However, there are possible negative side effects of economic improvements.

HSA and local microfinance initiatives compete with other claims on household resources. How will households balance the need for medicines against other economic demands? Social welfare funds collect regular, periodic contributions (30-50 KES) from community members, provide small sums for pressing individual or family needs, and invest surpluses in local businesses. How will participation in broader social welfare funds affect the amount available to put in HSAs? When need arises, will families look to social funds or microfinance for financial help to pay for care in health camps or for medicines?

Long-term use of appropriate medicines for chronic conditions is of paramount importance, and HSAs and microfinance schemes are one way to facilitate households' ability to purchase medicines. However, they may also lead to excess purchasing and grey-market sales, and indebtedness. How will health camps and other FN strategies (increased insurance enrolment, private sector care) affect long-term adherence, alter the economic trade-offs between other necessities (e.g., food) and prescribed medicines, and affect household resources?

Loop R4: Effects on lifespan and population

Participation in health camps is a key variable in the FN initiative. Diagnoses are made, medicines prescribed and acquired, and some follow-up care may occur in health camps, making them the initiative's initial centre of gravity.

Health camps are familiar settings for health care in Kenya. Health camps are sometimes organized by local officials as tangible gestures of gratitude to the electorate; medical school-sponsored camps allow trainees to provide social service. Camps tend to happen unpredictably, are usually free of charge, and are often overwhelmed with many patients seeking care. When over-crowded, time with patients is short, medical care quality is often sacrificed, and continuity of care is lacking.

FN-sponsored health camps are intended to be regular, but they cost an entrance fee of 20 KES per person. If needed, lab tests and medicines on the FN list are provided without additional charge. This raises several questions: How will the fixed entrance fee affect participation? Will FN health camps tend to draw those who are better off and willing to pay? If higher income families participate in FN health camps, will other facilities (e.g. government-run hospitals) have more capacity to serve the poorer populations? Will medical care in the FN health camps satisfy unmet need, or will it offset free medical care in public sector facilities or other paid private health services? How will local government officials and health providers respond to the establishment of regular health camps? How and under what conditions will patients attending camps need to be referred to other sources of care for services not provided in the camps?

Loop 5: Economic interests of pharmacies and pharmaceutical company

The FN initiative is a long-term strategic investment by Novartis Pharma. The company is willing to sustain financial losses while the program builds momentum and return on

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investment is not expected until about 4 years after the program's start. On the business side, FN engages with local physicians and pharmacists who ideally will volunteer their services in health camps, in return for gains in reputation and increased business in their private sector practices. This premise requires validation by local providers, who may see the health camps as a threat to their autonomy. Health camps would likely result in an increase in private provider patient volumes. Are the anticipated returns sufficient to maintain their involvement in the FN initiative? Will improved profitability invite new entrants to the marketplace and stimulate greater competition, both among pharmaceutical companies, private physicians, and retail drug outlets? What will be the long-term effects of the FN program on the structure of the drug supply system? Will other pharmaceuticals companies initiate competing programs that threaten the sustainability of FN?

Loop 6: Source of business for health care professionals

Government-sponsored and medical school-sponsored health camps depend on local doctors, medical students, nurses, and pharmacists as volunteers. Professionals receive little or no compensation for their work, but do receive lunch and a travel allowance. Ideally, FN health camps would be staffed by local volunteers as well. However, if there are not enough volunteers, FN health camps have engaged a local private health care firm to staff the camps. How will the more commercial policies of FN health camps be perceived by local health professionals? Will the existence of private camps change expectations about government-sponsored health camps? Will volunteering in health camps actually translate into increased business for local doctors and medical professionals?

System dynamics simulation

The initial conceptual systems model of the FN initiative and of the hypothetical behaviours of different actors in response to the initiative can be used to generate a large number of possible scenarios and outcomes. Interviews with different stakeholders are an important intermediate step toward building confidence in a simulation model, understanding the range of plausible possible consequences of the FN program, and highlighting potential side effects. At each stage of systems model development, a computer model based on the conceptual model can simulate alternative inputs and outcomes; identify potential problems in the hypothetical relationships in the model; and decide what aspects of the system are most important to monitor.

The process of progressive model development is called collaborative model building.^{32,33,34} In brief, representatives from each stakeholder group are interviewed about

³² Homer, J. B., & Hirsch, G. B. (2006). System dynamics modeling for public health: background and opportunities. *American Journal of Public Health*, 96(3), 452-458

³³ Vennix, J. A., Akkermans, H. A., & Rouwette, E. A. (1996). Group model-building to facilitate organizational change: an exploratory study. *System Dynamics Review*, 12(1), 39-58.

³⁴ Luna-Reyes, L. F., Martinez-Moyano, I. J., Pardo, T. A., Cresswell, A. M., Andersen, D. F., & Richardson, G. P. (2006). Anatomy of a group model-building intervention: building dynamics theory from case study research. *System Dynamics Review*, 22(4), 291-320.

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the topic of the system model. Annex 1 lists topics for inquiries with different stakeholders; Annex 2 lists questions by model loop; and Annex 3 lists sample indicators and potential data sources that could inform different parts of the model. Interviews and data are analysed for common themes and important system characteristics to be modified in the conceptual model and implemented in simulation model modifications.

Once completed, model inputs, connections and outputs can be reviewed with interviewees to verify that their thoughts are properly represented. When two or more interviewees disagree on how things are presented in the modified model, facts and assumptions can be checked. If there is no resolution, both representations can be retained in the model and as results accumulate, the more accurate representation is retained.

Summary

Pharmaceutical company-initiated social business initiatives are likely to grow because medicines situations in low and middle-income countries are inadequate and inequitable and pharmaceutical companies have multiple reasons to target lower income segments of the population, including enhancing global reputation, meeting corporate social responsibility goals, and developing business in emerging economies. Social business interventions may constitute a more sustainable, system-strengthening approach to do so than philanthropy. However, while potentially positive, the effects of social business initiatives remain largely unknown.

A key unresolved question is how performance of social business initiatives should be assessed. Companies need to demonstrate social returns on investment, which are beyond the scope of their usual financial metrics. Governments need to assess the health, social, and economic value of engaging in public-private partnerships. Measurement approaches are also needed to assess potential undesired effects of intervening in this way in complex health systems.

Questions that emerged from expert interviews to date suggest a more complicated and dynamically complex system than the conceptual model sketched in the figures above. Annex 2 offers a diagram with additional variables and connections for some of the questions. The diagram illustrates how a model could accommodate the perspectives of actual interviewees.

An important feature of the additions to the original sketch is the introduction of balancing feedback loops. While the business plan is composed of reinforcing feedback loops, additional variables such as inappropriate use of medicines or competition for savings in chamas could offset, moderate or even stall the growth plan. It is not necessary to predict accurately what will happen, only that there is structure in the model that can simulate such important features. In future interviews, one would want to explore possible conditions that would activate these mechanisms and refine the model accordingly with additional variables to monitor along with the outcomes they suggest. The more elaborate system shown in Annex 2 is more difficult to process mentally. In the original sketch, everything is continuously getting bigger (and better). The richer model includes variables

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that resist growth and can restrain the growth. How and under which system conditions will such variables and loops be active?

Because the conceptual models connote hypotheses, these can be tested in a model that simulates a closed system and in which the important results are generated endogenously. When translating a high-level map of the system into observable variables in a model, concepts sharpen and the important variables become obvious. Building a system dynamics model of social business interventions targeting medicines situations will be useful for highlighting stakeholders whose inputs need to be sought and identifying processes and outcomes that need to be monitored routinely.

Acknowledgment

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Annex 1. Key stakeholder groups and interview topics for collaborative model building

Given the different considerations that determine direction and magnitude of feedback loops in the conceptual model, inquiries are needed with multiple stakeholders on different topics. We list below domains for inquiries by stakeholder type.

Households and community members

- Patterns of household care seeking
- Types and cost of care and medicines received for key symptoms
- Volumes and quality of care and quality of medicines that households obtain
- Household experiences with health insurance coverage
- Economic status of households
- Experiences with chamas or other community financing schemes
- Relative allocation of household expenditures to health care, medicines, food, savings, investments
- Perceptions of households about the health care and medicines they receive

Health educators, community health workers

- Knowledge and volumes and quality of awareness raising, education provided
- Experiences with community meetings, linkages to health camps
- Job satisfaction
- Perceptions of the care system and their role

Government and private (mission) hospital administrators

- Volumes and quality of care provided
- Experiences with health camps, reputational value gain
- Perceptions of the care system and their role

Public and private sector physicians and health workers

- Knowledge and volumes and quality of care provided
- Experiences with health camps, reputational value gain
- Job satisfaction in health camps, public sector, private practice
- Perceptions of the care system and their role

Private and private sector drug sellers/pharmacies

- Purchasing patterns
- Promotion practices
- Availability of key medicines
- Medicines prices
- Knowledge and volumes and quality of care provided
- Experiences with health camps, reputational value gain
- Job satisfaction in health camps, public sector, private practice
- Perceptions of the care system and their role

Pharmaceutical wholesalers and distributors

- Utilization patterns
- Public and private sector sales
- Supply chain management: push or pull
- Supply chain effectiveness
- Perceptions of the care system and their role

Pharmaceutical manufacturers

- Local and international manufacturer marketing practices and sales
- Market changes
- Return on investment for social business partners
- Reputational value gains, locally and internationally

Health insurance administrators

- National health insurance program enrollment by socioeconomic category
- Benefit structure and recipients
- Expenditure patterns

Government and other local community stakeholders

- Population health and wealth
- Provider behavior, the pharmaceutical market, business development
- Behaviors of community, district, provincial health care officials
- Perceptions about activities of FN health educators and health camps

Annex 2: Refining the Model – Stakeholder Questions by System Loop

Below we summarize questions raised, with reference to feedback loop numbers and expand upon the initial conceptual model.

Loop 1

- Do patients who would otherwise not be treated attend health camps or seek treatment elsewhere due to FN educational efforts?
- Do doctors and pharmacists in health camps and private practice prescribe and dispense medicines that are appropriate for the patients' conditions (e.g., antibiotics only prescribed for bacterial respiratory infections, diarrhoea treated with oral rehydration salts and zinc)?
- Do patients obtain quality products and take them as prescribed?
- How affordable are the medicines purchases to patients and households? (B1)
- Are the frequency and dosage convenient and contribute to adherence?

Loop 2

- Which factors will have the strongest influence on the decision to purchase and continue purchasing medicines, especially when symptoms of disease are not yet apparent to the consumer? (R7)
- Will the FN activities be sufficient to overcome other system barriers to medication use?

Loop 3

- How will participation in broader social welfare funds affect the amount available to put in HSAs? (B2)
- When need arises, will families look to social funds or microfinance for financial help to pay for care in health camps or for medicines?
- How will health camps and other FN strategies (insurance financing, public sector care) affect long-term adherence, alter the economic trade-offs between other necessities (e.g., food) and prescribed medicines, and affect household resources?

Loop 4

- How will the fixed entrance fee affect participation? Will FN health camps tend to draw those who are better off and willing to pay? If higher income families participate in FN health camps, will other facilities (e.g. government-run hospitals) have more capacity to serve the poorer populations?
- Will medical care in the health camps satisfy unmet need, or will it offset free medical care in public sector facilities or other paid private health services?
- How will local government officials and health providers respond to the establishment of regular health camps?
- How and under what conditions will patients attending camps need to be referred to other sources of care for services not provided in the camps? (B3)

Loop 5

- Are the anticipated returns sufficient to maintain their involvement in the FN initiative?
- Will improved profitability invite new entrants to the marketplace and stimulate greater competition, both among pharmaceutical companies and retail drug outlets? (B4)
- What will be the long-term effects of the FN program on the structure of the drug supply system?
- Will other pharmaceuticals companies initiate competing programs that threaten the sustainability of FN?

Loop 6

- How will the more commercial policies of FN health camps be perceived by local health professionals?
- Will the existence of private camps change expectations about government-sponsored health camps? (“?”)
- Will volunteering in health camps actually translate into increased business for local doctors and medical professionals?

The causal loop diagram below (Figure 7) illustrates how select questions listed above can be added to the initial map.

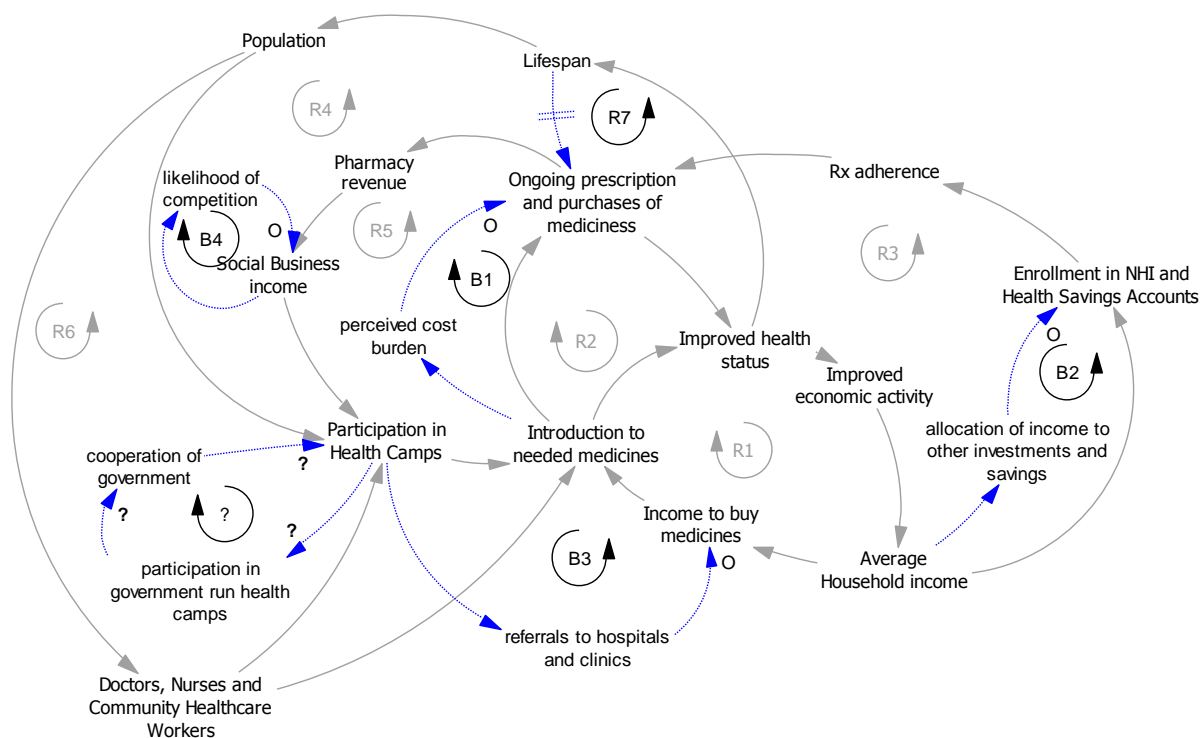


Figure 7: Elaborated FN model

One feedback loop designated with “?” indicates that it is uncertain whether it will reinforce or counterbalance the activity in the system.

In the initial conceptual model (Figure 6), every feedback loop reinforces positive results: any increase in the result of one variable leads to an increase in all variables. Not so in the more elaborate diagram, Figure 7. The connections designated with “O” indicate that an increase in the precedent causes a decrease in the object variable. For example, in B1, as referrals to hospitals and clinics increase, the amount of HH income available to purchase medicines decreases.

Not so obvious, the new connections influence other variables far removed in time and proximity. A small decrease here can lead to a large decrease elsewhere. Even the identification of feedback loops is a bit misleading because the number suggests only one loop was created with the addition of a variable. There are many more. Last, the terms used in the map are notional. When defined in real world terms, the detailed complexity will increase the dynamic complexity and makes prediction of the change in value of any variable on the map nearly impossible to guess.

The solution is to write the logic of the causal loop diagram in a closed mathematical argument: a computer model to simulate activity in the system. With such a system model, it becomes possible to do more than guess. One can trace the cause of change in the simulation to the variables influencing the change.

A crucial assumption in the social business plan is that doctors will prescribe and patients will use medicines appropriately. Appropriate utilization of medicines to treat a medical condition leads to improved health of the individual and collectively to the improved health status of the population. However, medicines are not always prescribed or utilized appropriately. Inappropriate use of medicines drives up system costs without health and economic benefit. And inappropriate medicines use can mask underlying conditions or contribute to worsening health status.

To represent the effects of appropriate and inappropriate medicines use, the figure below draws variables from Figure 7 and adds variables for proportion of medicines prescribed appropriately, appropriate and inappropriate use of medicines, and resources devoted to medicines education. These connect to improved health status and are driven by resources devoted to medicines education to create two new loops (Figure 8):

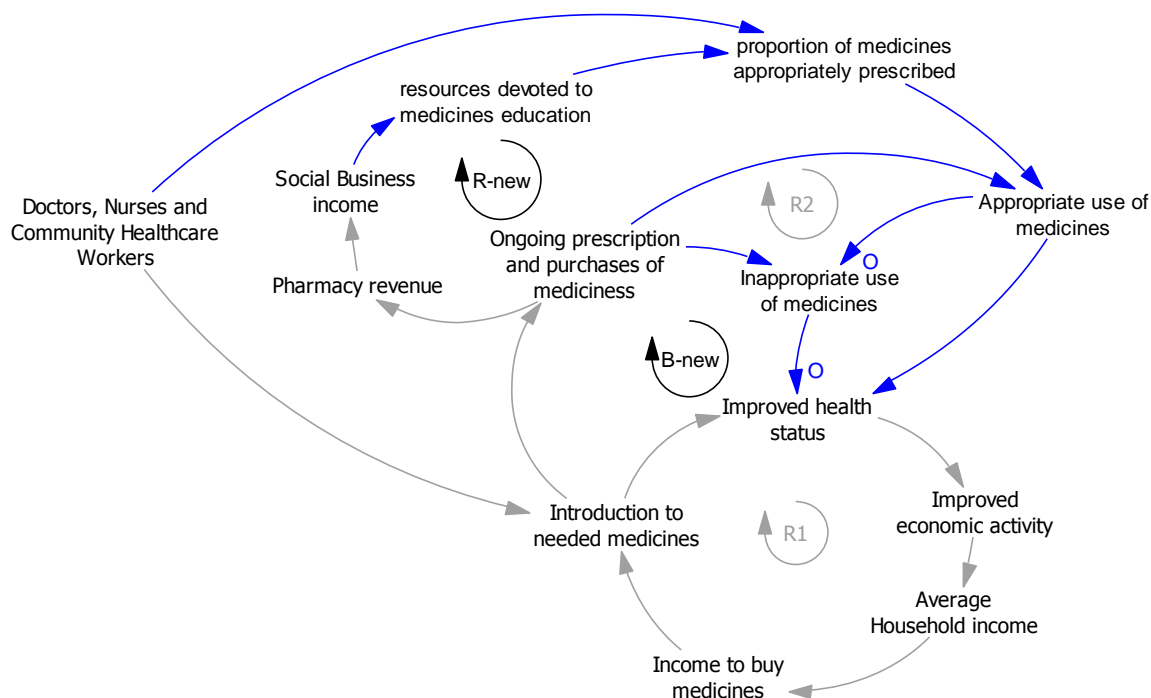


Figure 8: Growing appropriate use of medicines

The implication of the model structure in Figure 8 is that some proportion of medicines prescribed is inappropriate or inappropriately used. Inappropriate use of medicines does not improve health status and may make it worse than it otherwise would be, negatively impacting a system that is lacking needed resources (average HH income) to purchase and appropriately use needed medicines and undermining a virtuous cycle. To improve prescribing and usage, there is a connection between the pharmaceutical company's income and physician education. What fraction of income would be necessary is a question to parameterize in the simulation model and real world implementation.

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Annex 3: Refining the Model - Examples of Structural, Process, and Outcome Measures and Data Sources

Domain	Potential Foci	Potential Data Source(s)	Model Loop to Inform*
1. Structural Measures			
Health care delivery availability	Public and private hospitals, clinics, laboratories, etc. within reach, with pre-specified, functioning equipment, staffed, open for care	Central/local government data; Observation	B3
Health care delivery availability	Drug outlets within reach, staffed, open for care	Central/local government; Observation	R2
Health care financing availability	Insurance offices within reach, staffed, open for business	Central/local insurance office; Observation	B2
2. Process Measures			
Symptom recognition and care need knowledge	Individual knowledge about symptoms and appropriate care seeking	Household survey	R4, ?
Care seeking	Patients with symptoms seeking care at different levels in the system	Household survey	R4, ?
Access to care and medicines	Individuals who need care and medicines receiving care and medicines	Household survey; Community health worker, dispensary, physician records	R2
Provider treatment knowledge	Community health worker and physician care knowledge	Case vignettes	R1, R2, B-new

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Domain	Potential Foci	Potential Data Source(s)	Model Loop to Inform*
Quality of care	Community health worker and physician care recommendations according to standard treatment guidelines	Community health worker records; Physician records; Household survey	R1, R2, B-new
Quality of medicines use	Medicines prescribed and dispensed according to standard treatment guidelines	Prescribing records; Dispensing records; Household survey	R1, R2, B-new
Health insurance utilization	Eligible individuals who are aware of, enrolled in, and use insurance to pay for care	Household survey; Insurance records	B2
Supply chain functioning	Availability of needed medicines in outlets; stock outs	Dispensary data	R2, R5
Medicines prices	Retail prices of products	Dispensary data	
3. Intermediate Outcome Measures			
All: Preventable inpatient treatment	Inpatient care episodes for each condition (assumed to be preventable with appropriate outpatient care)	Household survey; Hospital data	R1, B3
HTN, DM: Adherence to prescribed medications	Patients who refill medications as prescribed	Pharmacy/drug outlet dispensing data; Household survey	R3
HTN: Blood pressure control	Patients with blood pressure in recommended range	Point of care (pharmacy/drug outlet) blood pressure measurements; Household visit with exam by trained staff	R1
DM: Blood sugar control	Patients with blood sugar (and/or HbA1c) in recommended range	Point of care (pharmacy/drug outlet) blood sugar measurements; Household visit with exam by trained staff	R1

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Domain	Potential Foci	Potential Data Source(s)	Model Loop to Inform*
Diarrhea: Recovery	Time to recovery from diarrhea	Household survey;	R1
ARI: Recovery	Time to recovery from ARI	Household survey;	R1
4. Outcome Measures – Health & Wellbeing			
HTN: Strokes, heart attacks	Reduction in strokes, heart attacks	Household survey; Hospital/clinic records	R1
DM: Micro-vascular complications	Reduction in retinopathies, blindness, amputations	Household survey; Hospital/clinic records	
Diarrhea: Childhood mortality from diarrhea	Decreased cause-specific childhood mortality	Household survey (verbal autopsy); Community death records	R1
ARI: Childhood mortality from ARI	Decreased cause-specific childhood mortality	Household survey; (verbal autopsy) Community death records	
Self-reported health status	Physical, mental, social health and well-being	Household survey	R1
5. Outcome Measures – Satisfaction			
Patient satisfaction	Patient satisfaction with access to, affordability, quality of medicines; care provided by community health workers; care provided by physicians	Household survey	R2, R4
Provider satisfaction	Provider (community health worker, urban physician, pharmacist/dispenser) satisfaction with the system, professional roles, remuneration	Provider survey	R2, R4
6. Outcomes Measures – Economic			
Income lost to	Days of work missed	Household survey	R1

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Domain	Potential Foci	Potential Data Source(s)	Model Loop to Inform*
illness			
Education lost to illness	Days of school missed	Household survey	R1
Out-of-pocket expenditures on medicines and care	Household spending on medicines and care (inpatient and outpatient)	Household survey	R1
System expenditures on medicines and care	Per capita local government/insurance spending on medicines and care (inpatient and outpatient)	Government records; Insurance records	Not in present model
Affordability of medicines and care	Household spending on medicines and care as percentage of total consumption spending	Household survey	R1
Affordability of medicines and care	Household strategies used to finance medicines and care (e.g., borrowing, selling assets, decreasing spending on food, education, etc.)	Household survey	R1
Financial protection	Percent of cost of medicines and care covered by insurance	Household survey; Insurance data	R1, B2

*Referring to Figures 7 and 8 in Annex 2; HTN= hypertension; DM=diabetes; ARI=acute respiratory tract infection