RESEARCH ARTICLE

Open Access

Human-centered design as a guide to intervention planning for non-

- communicable diseases: the BIGPIC study
 from Western Kenya
- 6 Claudia L. Leung^{1,2}, Mackenzie Naert³, Benjamin Andama⁴, Rae Dong³, David Edelman², Carol Horowitz³,
- ⁷ Peninah Kiptoo⁴, Simon Manyara⁴, Winnie Matelong⁴, Esther Matini⁴, Violet Naanyu⁵, Sarah Nyariki⁴,
- 8 Sonak Pastakia⁶, Thomas Valente⁷, Valentin Fuster³, Gerald S. Bloomfield³, Jemima Kamano⁵ and
- n Rajesh Vedanthan^{8*}

18 Abstract

- Background: Non-communicable disease (NCD) care in Sub-Saharan Africa is challenging due to barriers including poverty and insufficient health system resources. Local culture and context can impact the success of interventions and should be integrated early in intervention design. Human-centered design (HCD) is a methodology that can be used to engage stakeholders in intervention design and evaluation to tailor-make interventions to meet their specific needs.
- 24 **Methods:** We created a Design Team of health professionals, patients, microfinance officers, community health 25 workers, and village leaders. Over 6 weeks, the Design Team utilized a four-step approach of synthesis, idea
- 26 generation, prototyping, and creation to develop an integrated microfinance-group medical visit model for NCD.
- We tested the intervention with a 6-month pilot and conducted a feasibility evaluation using focus group discussions with pilot participants and community members.
- 29 **Results:** Using human-centered design methodology, we designed a model for NCD delivery that consisted of
- 30 microfinance coupled with monthly group medical visits led by a community health educator and a rural clinician.
- Benefits of the intervention included medication availability, financial resources, peer support, and reduced
- 32 caregiver burden. Critical concerns elicited through iterative feedback informed subsequent modifications that
- resulted in an intervention model tailored to the local context.

(Continued on next page)

* Correspondence: Rajesh.Vedanthan@nyulangone.org ⁸New York University Grossman School of Medicine, 180 Madison Avenue, 8th Floor, New York, NY 10016, USA

Full list of author information is available at the end of the article



[©] The Author(s). 2020 **Open Access** This article is licensed under a Creative Commons Attribution 4.0 International License, which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons licence, and indicate if changes were made. The images or other third party material in this article are included in the article's Creative Commons licence, unless indicated otherwise in a credit line to the material. If material is not included in the article's Creative Commons licence and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder. To view a copy of this licence, with http://creativecommons.org/licenses/by/4.0/. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated in a credit line to the data.

(Continued from previous page)

Conclusions: Contextualized interventions are important in settings with multiple barriers to care. We demonstrate 34 the use of HCD to guide the development and evaluation of an innovative care delivery model for NCDs in rural 35 Kenya. HCD can be used as a framework to engage local stakeholders to optimize intervention design and 36 37 implementation. This approach can facilitate the development of contextually relevant interventions in other lowresource settings. 38 Trial registration: Clinicaltrials.gov, NCT02501746, registration date: July 17, 2015. 39 Keywords: Non-communicable diseases, Kenya, Human-centered design, Delivery of healthcare, Problem-solving, 40 Microfinance 41

42 Background

Globally, non-communicable diseases (NCDs) are the 43 most common cause of premature mortality [1, 2]. Asso-44 ciated with mortality and prolonged disability, NCDs 45 have negative impacts at the individual, community, and 46 societal level due to increased utilization of health ser-47 vices, as well as loss of income and decreased productiv-48 ity [3, 4]. NCD incidence and outcome are closely linked 49 to social, economic, and environmental factors, dispro-50 51 portionately impacting poor and vulnerable populations [5-7]. In Kenya and other low- and middle-income 52 53 countries, NCDs are associated with a substantial household financial burden of care, which significantly impacts 54 access to care [8]. 55

In Kenya, multiple studies have demonstrated the 56 positive impact of microfinance on poverty [9, 10], and a 57 58 small but increasing number of studies have demonstrated the synergistic effect of integrating microfinance 59 and health interventions [11]. Most interventions com-60 bined microfinance with health education and did not 61 affect the more complex task of healthcare delivery [12]. 62 The Village Savings and Loans Association (VSLA) 63 model, on which the microfinance model in this paper is 64 derived, has improved food security and strengthened 65 household income indicators in Africa [13, 14]. In this 66 model, participants save money together through buying 67 shares and can access loans by borrowing against their 68 69 savings. Interest is paid back to the group, and accumulated shares and interest are later shared out to all the 70 group members [15]. Additional informal and formal 71 group-based savings and credit models also exist in 72 73 Kenya, including microcredit lending through institutions and local moneylenders, savings via investment in 74 livestock, and the Rotating Savings and Credit Associa-75 76 tions (ROSCA) model, commonly referred to as merrygo-round, in which members take turns receiving a pot 77 78 of shared savings over a particular time period [16].

79 The need for contextualized interventions

Lack of transport, poverty, and poor quality of care are known barriers to NCD care in western Kenya [17].

82 Skepticism regarding the health system, fear of stigma,

and socio-economic fragility also contribute to low 83 utilization of available healthcare resources [18, 19]. This 84 complex milieu necessitates targeted solutions that address both the health and economic realities faced by 86 this population. Rather than replicate existing interventions in high-resource settings, development of new 88 interventions must be innovative, striving to provide 89 high-quality care while accounting for resource constraints and contextual factors [5]. Ideally, a replicable 91 intervention design and evaluation process should be 92 used, allowing for the flexibility to develop a contextualized intervention while using a standardized process that can be applied in diverse settings. 95

Human-centered design (HCD) is a problem-solving 96 approach that utilizes a series of iterative, often non-97 linear steps to tailor-make solutions for complex prob- 98 lems [20, 21]. While similar to other participatory 99 research frameworks in its inclusion of end-user feed- 100 back, HCD differs in its endeavor towards empathy, a 101 deep understanding of the motivations and desires that 102 govern human behavior, as the inspiration and core of 103 intervention development [20, 22]. In this approach, 104 end-users are invited to partner in the design and evalu-105 ation process in order to better understand, meet, and 106 even preempt their needs. In a low-resource, complex 107 setting where the phenotypic manifestations of disease 108 drivers may differ significantly from well-resourced set-109 tings, these key principles of HCD can be leveraged to 110 optimize intervention development and implementation. 111

In this paper, we describe how we adapt a four-step 112 HCD approach to guide the development of an integrated model of group care and microfinance for NCD 114 care in rural Kenya. We use this case to describe the potential of utilizing a HCD approach to guide the development of complex interventions in a resource-limited 117 setting. 118

Methods Setting

119

120

The Academic Model Providing Access to Healthcare 121 (AMPATH), initiated in 2001, is a partnership between 122 Moi University College of Health Sciences, Moi 123

Teaching and Referral Hospital, and a consortium of 124 North American academic medical centers 125 [23].AMPATH established a system of HIV care in western 126 Kenya and has since expanded its clinical scope to in-127 clude population health and NCDs [24]. At the time that 128 129 this study was conducted, the Chronic Disease Management program at AMPATH had enrolled over 2000 130 patients with diabetes and 40,000 patients with hyper-131 tension, who were being cared for at nine rural health 132 centers and 30 rural dispensaries. The program dis-133 patches clinicians to rural clinics monthly, which are 134 otherwise staffed by nurses. This study was conducted as 135 part of the Bridging Income Generation and Group Inte-136 grated Care (BIGPIC) study which aims to evaluate the 137 combination of microfinance and group medical visits 138 for cardiovascular risk reduction in the AMPATH catch-139 ment area across four counties in western Kenya [25]. 140

141 Intervention design

In this project, we adapted a pilot BIGPIC model that 142 consisted of microfinance coupled with monthly group 143 144 medical care visits with a rural clinician [26]. In this pilot model, participants with diabetes or hypertension 145 are recruited to join the group and consist of at least 146 50% of group members. Group medical visits with a 147 clinician occur immediately after each microfinance 148 meeting. In order to further refine and adapt this ap-149 proach to the local context, we utilized a HCD frame-150 work consisting of four steps - Discover, Design, Test, 151 and Refine - with an emphasis on community and end-152 **F1** 153 user engagement at each stage (Fig. 1). As HCD is an iterative process, the steps are described in sequence in 154

155 the Methods and Results sections.

156 Step 1. DISCOVER: understanding the community

The first step in refining the BIGPIC model was to 157 understand the strengths and needs of the local commu-158 nity. We utilized a combination of qualitative research 159 methodologies to explore community and individual 160 perspectives. The primary goals were to identify existing 161 barriers to NCD care, and to identify contextual factors, 162 163 barriers, and facilitators that could impact intervention design, implementation, and sustainability. We held 164 165 mabaraza, traditional East African community gatherings, to discuss community perspectives in an open for-166 mat. We also hosted focus group discussions (FGDs) 167 consisting of 10-15 individuals with common character-168 169 istics (rural clinicians, community health workers, pa-170 tients with NCDs, and microfinance group members) to explore individual perspectives. All qualitative studies 171 were led by local team members utilizing a semi-172 structured guided interview in local languages. 173

174

Step 2. DESIGN: designing the intervention

Design team formation A transdisciplinary team of re-175 searchers and community stakeholders led the interven-176 tion design, implementation planning, and evaluation 177 process (Fig. 2). The goals of the Design Team were to 178 F2 define the challenges to NCD care based on community 179 input and design an intervention model to meet the 180 needs and challenges of the end-users. Potential partici-181 pants were identified through snowball sampling and 182 local connections and invited to participate based on 183 personal or professional experiences with NCDs or 184 microfinance. All Design Team members represented 185 end-users, those who may deliver or receive the 186 intervention. 187

Design team meetings Design Team meetings were 188 conducted in a series of weekly three-hour meetings 189 over 6 weeks, following objectives and activities adapted 190 from HCD methodology [21]. An initial agenda was developed, however, timing for each step was flexible. 192

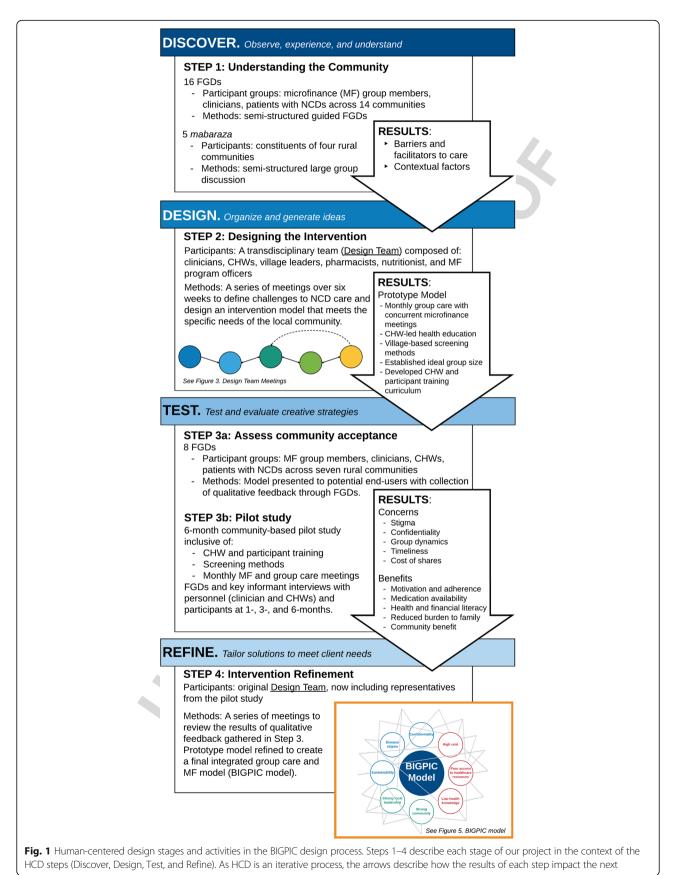
The specific objectives and activities utilized in the De-193 sign Team meetings are described in Fig. 3. The forum 194 and structure of the meetings were intentionally collab-195 orative and interactive to encourage discussion and cre-196 ativity. In Synthesis meetings, Design Team members 197 reviewed qualitative data gathered in Step 1 and shared 198 their insights, experiences, and questions to help engen-199 der a deep understanding of the strengths and barriers 200 related to NCD care in western Kenya. Insights were 201 posted visually and reorganized into broad themes which 202 represented potential intervention barriers, facilitators, 203 or unmet needs (Fig. 6, Table 1). Within each theme, 204 questions were developed to facilitate brainstorming in 205 Ideate meetings. For example, for the theme "Informa-206 tion/Engagement," we asked, "how might we incorporate 207 health education into patient care?" We learned in Step 208 1 that microfinance is generally considered a women's 209 activity which may preclude male participation, so for 210 the theme, "Gender," we asked, "how might we create a 211 model that is responsive to the needs of men?" Each 212 question was formed to catalyze group discussion to ad-213 dress important and nuanced aspects of the intervention 214 that would ultimately impact intervention acceptability 215 and sustainability. 216

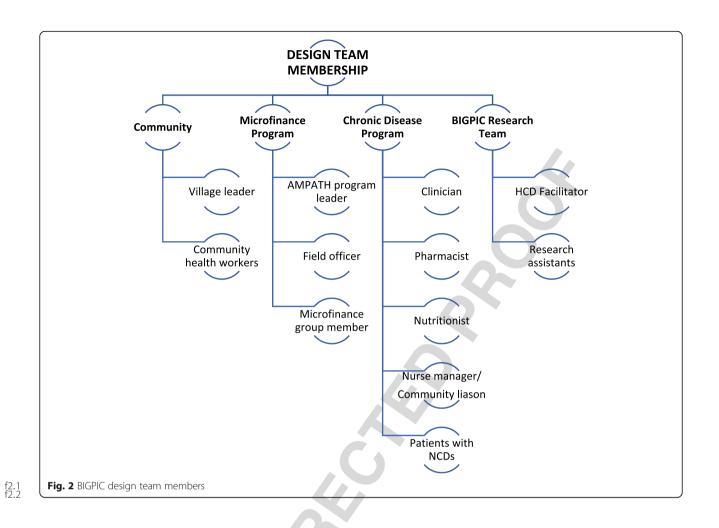
All ideas were noted and subsequently evaluated in 217 group discussion for pros, cons, and feasibility in <u>Proto-</u>218 type meetings. In the latter example above, we considered gender-specific groups, targeted screening locations 220 when men tend to congregate, and community education, particularly through male leadership involvement. 222

Synthesis, brainstorming, and prototyping were 223 cyclical and iterative steps that raised new questions in- 224 fluencing idea generation. In <u>Create</u> meetings, an initial 225

F3

T1

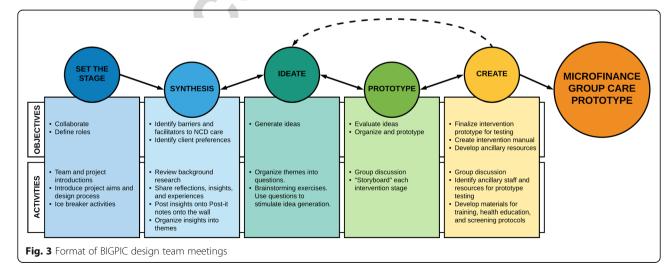




prototype model was developed that combined group
medical care and microfinance. Elements crucial to testing the prototype were developed in this step, including
participant education materials, healthcare worker training curricula, and screening and evaluation protocols.

Step 3. TEST: assess community acceptance and pilot study 231

Acceptability studies Qualitative feedback was gathered 232 to assess community receptiveness to the proposed 233 prototype model. FGDs of 10–15 individuals were 234



Themes, along with member contributions of personal insights and experiences conducted with groups of rural clinicians, microfinance 235 group members, patients with NCDs, and CHWs. A 236

question guide was used to steer the discussion in a 237 semi-structured format. We performed a thematic ana-238 lysis of the qualitative feedback utilizing NVivo. 239

Feasibility pilot study Implementation strategies and 240 the prototype, as defined in Step 2 Results, were piloted 241 in one rural community in western Kenya. Adults who 242 screened "positive" were those with elevated blood pres-243 sure or elevated fasting blood glucose. Inclusion criteria 244 of those who screened positive were newly screened 245 246 adults, previously screened adults who had never linked to care, or existing patients who had linked to care in 247 the last 6 months. Those with diabetes or hypertension 248 who did not meet the inclusion criteria were able to join 249 250 the group as non-study participants to a maximum 251 group size of 30 members. Participants and local CHWs subsequently received training in microfinance, hyper-252 tension, and diabetes. Qualitative feedback was elicited 253 from the participating rural clinician, CHWs, and group 254 participants at one, three, and 6 months using guided in-255 terviews and FGDs. 256

Step 4. REFINE: intervention refinement 257

The Design Team subsequently reconvened to evaluate 258 the results of the acceptability studies and feasibility 259 260 pilot study. In addition to the original team, representatives from among the pilot study participants were 261 elected by their peers to take part in the reevaluation 262 263 process. In a series of meetings, the Design Team reviewed the feedback and developed a final BIGPIC 264 265 model.

Results 266

Step 1. DISCOVER: understanding the community 267

Five mabaraza and 16 focus group discussions were 268 269 conducted across 11 sub-counties in western Kenya. Results from these qualitative studies indicated that cost, 270 lack of medication availability, distance to health facil-271 ities, earned skepticism of the health system, socio-272

economic fragility, and stigma were significant barriers 273 to accessing and maintaining NCD care [27]. 274

Step 2. DESIGN: designing the intervention

Our iterative design process resulted in an initial proto-276 type model combining microfinance with monthly group 277 medical care visits with a rural clinician. Compared to 278 the original BIGPIC pilot model, this prototype engaged 279 community health workers (CHWs) as group liaisons, 280 included a CHW-led health education didactic at every 281 meeting, and emphasized community-based recruitment 282 approaches. 283

Step 3. TEST: assess community acceptance and pilot study

Approximately 90 individuals in the community were 286 screened, and 31 participants (12 male, 19 female) were 287 enrolled to form the pilot study group. The group in-288 cluded a mix of different ethnic tribes and participants 289 ranged in age from 36 to 75. In total, 17 FGDs and 290 guided interviews were conducted (N = 110) at which 291 point we achieved content saturation. 292

In general, the initial BIGPIC prototype model was 293 found to be acceptable, with multiple perceived and an-294 ticipated benefits at the individual, family, and commu-295 nity levels (Fig. 4). Participants reported improved access 296 to medical services by mitigating the need to travel, de-297 creased cost of medications, peer support, and medica-298 tion reliability as important benefits. Community level 299 feedback provided additional insight to alleviate preexist-300 ing concerns regarding the prototype model, highlight 301 persisting concerns, or raised new concerns not previ-302 ously identified. 303

For example, one concern alleviated by the initial 304 prototype regarded gender and group dynamics. In 305 qualitative studies in Step 1 and Step 3, some commu-306 nity members expressed concern that differences in age 307 and gender could affect group participation, given a 308 strong culture of both gender and age-based hierarchy. 309 Unintentionally, our pilot testing group was mixed not 310 only in gender but also age and ethnic tribe. Yet, partici- 311 pants stated they found diversity in age, gender, and 312 background to be a strength of the group, providing a 313 sense of healthy competition between old and young, 314 and allowing the younger members to take leadership 315 roles and provide translation to their local language for 316 the older members. Elected leaders in the group were 317 both male and female, and gender differences did not 318 negatively impact group dynamics. 319

New concerns elicited through this process included 320 maximum group size and concern that this could lead to 321 clinician burn out. Additionally, participants requested 322 increased flexibility in scheduling monthly meetings so 323 as not to interfere with their annual harvest schedule, 324

Table 1 Key themes identified in Step 2, Synthesis meetings t1 1

C1.1	They diemes identified in step 2, synthesis mee
t1.2	Key Themes
t1.3	Information/engagement
t1.4	Gender
t1.5	Finance/Cost
t1.6	Attitude/Commitment
t1.7	Time
t1.8	Confidentiality

t1.9 Knowledge

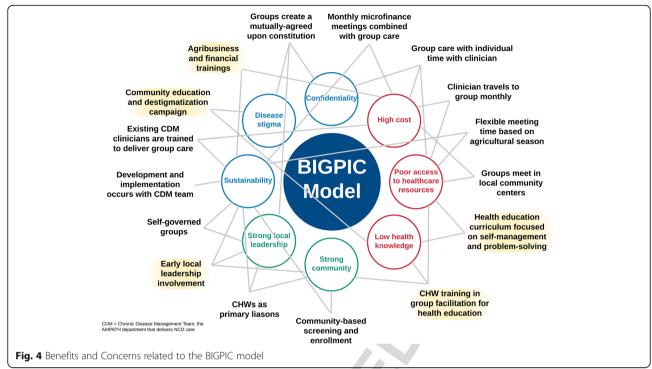
t1.10 Preliminary results from Step 1 presented to the Design Team were organized into t1.11

275

284

285

F4



f4.1

and to expanded availability of commonly used medica-325 326 tions. Researchers and CHWs noted low interest and engagement in the health education didactic sessions 327 provided by the CHWs. 328

Persisting concerns shared by pilot participants in-329 330 cluded apprehension that participation would be limited 331 by stigma associated with illness such as HIV. Participants emphasized the importance of anticipatory com-332 munity education to enhance community receptiveness, 333 and suggested strategies to facilitate this. Based on their 334 prior experiences with brief lifecycles of programs due 335 336 to limitations in funding and service delivery, participants and local leaders also expressed concern regarding 337 the sustainability of the program, and noted these prior 338 experiences may discourage some from joining. They 339 also reported that income generally is low among their 340 341 community and requested seed money or incentives to jump start their savings. 342

Step 4. REFINE: intervention refinement 343

The final BIGPIC model consists of an integrated group 344 345 care and microfinance model, with specific changes to the prototype model described in Table 3. These include 346 expanded access to common medications, a reduction in 347 maximum group size, and clarification of protocols with 348 349 CHWs to coordinate changes in meeting times during 350 the harvest season.

In response to the low interest in health education di-351 dactic sessions, our final model included a redesigned 352 education curriculum, which shifted the focus from 353

didactic sessions on NCD topics to strategies of shared 354 learning. This included a group facilitation curriculum 355 to help CHWs facilitate and guide discussions. For ex-356 ample, the CHW may choose a topic such as medication 357 adherence, and guide a discussion of challenges to medi-358 cation adherence, encouraging participants to share 359 potential strategies to improve. Examples of other sug-360 gested topics include diet, exercise, oral hygiene, alcohol 361 use, and stress management. 362

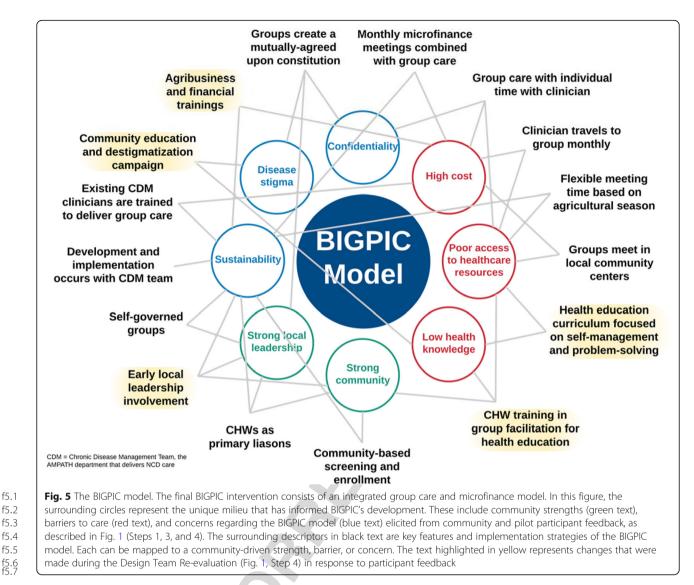
As suggested by local leaders and community mem-363 bers, our final implementation strategy included in-364 creased efforts towards community sensitization of our 365 intervention and NCDs. We placed an increased em-366 phasis on partnership with local community leaders, and 367 provided reassurance that our BIGPIC model remains 368 under Chronic Disease Management Team purview, a 369 known and trusted presence in the community. 370

Finally, an extensive discussion took place regarding po-371 tential program incentives and seed money. Given com-372 munity concerns for sustainability, the Design Team felt 373 strongly that providing seed money for each newly formed 374 group would be counterproductive as it would be 375 dependent on grant funding. An intentional decision was 376 made not to provide monetary incentives, but to instead 377 scale up training in money management and agribusiness. 378

Discussion

The refined BIGPIC model was developed using a four-380 step HCD framework, resulting in the development of a 381 health care delivery model targeting health behaviors, 382

379



f5.5 f5.6

T3

medication adherence, and financial barriers to accessing 383 healthcare in rural Kenya. We gathered insights and opin-384 ions from the community and formed a transdisciplinary 385 Design Team of health professionals and community 386 members to evaluate our data and create an initial proto-387 type. This prototype was tested over six months and fine-388 tuned through community feedback to enhance accept-389 390 ability and sustainability. The resulting BIGPIC model 391 combines the benefits of microfinance with the peer sup-392 port available through group medical care to enhance management of hypertension and diabetes. Key insights 393 that developed through the HCD process informed both 394 prototype features and implementation strategies and can 395 396 be mapped directly to the strengths, needs, and concerns T2F5 397 elicited from the community (Fig. 5, Tables 2-3). Cur-398 rently, this product is the primary intervention of a fourarm randomized control trial to fully evaluate its impact 399 [25]. Pending the final results of the randomized control 400

trial, we are committed to working with stakeholders to 401 scale up the model if it is found effective. 402

While the potential to leverage HCD for NCD care 403 has been previously described [28], our study is one of 404 the first to our knowledge to use HCD for a complex 405 NCD intervention of this scale [12]. As described by the 406 recent Lancet Taskforce on NCDs, poverty stems from 407 and is exacerbated by the global burden of NCDs, and 408 innovative means are needed to address the household 409 economic burden of care in order to alleviate global pov-410 erty, decrease premature deaths, and progress towards 411 the United Nations' Sustainable Develop Goals in Kenya 412 and other low- and middle-income countries [3, 29, 30]. 413 Empathy-driven HCD at its core strives to understand 414 the key drivers of human behavior and can be leveraged 415 to help bridge the "knowing doing gap" that frequently 416 characterizes poor adherence to prescribed lifestyle 417 changes for NCD management such as dietary changes, 418

Table 2 Key insights and BIGPIC prototype features t2.1

t2.2 t2.3

t2.4

t2.5 t2.6

t27 t2.8

t2.9 t2.10 t2.11 t2.12

t2.13 t2.14 t2.15

t2.16

t2.17

t2.18

KEY INSIGHTS	PROTOTYPE FEATURES	IMPLEMENTATION STRATEGY
<i>Strength:</i> Community, sense of brotherhood	Group-based care model to provide peer support and education Locally-based CHWs facilitate group formation	Community-based health screening to ensure local group formation
Strength: Community leadership	Participants elect group leaders and are self-governed by a mu- tually agreed upon constitution.	
<i>Barrier</i> : High cost of care (medications, transport, cost of services, caregiver burden)	Group care is combined with a microfinance program to increase individual access to funds for personal or medical use. Clinician brings basic medication supply box at every visit	Community-based health screening to ensure local group formation. Rural clinician and CHWs travel to group meetings at local community centers.
<i>Barrier:</i> Far distance to health facilities and poor quality roads	Community-based groups are linked with a local CHW.	Community-based health screening to ensure local group formation. Rural clinician and CHWs travel to group meetings at local community centers.
<i>Barrier:</i> Poor quality of existing physician- patient relationships	Same physicians return to the group as much as possible. Clinicians trained in group care are existing CDM clinicians.	
<i>Concern</i> : Variable group dynamics, particularly between age groups and gender	Participants create and sign a mutually agreed upon constitution that emphasizes self-governance and conflict resolution. Groups have a minimum number of study participants, and participants can bring additional friends/family to join the group until the maximum group size is attained.	
<i>Concern:</i> Stigma associated with illness or with AMPATH's reputation as an organization for people with HIV.		Increased efforts for community education and destigmatization. Remove AMPATH logo from trucks.
Concern: Confidentiality	Group constitution includes a confidentiality clause that is created by the group members. Time is allotted for individual clinician assessment at every group care meeting.	

value) may prohibit some from joining group. Limited number of shares can be bought per meeting. No external funding/seed money is required to start a t2.19 Concern: Sustainability of new programs Early local and governmental microfinance group. leadership involvement. Clinicians trained in group care are existing CDM employees. Implementation occurs with existing CDM teams.

Group members agree upon share value at the start of the

t2.20Key insights elicited from the design process can be mapped directly to prototype features and implementation strategies. CDM - Chronic disease management

weight management, and tobacco use [28, 31]. In limited 419 resource settings, HCD is a process that can comple-420 421 ment and support existing approaches to shaping NCD control such as the World Health Organization STEP-422 wise approach [32]. HCD is one approach to optimize 423 424 stakeholder engagement, and as in the example of BIG-PIC, it can propel an understanding of local factors into 425 426 the development of a contextualized intervention. In this study, our approach utilizing HCD for complex interven-427 428 tion design aligns with the Medical Research Council guidelines for developing complex interventions, utiliz-429 ing a systematic approach to a development-evaluation-430 431 implementation process that is tailored to local circumstances [33]. Similar approaches to design-thinking have 432 been described with other disease processes in low-433 resource settings [34–36]. 434

Concern: High cost of participation (share

Health inequities including those experienced by 435 our catchment communities in Kenya are deeply 436 rooted in complex social determinants, and increas- 437 ingly need to be addressed in cross-sector and trans-438 disciplinary partnerships [37]. Our HCD process 439 provided a means to gather data and interact with the 440 community to understand strengths and barriers to 441 care, while also inviting community members to par- 442 ticipate in innovation to enact changes in priority 443 areas [38]. Through early involvement of stakeholders, 444 we were able to not only address critical concerns 445 early in the intervention design process, but also build 446 partnerships with local stakeholders that would later 447 be critical to the success of intervention implementa- 448 tion. Many components of our intervention and im- 449 plementation strategies were illuminated through 450

t3.1 Table 3 BIGPIC Re-evaluation changes

t3.2	INITIAL PROTOTYPE FEATURE	FEEDBACK/CONCERNS	MODIFICATIONS
t3.3 t3.4	Monthly meeting time determined by clinician availability.	Participant availability may change based on agricultural season.	CHWs function as primary liaison with medical team to coordinate best meeting time before the end of each month.
t3.5 t3.6 t3.7	Group education on NCDs at the time of group formation and before every monthly meeting.	There is low interest in group education.	Health education time is modified from didactic teaching to facilitated group discussions on self- management and problem solving. CHWs receive training in group facilitation.
t3.8	Maximum group size of ~ 30 participants.	Large groups may overburden clinicians.	Maximum group size is decreased to ~ 20 participants.
t3.9 t3.10	Village-based health screenings to recruit intervention participants.	Concern for disease stigma may preclude willingness to join groups	Renew efforts to increase community health and intervention awareness. Remove AMPATH logo from clinician vehicles.
t3.11 t3.12 t3.13	Clinician brings a toolkit of common medications for chronic disease management.	Availability of other commonly used medications (i.e., ibuprofen, antibiotics).	Toolkit of medications needed communicated to AMPATH pharmacy.
t3.14 t3.15	Community entry focused on local leadership.	Concerns regarding program sustainability.	Community entry and scale up includes multiple levels of leadership. Given CDM program is well known, emphasize roll out is in partnership with the existing CDM program. No seed money provided, but increased agribusiness and financial trainings.
t3.16 t3.17 t3.18	Microfinance training during group enrollment, and CHW-led health education didactic sessions every month.	There is low income generation among community members, particularly elderly and those with low education levels.	Agribusiness and financial trainings are incorporated. Health education time is modified as above.

t3.19 Feedback and concerns elicited from pilot participant feedback informed key intervention modifications

critical insights from end users throughout our HCD 451 process. For example, multiple community members 452 voiced concern for a sustainable intervention that 453 would engage with local leaders and not be 454 455 dependent on external funding. The use of an economic-based intervention as well as many of the 456 features of this microfinance and group care model 457 are in response to these lessons learned. 458

459 Facilitators of success

Our intervention development operated on the backdrop 460 of AMPATH's existing partnerships with communities 461 in its catchment areas. Its existing programs in NCD 462 management and microfinance, network, and presence 463 in rural communities helped to facilitate participant re-464 cruitment as well as engage with local leadership. 465 AMPATH's existing Chronic Disease Management pro-466 467 gram and resources including rural clinicians, clinical liaisons, and knowledge of the local communities allowed 468 us to scale up our prototype more quickly and effect-469 ively. Increased availability of cellular service in rural 470 areas made it possible for us to access patient records 471 472 even in remote areas for continuity of care.

473 Notably, the Kenyan National Hospital Insurance Fund
474 (NHIF) has recently extended its benefits to include
475 NCD care in its benefits package. Our HCD process can
476 provide insight as to the development and type of

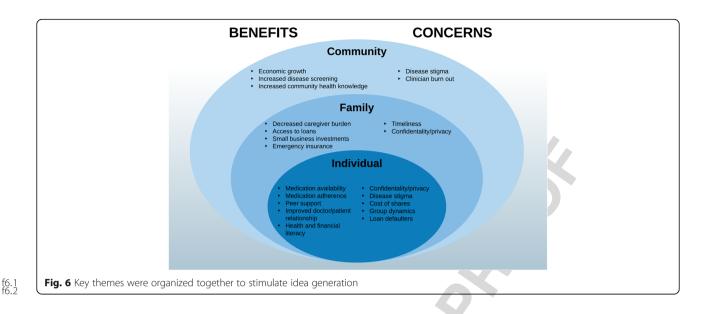
intervention that can be successfully incorporated under 477 the benefits offered by NHIF. 478

Limitations

Perhaps one of the greatest strengths of HCD and a vital 480 lesson-learned in our design process is the importance 481 of listening to and collaborating with our participants, 482 which helped us to better understand their challenges 483 and priorities. However, HCD can be a time-consuming 484 process that may not be feasible for all project timelines 485 and resources. Stakeholder buy-in and active engage-486 ment throughout the HCD cycle is essential, both at the 487 personnel, institutional, and governmental level. This 488 may be difficult to garner in some circumstances 489 whether through lack of availability or lack of familiarity 490 with this specific approach to intervention development. 491

Additionally, as use of HCD is still fairly novel in 492 resource-limited settings, the presence of a facilitator fa-493 miliar with the HCD process and tools is necessary but 494 may be cost- and time-prohibitive, particularly if inter-495 vention development takes place over weeks to months. 496 Similarly, while the formation of a multidisciplinary de-497 sign team is a critical strength of HCD that begets a dee-498 per understanding of the local context and paves the 499 way for future intervention implementation, coordin-500 ation of a 10 to 15 person team across diverse educa-501 tional, language, and geographical backgrounds may be 502 challenging. To combat this, HCD practitioners may 503

479



consider shorter and faster cycles of prototyping for less
complex interventions, in order to efficiently evaluate
ideas and integrate lessons-learned for continuous improvement and sustainability. Beginning with shorter cycles may also help gain stakeholder support for
subsequent longer cycles of more complex intervention
development.

We also recognize that HCD is a process that re-511 quires tolerance of ambiguity, pivots, and prototyp-512 ing-factors that can seem to be in opposition to 513 traditional hypothesis-driven research methodologies 514 515 [38]. However, we feel that HCD is a process for the design and development of interventions and imple-516 mentation strategies that are both desirable and feas-517 ible in the local context, which can then be evaluated 518 with traditional hypothesis-driven statistical method-519 520 ologies. In our study, we have combined HCD with a more traditional randomized controlled implementa-521 tion research trial to evaluate the effectiveness of the 522 523 intervention [25].

Finally, there is growing enthusiasm in both academic 524 525 medicine and global health spheres for social innovation and design thinking as tools that are more capable and re-526 sponsive to the needs of end users [38-40]. However, there 527 528 is still limited evidence regarding the impact of design thinking methodologies and related concepts on health out-529 530 comes [41]. Additional research is needed to evaluate the impact of participatory methodologies such as design think-531 ing and social enterprises on health outcomes. 532

533 Application to other contexts

The development and implementation of BIGPIC is one example of how HCD concepts can be used in resourcelimited settings. Of particular relevance was the inclusion of transdisciplinary community stakeholders on our Design Team, who represented not only healthcare pro- 538 fessionals, but also local community members, leaders, 539 and microfinance experts. Our HCD process was inher-540 ently inclusive and collaborative, inviting innovation and 541 feedback in every stage of development, and thrived 542 through partnership and collaboration [42]. Its applica-543 tions can be imagined broadly in both complex interven-544 tion development such as ours, or in more simple settings 545 of adapting a known model or intervention to local con-546 text [38]. While it is unlikely that our exact HCD design 547 and group care and microfinance model will be replicated 548 wholesale in other contexts, our described process offers 549 relevant lessons in low-resource settings both in the 550 United States as well as abroad, in line with a scoping re-551 view of design thinking in global settings [38]. 552

Recognizing that there are universal elements to care 553 that are common across geopolitical and financial landscapes, we advocate for context-specific interventions 555 that can help to optimize care in these settings. However, we recognize that potential unintended consequence is that such specificity may lead to variability and 558 inequities in care. For this reason, we urge caution with 559 planning for context-specific settings. 560

Conclusions

In this study, we describe how a four-step HCD frame-562 work was used to tailor NCD service delivery to address 563 multiple barriers to care for patients with hypertension 564 and diabetes in western Kenya. HCD provided a means 565 to engage early with local stakeholders, and the process 566 of iteration and feedback was critical to address stake-567 holder concerns and optimize intervention design and 568 implementation. While this approach to NCD interven-569 tion planning may be time-intensive, it resulted in an 570 intervention package that is tailored to the local context 571

561

572 and well-received by stakeholders. Future initiatives can

- use HCD to partner with local stakeholders to find in-573
- novative ways to address complex health problems in 574
- 575 resource-constrained settings.

576 Abbreviations

- 577 AMPATH: Academic Model Providing Access to Healthcare; BIGPIC: Bridging
- Income Generation with Group Integrated Care; CARE: Cooperative for 578
- Assistance and Relief Everywhere; CDM: Chronic disease management; 579
- 580 CHW: Community health worker; FGDs: Focus group discussions;
- 581 HCD: Human-centered design; MF: Microfinance; NCD: Non-communicable
- 582 disease; VSLA: Village Savings and Loan Association; NHIF: National Hospital 583 Insurance Fund

584 Acknowledgements

- 585 The authors would like to thank Aileen Li and Julia Dickhaus for editorial
- assistance and the Design Team for their time and participation. We also 586
- 587 gratefully acknowledge research participants who took their valuable time to 588 participate in this study.

589 Authors' contributions

- 590 CL, RV, GSB, SP, TV, VF, JK made substantial contributions to the conception
- 591 and design of the work. CL, RD, BA, PK, SM, WM, EM, SN, and SP contributed
- 592 to the acquisition of data. CL, MN, BA, DE, CH, SM, PK, WM, EM, VN, SN, and
- 593 SP contributed to the analysis of the data and the interpretation of the
- results. CL, RV were major contributors in writing and/or substantially 594
- 595 revising the manuscript. All authors read and approved the final manuscript.

596 Funding

- 597 Research reported in this publication was supported by the National Heart,
- 598 Lung, and Blood Institute (NHLBI) under grant number 5R01HL125487. The
- 599 content is solely the responsibility of the authors and does not necessarily
- 600 represent the official views of the National Institutes of Health (NIH) and NHI BI 601

602 Availability of data and materials

- This study complies with the NIH Public Access Policy, which ensures that 603
- the public has access to the published results of NIH funded research, and 604
- 605 therefore, all results have been (and will be made) available from final peerreviewed journal manuscripts (including this one) via the digital archive 606
- 607 PubMed Central upon acceptance for publication.

- 608 Ethics approval and consent to participate
- 609 This study obtained ethics approval by the NYU School of Medicine
- 610 International Review Board (IRB) in New York, NY (study number i18-01260), 611
- as well as the Moi University School of Medicine Institutional Research and 612 Ethics Committee (IREC) in Eldoret, Kenya (IREC Approval Number 0001368).
- Written informed consent was obtained by each participant at the time of 613
- 614 enrollment.

615 Consent for publication

Not applicable. 616

Competing interests 617

The authors declare that they have no competing interests. 618

619 Author details

- 620 ¹Duke University Medical Center, 10 Duke Medicine Circle, Durham, NC
- 27710, USA. ²Division of General Internal Medicine, Duke University School of 621
- Medicine, 200 Morris St. 3rd floor, Durham, NC 27701, USA. ³Icahn School of 622
- 623 Medicine at Mount Sinai, 1 Gustave L. Levy Pl, New York, NY 10029, USA
- ⁴Academic Model Providing Access to Healthcare (AMPATH), P.O. Box 4606, 624
- 625 Eldoret 30100, Kenya. ⁵Department of Behavioral Sciences, School of
- 626 Medicine, College of Health Science, Moi University College of Health
- Sciences, Eldoret, Kenya. ⁶Purdue University, Purdue University College of 627
- Pharmacy, Purdue-Kenya Partnership, West Lafayette, IN, PO Box 5760, 628
- 629 Eldoret 30100, Kenya. ⁷Department of Preventive Medicine, Keck School of
- 630 Medicine, University of Southern California, Los Angeles, CA, USA. ⁸New York
- 631 University Grossman School of Medicine, 180 Madison Avenue, 8th Floor,
- 632 New York, NY 10016, USA.

Received: 25 April 2019 Accepted: 7 April 2020	633
Published online: 12 May 2020	634

References

635 Roth GA, Johnson C, Abajobir A, Abd-Allah F, Abera SF, Abyu G, et al. 636 1 Global, regional, and National Burden of cardiovascular diseases for 10 637 causes, 1990 to 2015. J Am Coll Cardiol. 2017;70(1):1-25. 638 2 World Health Organization. Global Status Report on Non-Communicable 639 Diseases 2014. Geneva; 2014. p. 302. 640 Jan S, Laba T-L, Essue BM, Gheorghe A, Muhunthan J, Engelgau M, et al. 641 3 Action to address the household economic burden of non-communicable 642 diseases. Lancet. 2018;391(10134):2047-58. 643 World Health Organization, World Economic Forum. From Burden to "Best 644 4 Buys": Reducing the Economic Impact of Non-Communicable Diseases in 645 Low- and Middle-Income Countries. Geneva; 2011. p. 1-12. 646 5. Alleyne G, Binagwaho A, Haines A, Jahan S, Nugent R, Rojhani A, et al. 647 Embedding non-communicable diseases in the post-2015 development 648 agenda. Lancet. 2013;381(9866):566-74. 649 Joseph P, Leong D, McKee M, Anand SS, Schwalm J-D, Teo K, et al. 6 650 651 Reducing the global burden of cardiovascular disease, part 1: the epidemiology and risk factors. Circ Res. 2017;121(6):677-94. 652 7 Leong DP, Joseph PG, McKee M, Anand SS, Teo KK, Schwalm J-D, et al. 653 Reducing the global burden of cardiovascular disease, part 2: prevention 654 and treatment of cardiovascular disease. Circ Res. 2017;121(6):695-710. 655 Kankeu HT, Saksena P, Xu K, Evans DB. The financial burden from non-656 8 communicable diseases in low- and middle-income countries: a literature 657 review. Health Res Policy Syst [Internet]. 2013;11(1):31 Available from: http:// 658 health-policy-systems.biomedcentral.com/articles/10.1186/1478-4505-11-31. 659 Goldberg N. Measuring the impact of microfinance: taking stock of what we 660 know. Grameen Foundation USA; 2005. 661 10 Khandker SR. Microfinance and Poverty: Evidence Using Panel Data 662 from Bangladesh. World Bank Econ Rev Oxford University Press. 2005; 663 19(2):263-86. 664 11. Leatherman S, Metcalfe M, Geissler K, Dunford C. Integrating microfinance 665 and health strategies: examining the evidence to inform policy and 666 practice. Health Policy Plan Oxford University Press. 2012;27(2):85-101. 667 12 Lorenzetti LMJ, Leatherman S, Flax VL. Evaluating the effect of integrated 668 microfinance and health interventions: an updated review of the evidence. 669 670 Health Policy Plan. 2017;26:czw170-25. 13. Ksoll C, Lilleør HB, Lønborg JH, Rasmussen OD. Impact of village savings and 671 loan associations: evidence from a cluster randomized trial. J Dev Econ The 672 673 Authors. 2016;120(C):70-85 Beaman L, Thuysbaert B. Saving for a (Not So) Rainy Day: a Randomized 674 675 Evaluation of Savings Groups in Mali. National Bureau Econ Res. 2014;7:1-43. Karlan D, Savonitto B, Thuysbaert B, Udry C. Impact of savings groups on 676 15. the lives of the poor. Proc Natl Acad Sci U S A. 2017;114(12):3079-84. 677 16. Dupas P, Green S, Keats A, Robinson J. Challenges in Banking the Rural 678 Poor: Evidence from Kenya's Western Province. NBER Work Paper Series. 679 Cambridge: National Bureau of Economic Research; 2012. p. 1-42. Report 680 No.: NBER Working Paper No. 17851. 681 Naanyu V, Vedanthan R, Kamano JH, Rotich JK, Lagat KK, Kiptoo P, et al. 17. 682 Barriers influencing linkage to hypertension Care in Kenya: qualitative 683 analysis from the LARK hypertension study. J Gen Intern Med. 2016;31(3): 684 304-14 685 Dong R, Leung C, Naert M, Naanyu V, Kiptoo P, Matelong W, et al. Abstract 686 18. 15036: Chronic Disease Stigma, Skepticism of the Health System, and Socio-687 Economic Fragility: Factors Impacting Receptiveness to a Non-688 Communicable Disease Intervention in Rural Kenya. Circulation American 689 Heart Association. 2018;138(Suppl_1):A15036. 690 19. Naert M, Leung C, Andama B, Dong R, Edelman D, Horowitz C, et al. 691 692 Addressing perceived corruption, transparency, and stigma: increasing community receptiveness to a non-communicable disease intervention 693 involving microfinance in rural Kenya. Atlanta: American Public Health 694 Association; 2017. 695 Brest P, Roumani N, Bade J. Problem solving, human-centered design, and 696 20. 697 strategic processes. Stanford: Stanford PACS; 2015. p. 1-32. IDEO.org. The Field Guide to Human-Centered Design. 2015. 192 p. 698 21. Hoover C. Human-Centered Design vs. Design-Thinking: How They're 699 22. Different and How to Use Them Together to Create Lasting Change 700 [Internet]; 2018. p. 1-7. [cited 2019 Nov 24]. Movingworlds.org. Available 701 702 from: https://blog.movingworlds.org/human-centered-design-vs-design-

703		thinking-how-theyre-different-and-how-to-use-them-together-to-create-
704 705	23.	lasting-change/. Einterz RM, Kimaiyo S, Mengech HNK, Khwa-Otsyula BO, Esamai F, Quigley F,
706	25.	et al. Responding to the HIV pandemic: the power of an academic medical
707		partnership. Acad Med. 2007;82(8):812–8.
708	24.	Mercer T, Gardner A, Andama B, Chesoli C, Christoffersen-Deb A, Dick J,
709		et al. Leveraging the power of partnerships: spreading the vision for a
710		population health care delivery model in western Kenya. Glob Health. 2018;
711		5:1–11.
712	25.	Vedanthan R, Kamano JH, Lee H, Andama B, Bloomfield GS, Delong AK,
713		et al. Bridging income generation with group integrated care for
714		cardiovascular risk reduction: rationale and design of the BIGPIC study. Am
715 716	26.	Heart J. 2017;188:175–85. Pastakia SD, Manyara SM, Vedanthan R, Kamano JH, Menya D, Andama B,
717	20.	et al. Impact of bridging income generation with group integrated care
718		(BIGPIC) on hypertension and diabetes in rural Western Kenya. J Gen Intern
719		Med. 2017;32(5):540–8.
720	27.	Dong R, Leung C, Naert M, Naanyu V, Kiptoo P, Matelong W, et al. Chronic
721		disease stigma, skepticism of the Health system, and socio-economic
722		fragility: factors impacting receptiveness to a non-communicable disease
723		intervention in rural Kenya. Am Heart Assoc. 2018.
724	28.	Matheson GO, Pacione C, Shultz RK, Klügl M. Leveraging human-centered
725 726		Design in Chronic Disease Prevention. Am J Prev Med Elsevier. 2015;48(4): 472–9.
720	29.	472–9. Nugent R, Bertram MY, Jan S, Niessen LW, Sassi F, Jamison DT, et al.
728	29.	Investing in non-communicable disease prevention and management to
729		advance the sustainable development goals. Lancet. 2018;391(10134):2029–
730		35.
731	30.	Niessen LW, Mohan D, Akuoku JK, Mirelman AJ, Ahmed S, Koehlmoos TP,
732		et al. Tackling socioeconomic inequalities and non-communicable diseases
733		in low-income and middle-income countries under the sustainable
734		development agenda. Lancet. 2018;391(10134):2036–46.
735	31.	, 5 5 1
736 737	32.	School Press; 2004. p. 1–8. Riley L, Guthold R, Cowan M, Savin S, Bhatti L, Armstrong T, et al. The World
738	52.	Health Organization STEPwise approach to noncommunicable disease risk-
739		factor surveillance: methods, challenges, and opportunities. Am J Public
740		Health. 2016;106(1):74–8.
741	33.	Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M.
742		Developing and evaluating complex interventions: the new Medical
743		Research Council guidance. BMJ. 2008;29:a1655–6.
744	34.	Lunze K. Innovative approaches for improving maternal and newborn
745		health - A landscape analysis. BMC Pregnancy Childbirth. 2015;16:1–19.
746	35.	Hirschhorn LR. Learning before leaping: integration of an adaptive study
747 748		design process prior to initiation of BetterBirth, a large-scale randomized controlled trial in Uttar Pradesh, India. Implement Sci. 2015;12:1–9.
749	36.	Mohr DC, Lyon AR, Lattie EG, Reddy M, Schueller SM. Accelerating digital
750	50.	mental Health Research from early design and creation to successful
751		implementation and sustainment. J Med Internet Res. 2017;19(5):e153–16.
752	37.	Marmot M, Friel S, Bell R, Houweling TA, Taylor S, Health OBOTCOSDO.
753		Closing the gap in a generation: health equity through action on the social
754		determinants of health. Lancet Elsevier Ltd. 2008;372(9650):1661-9.
755	38	Bazzano AN Martin L Hicks E Faughnan M Murphy L Human-centred

- Bazzano AN, Martin J, Hicks E, Faughnan M, Murphy L. Human-centred design in global health: a scoping review of applications and contexts.
 Virgili G, editor. PLoS One. 2017;12(11):e0186744–24.
- McLaughlin JE, Wolcott MD, Hubbard D, Umstead K, Rider TR. A qualitative review of the design thinking framework in health professions education.
 BMC Med Educ. 2019;3:1–8.
- 761 40. Deitte LA, Omary RA. The power of design thinking in medical education.
 762 Acad Radiol. 2019 Oct;26(10):1417–20.
- 763 41. Roy MJ, Donaldson C, Baker R, Kerr S. The potential of social enterprise to enhance health and well-being: a model and systematic review. Soc Sci Med Elsevier Ltd. 2014;123(C):182–93.
- Nastasi BK, Varjas K, Schensul SL, Silva KT, Schensul JJ, Ratnayake P. The participatory intervention model: a framework for conceptualizing and promoting intervention acceptability. Sch Psychol Q. 2000;15(2):207–32.

769 Publisher's Note

770 Springer Nature remains neutral with regard to jurisdictional claims in

771 published maps and institutional affiliations.

Ready to submit your research? Choose BMC and benefit from:

2400

- fast, convenient online submission
- thorough peer review by experienced researchers in your field
- rapid publication on acceptance
- support for research data, including large and complex data types
- gold Open Access which fosters wider collaboration and increased citations
- maximum visibility for your research: over 100M website views per year

At BMC, research is always in progress.

Learn more biomedcentral.com/submissions

