GACD PROJECT DETAILS	DESIGN TO IMPLEMENTATION CHANGES	LESSONS LEARNED

Title: SMARThealth India
Setting/Context: Andhra Pradesh, India (LMIC). Rural communities, primary health centres.
Aim: To determine whether a primary healthcare worker led support system will increase the proportion of high-risk individuals achieving BP levels that are recommended in guidelines.
Task Shifting: Primary Healthcare Workers (ASHAs), with support of an m-health decision support tool, were trained to screen and identify hypertension and refer for treatment when required.
Expected Outcome: To determine whether a higher proportion of high risk individuals in the intervention group will achieve optimal BP than in the control group. The process and intervention data indicate that more people with a high risk of CVD in the intervention group are being identified and put on the management pathway.
	Pilot Study: Yes. Pilot study led researchers to make changes to the intervention before it was implemented.
	
	Design to Implementation Changes: Partnership with local Government was sought to ensure regular medications supply.
		Barriers:
		• System Level:
		  ○ Conflicting priorities of health workers
		  ○ Conflict (power play) between health workers and health professionals of different authorities
		• Intervention Level:
		  ○ Hardware and software challenges
		  ○ Creating consensus of work processes
		  ○ Staff turnover
		  ○ Additional responsibility for CHW
		Enablers:
		• Community interest in screening by health workers
		• Acceptability of program by stakeholders
		• Improved CHW status in the community
		• CHW interest in upgrading their skills
		• Usage of technology and availability of instruments near them
		• Remuneration of CHWs
		• Recognition of CHWs at primary health centre (PHC) and visibility to the doctor
		• Ready access to project manager as required.
		Overall Themes:
		• Adequate training of CHWs/NPHWs is critical to the success of the intervention
		• Frequent meetings / interactions between health workers and their supervising clinicians (maybe the researchers as well?) are important.

Title: The LARK Hypertension Study **Setting/Context**: Rural communities surrounding Eldoret, Kenya (LMIC). **Aim:** To develop and evaluate innovative community-based strategies, including mobile technology, to optimize linkage and retention to management of hypertension among individuals with elevated blood pressure. **Task Shifting**: CHWs trained in motivational interviewing and tailored communication, and supported by a mobile based decision support tool, to link patients with hypertension to the health system, follow them up, and encourage compliance with treatment. **Expected Outcomes:** To determine whether CHWs, with specialized training and appropriate decision support tools, will improve linkage and retention rates to control of hypertension compared to the control group.	**Pilot Study:** We did not perform a pilot. We wish we had conducted a pilot as this would have informed us earlier of certain aspects of the strategy that would have needed changing. **Design to Implementation Changes**: Numerous small changes were made on multiple occasions. Initially we planned to engage all community health volunteers (CHVs) and have a common payment to each CHV, within all community units included in the study. However, over time it became clear that only a few CHVs from each community unit were sufficiently motivated and had the commitment to work with us. Yet we had to keep paying the stipend to all CHVs as per initial plans. In addition, due to national and institutional policy, we were unable to pay individual CHVs. Instead, we had to wait until the CHVs formed community-based organizations (CBOs), with payments then being made to the pooled CBO. Within each CBO, the CHVs could then decide on how to share or invest these funds. In theory, this was meant to keep them accountable to each other and get the job done since the CBO would only be paid if they met required pre-specified targets. However, we commonly encountered the "free rider" challenge. The changes had variable success. Some CHVs were committed, but several remained unmotivated and disengaged. We therefore realized that we had to engage the committed ones more deeply. So, we introduced reimbursement for	**Barriers:** • Motivation of CHWs in face of competing obligations and remuneration issues. • Inadequate fidelity to intervention components by CHWs. • Conflicting medical views in participating sites (i.e. Western medicine versus a naturopathic approach) • Group performance-based payments for the community units didn't work well **Enablers:** • Acceptance and trust of the CHWs by the community • Ability of CHWs to provide both logistical and psychosocial support **Overall Themes:** • CHW reimbursement / remuneration can be challenging if there are no standardized practices. In some settings, CHWs normally work on a volunteer basis further complicating their role in interventions that are being evaluated in research projects. • It is often easier to use fewer CHWs who are motivated and interested in participating in a research study than use more who aren't completely supportive. • Frequent communication between members of the research team, investigators, and implementing partners (CHWs, participating communities) are crucial to adapt and make pragmatic changes as required to ensure the success of the intervention.

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	transport and lunch whenever they had to travel to submit reports or attend meetings. We also replaced some CHVs in a few community units. Again, these responses and alterations had variable success.	
Title: Heart Outcomes Prevention and Evaluation (HOPE-4) Study **Setting/Context:** HOPE-4 has been established in 50 rural communities in Colombia and Malaysia. Both countries are classified as lower-middle income countries. **Aim:** To create an evidence-based program for hypertension and CVD risk assessment involving: **(**i) simplified algorithms implemented by NPHW and supported by e-technologies, (ii) initiation of evidence-based cardiovascular medication**,** (iii) support to optimize long term medication and lifestyle adherence. **Task Shifting & Health System**: Malaysia and Columbia both have private and public health care. The public health care systems in both countries are burdened by a surplus of patients and a deficit in healthcare delivery. Both countries have recently seen an increase in government support for the use of NPHWs to address common ailments such as upper respiratory tract infections, other communicable diseases and reproductive health. Using NPHW for detection, management, and follow-up of non-communicable diseases such as hypertension and CVD risk is novel in these countries. **Expected Outcomes:** To determine whether there is a significant reduction (6-points) in Framingham Risk Score from baseline to 12 months between intervention groups and control communities.	**Pilot Study:** No pilot study was conducted. A pilot may have helped identify the challenges in a cluster randomized design, but would not likely have significantly changed our approach. We did do a stepwise approach to recruitment and randomization to address implementation logistics. **Design to Implementation Changes:** The governments of participating countries changed their priorities, and so part way through the study the researchers had to supplement the compensation of the NPHWs. The researchers also adapted who were recruited as NPHWs depending on the local contexts and resources. In Canada, we recruited fire fighters, while in Colombia we used lay health workers who were already being used within the health care system. In Malaysia, the NPHWs were primarily research assistants trained to undertake this role. The researchers believed that the changes made to the intervention resulted in the intervention being more successful.	**Barriers:** • In Malaysia, the national Medical Research and Ethics Committee (MREC) required that PIs at each site (medical officers at participating health clinics) must have a GCP certification. As this is a non-standard requirement for Medical Officers they had to be trained at a special course. • Adaptation of e-technologies (tablet devices with algorithm based decision support) by NPHWs. **Enablers:** • Governmental support regarding use of NPHWs to treat common ailments. • Ability of NPHWs to prescribe medicines • Staggered enrollment of participants gave the coordinating centre time to work through technological issues. **Overall Themes:** • Understanding NPHWs beliefs about an intervention (ideally after training and before implementation) is crucial and can lead to modifications that improve the acceptability and efficacy of the intervention. • Community based interventions require committed participants and insuring interest in ongoing follow-up is important.
Title: The Controlling Hypertension in Rural India (CHIRI) Study **Setting/Context**: Three rural regions in India (LMIC) at different stages of economic/epidemiological transition (early, middle, late). **Aim:** To determine the prevalence, awareness and treatment of hypertension in rural India and utilise the findings to develop and test an intervention to improve control of hypertension. **Task Shifting & Health System**: In the study regions, the state government provides healthcare via the National Health Mission (NHM) including Primary Health Centres (PHCs) and Accredited Social Health Activists (ASHA). One of the goals of NHM is to have an ASHA in every village. ASHAs are women with a minimum of a grade 8 education and are chosen through a rigorous, locally led, selection process. In the task shifting intervention, ASHAs led community-based self-management and education support groups. Tasks shifted to the ASHAs included measurement of BP, education about risk factors for hypertension, lifestyle change, and management of hypertension with an ASHA-doctor team. ASHAs were paid per patient meeting **Expected Outcomes:** To determine whether communities with a registry, to follow up and manage hypertension in patients, would result in greater control of BP than communities without a registry.	**Pilot Study:** The training provided to the ASHAs was piloted with four ASHAs from non-study villages. **Design to Implementation Changes:** Originally, the researchers planned to use a basic record card for patients to keep at home and an individualized approach to management of hypertension. The intervention that was implemented incorporated use of ASHAs to educate people about their hypertension. We also changed to a group-based, rather than individualised, approach to encourage peer support and to minimize the workload for ASHAs. Prior to implementing the ASHA training, study staff and clinicians critically reviewed the materials to ensure the training tools were culturally appropriate and relevant to the communities included in the study. This process led to substantive changes to the materials including changing to the images so that they were more culturally relevant. Piloting the training of ASHAs yielded additional feedback that enabled additional modification and refinement of the materials. ASHAs also provided feedback on the required duration of training, especially the practical aspects, to ensure competence. In one site there were insufficient ASHAs available, and so additional ASHAs were recruited by the researchers prior to implementation. The	**Barriers:** • Convincing the government to fund extra tasks for ASHAs • Overburdening ASHAs with additional tasks (this will be evaluated) • Group-based approach was not acceptable to some participants because it was more time consuming and some had farming duties and household responsibilities. o In one region the intervention coincided with the first rain for many months so participants were engaged in planting their crops while the group meetings occurred. • In one site there were not enough ASHAs in the villages and so the researchers had to recruit and train new ASHAs for the intervention. • Participants attending the group intervention expected to receive antihypertensive medications. Prior to implementation, the study team identified that the supply of antihypertensive medications would be problematic in some regions but it was challenging to address this issue. • Some participants refused to return after the first session because of this unfulfilled expectation. This also led to two ASHAs not attending the last 1-2 meetings as they felt that villagers were disgruntled that they were not provided medications. **Enablers:** • The intervention could be simply applied within the structure of the existing health system. • ASHAs were very enthusiastic and reported that they wanted to learn new skills.

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	researchers also originally intended to conduct the cluster randomized trial in all of the primary sampling units (PSUs) utilised in the baseline survey. However, only a subset of these PSUs were used due to timeline and study constraints.	• Extensively reviewing the training program for NPHWs ensured that it was efficacious, culturally sensitive and relevant. **Overall Themes:** • Group-based approaches to support and care for people with hypertension do reduce the workload for NPHWs, but they may be less convenient and more time consuming for patients. • Group meetings must be scheduled to minimise conflict with seasonal variations in farming workload in rural areas. In certain seasons, it can be much harder to get participants to attend and adhere to the program because of their agricultural duties. • The effectiveness of NPHWs is largely determined by the quality of training they receive. Even though the researchers in this study had to delay implementation and it increased budgetary pressures, results of the ASHA evaluation indicated that the extensive field testing, piloting and reviewing of the NPHW training program led to a highly successful exercise. The researchers recommend a similar approach for any new training program. • Estimating the required number of NPHWs and ensuring their availability for an intervention can be challenging. The researchers recommend overestimating, rather than underestimating, the number of NPHWs required.
Title: Task Shifting and Blood Pressure Control in Ghana: A Cluster-Randomized Controlled Trial (TASSH) **Setting/Context:** This project has been established equally in 32 urban and rural regions in Ghana (LMIC). Ghana has an established CHW program which provides a solid platform to evaluate implementation of the WHO task-shifting strategy. **Aim:** To evaluate the comparative effectiveness of the implementation of the WHO CVD risk package provided by trained community health nurses vs. provision of health insurance coverage on reduction in blood pressure at 12 months. **Task Shifting & Health System**: The intervention, consisting of the WHO CVD risk assessment package, patient education, initiation and management of antihypertensive medications, lifestyle and behavioural counselling, and adherence management, was provided by community health nurses who received extensive training.	**Pilot Study:** It was important to adapt our intervention to the cultural context and ensure that it was well integrated into the current health care system. Piloting the intervention led to the modifications described below. These changes ensured a smooth implementation process and led to increased patient retention. **Design to Implementation Changes:** Initially only one nurse was to be trained at each health centre. However this was modified to two nurses to accommodate instances where one of the nurses was not available for an extended period (maternity leave, educational LOA). In addition, home visits were an important modification that ensured improved retention of patients. Study staff were community members that could visit the houses of patients if they were unable or unwilling to come to the clinic for BP readings.	**Barriers:** • Lack of space to freely operate during TASSH visits. • Participant noncompliance with scheduled study visits especially in the control group in which participants were responsible for seeking care themselves. • Difficulties with nurses maintaining patient documentations (not part of their regular duties) • Loss of contact with participants due to relocation/disconnected phone numbers. **Enablers:** • Piloting the intervention led to a smooth implementation. • Engaging stakeholders (but done after the fact) elicited valuable feedback. **Overall Themes:** • The required NPHW human resources were initially underestimated. Ensuring adequate NPHW capacity reduced the work burden on each one and increased acceptance of the intervention. • Engaging ALL relevant stakeholders (at ALL levels) before implementation of an intervention of this scale is almost universally advantageous. Taking the time to engage stakeholders increases acceptability, efficacy and makes interventions fit better into the existing health system.

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Title: The Nkateko Trial: A clinic-based lay health worker to enhance integrated chronic care. **Setting/Context:** This project has been established in eight rural clinics in the Mpumalanga Province, South Africa (LMIC). **Aim:** To test whether Lay Health Workers (LHWs) would improve management of hypertension in rural clinics in South Africa by undertaking simple tasks and freeing nurses to focus on clinical work. **Health Care System & Task Shifting:** Primary health care centres are overburdened with chronic patients through referral of HIV management and stable chronic patients from central hospitals to regional clinics. **Outcomes**: The intervention was not successful in improving population-level control of blood pressure as defined by the trials primary outcome. The intervention was successfully delivered and improved the day-to-day efficiency of the participating clinics.	**Pilot Study:** Implementation of the pilot began three months before the study began, and continued throughout the implementation period of the main trial. This design in piloting the intervention was helpful as there was continuous learning from the pilot site throughout the implementation phase. It further better prepared the Implementation Manager in anticipating the challenges. **Design to Implementation Changes:** The pragmatic nature of the trial led to slight changes in the way it was implemented. The use of SMS as a method of contact was modified during the study as many community members were elderly and could not read very well.	**Barriers**: • Poorly maintained resources, broken BP machines, • Inconsistent drug supply, • Conflict between LHWs and nurses. • Poorly defined/understood roles and responsibilities for LHWs. • Some LHWs were unable to meet the demands of the work required in the intervention. **Enablers**: • LHWs functioned effectively in clinics with pro-active managers. • Patients and nurses were enthusiastic about the role of LHWs. • LHWs were able to help nurses correctly identify patients with hypertension in some clinics. **Overall Themes**: • Task shifting increased patient compliance with follow-up appointments. • Underestimating the resource requirements and assuming existing health system resources will be adequate can be detrimental to the efficacy of interventions. • Roles and responsibilities of multidisciplinary teams, including NPHWs, need to be defined. All stakeholders need to be engaged prior to implementing task shifting interventions to understand any actual or perceived barriers to task-shifting to NPHWs.
Title: The DREAM-GLOBAL Study **Setting/Context**: Rural and remote indigenous communities in Canada and rural communities in Kilimanjaro region Tanzania (LMIC). **Aim:** To determine whether a multidisciplinary implementation research approach to task-shifting improved control of hypertension. **Task Shifting**: In Canada, community health representatives (NPHWs) and nurses were trained to measure BP using an automated blue tooth enabled device that was linked to a mobile platform that sends SMS messages to the study participants. In Tanzania, task shifting was more complex with CHWs trained to measure BP using the automated blue tooth enabled device in households in their	**Pilot Study:** We performed a BP screening study at each site which served as a pilot to evaluate the ability of the CHWs to accurately measure BP and diagnose HTN in their communities. We did not perform a pilot of the use of the simplified HTN treatment guidelines among Tanzanian health providers. However, the health providers at each site did provide input through recurrent focus groups that guided the simplification of the guidelines and input as to their ease of use and expected challenges in operationalizing the guidelines in their government health centers. **Design to Implementation Changes:**	**Overall Themes:** • Piloting the intervention led to a smooth implementation. • Group-based approaches to support and care reduce workload for NPHW but are not always accepted by patients (less convenient, more time consuming) • Group meetings must be scheduled considering seasonal variations in farming workload in rural areas. In certain seasons, it can be much harder to get participants to attend and adhere to the program because of their agricultural duties. • CHW reimbursement / remuneration can be challenging if there isn't standardized practices. In some settings, CHWs normally work on a volunteer basis further complicating their role in interventions that are being evaluated in research projects. • It is often easier to use fewer CHWs who are invested and interested in participating in a research study than use more who aren't completely supportive and want to

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catchment villages. Task-shifting also took place in the community health centers with nurses and clinical officers receiving training in management of hypertension using a simplified treatment algorithm based on the Tanzanian Standard Treatment Guidelines. **Expected Outcomes:** To determine whether an individual approach to detect hypertension (Canada and Tanzania) with additional NPHWs to providers to implement guideline-based management at community health centers (Tanzania only), improves detection and management of blood pressure.	In Tanzania, the piloting of the Tanzanian standard treatment guideline simplified algorithm (above) led to the determination that a number of other challenges/barriers were in place that would lead to potential failure of the intervention. The guidelines were simplified further based on local availability of anti-hypertensive agents and costs (all drugs on the Tanzanian guidelines are not readily available through the government medical stores department and others that are available at private pharmacies are at significant costs). In Canada, no significant design to implementation changes were made. In Tanzania, we had to implement the more simplified guidelines and substitute anti-hypertensives that were in the same class but more readily available for similar costs. We also introduced an eVoucher (SMS voucher) for subsidized medication to be issued by nurses and delivered to the participant's mobile phone after the trial has been underway for 6 months. The eVoucher will provide an additional (and more sustainable) option for patient's to receive medications at local private pharmacies.	participate to be remunerated but are not invested in the program to improve health of the community. • Task shifting increased patient compliance with follow-up appointments • Underestimating the resource requirements and assuming existing health system resources will be adequate can be detrimental to the efficacy of interventions. • Roles and responsibilities of multidisciplinary teams including NPHWs need to be defined. All stakeholders need to be engaged prior to implementing task shifting interventions to understand any actual or perceived barriers to task-shifting to NPHWs. • Understanding NPHWs beliefs about an intervention (ideally after training and before implementation) is crucial and can lead to modifications that improve the acceptability and efficacy of the intervention. • Community based interventions require committed participants and insuring interest in ongoing follow-up is important.

ASHA, Accredited Social Health Activist; CVD, cardiovascular disease, LMICs, low- to middle-income countries; CHW, Community Health Worker; CHV, Community Health Volunteer; NPHW, non-physician health worker; PHC, Primary Health Centre; CBO, Community-based organisation; MOH, Ministry of Health; LARK, Optimizing linkage and retention to hypertension care in rural Kenya; HOPE, Heart Outcomes Prevention and Evaluation study; CHIRI, Controlling hypertension in rural India; NHM, National Health Mission; PSU, Primary sampling Unit; WHI, World Health Organization; BP, blood pressure; LOA, leave of absence; LHW, Lay Health Worker