

C-QIP EXPERT CONSULTATION MEETING REPORT 19 November 2020

Project Title: Developing and testing Collaborative Quality ImProvement initiative for the secondary prevention of cardiovascular disease in India (C-QIP study)

Funding support:

Fogarty International Centre, National Institutes of Health, USA

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EXECUTIVE SUMMARY

This report is based on a virtual expert consultation meeting that was held on November 19, 2020. This meeting was attended by leading thinkers, cardiologists, physicians, health services researchers, and program implementers from India, US, and Australia with expertise in clinical research, public health, cardiology, mHealth, information systems, and policy. The meeting agenda and deliberations were informed by a scoping review and qualitative interviews with stakeholders (i.e., providers, patients, care givers and health administrators), based on which we proposed an initial list of interventions for cardiovascular quality improvement and conducted a two-round Delphi survey among experts to prioritize the quality improvement (QI) strategies for secondary prevention of cardiovascular diseases in Indian context. With a co-design approach in mind, we invited experts to respond to our proposed list of QI strategies (e.g., electronic health records-decision support system, involving non-physician health workers, and text-messages for healthy lifestyle) as well as a series of questions about their perspectives on how to implement, and sustain QI strategies in the existing clinic flow.

The high-level objectives of this expert meeting were to discuss the formative research results and seek further inputs from the experts and brainstorm on how to contextualize, adapt, implement, and evaluate collaborative QI strategies in secondary prevention of CVD in India. Small groups discussed these points in relation to three thematic areas by answering the following questions: 1) What is the existing evidence base and what gaps need to be addressed before implementation and uptake of C-QIP strategy? 2) What additional resources (e.g., manpower, infrastructure) will be required to take this project idea forward? 3) What are the next steps and actions to bring these aims to fruition?

Together with feedback on this expert consultation meeting report, pre-consultation Delphi survey responses, and discussions risen during the expert meeting will form the basis of a manuscript to be submitted for peer-review in the near future.

BACKGROUND & CONTEXT

Implementation of evidence-based strategies to reduce the growing burden of cardiovascular diseases (CVD) and their co-morbidities is a significant challenge globally, particularly in countries with major resource constraints, like India. Given the increasing rates of CVD, their risk-factors and comorbidities, this situation requires urgent action and novel approaches for their prevention, screening, education, treatment and management^{1,2}. This report is based on a virtual expert consultation meeting that was held on November 19, 2020. This meeting was attended by leading thinkers, program implementers, cardiologists, and researchers from India, US, and Australia with expertise in public health, cardiology, medicine, mHealth systems, and health services research.

There is a need for multiple stakeholders on a common platform (team-based approach) to inform

the development of complex, multi-level interventions such as involving technology, non-physician health workers and text-messages to improve outcomes in patients with cardiovascular diseases (**Figure 1**). Making better use of the co-design framework at each stage of intervention development, implementation, and evaluation is important to ensure that the intervention is increasingly user-centric rather than resource-centric or technology-driven³. It is also essential to integrate available data and utilize it to improve health outcomes.



Figure 1. Team approach to successful project delivery

MEETING OBJECTIVES

The specific objectives of the meeting were:

- 1. To discuss the results of formative research and seek experts' opinions on the components of collaborative quality improvement (C-QIP) intervention in secondary prevention of CVD.
- 2. To locally adapt and contextualize the C-QIP intervention using modified Delphi technique to achieve group consensus.
- To brainstorm how the C-QIP intervention can possibly be integrated into the existing care pathways to manage cardiovascular diseases.

MEETING SUMMARY & LEARNINGS

Due to the COVID-19 pandemic, we conducted a virtual Zoom meeting to discuss the formative research findings and to seek further inputs from experts. The meeting was conducted in 8 sessions (**Appendix I**), and brief summaries and outcomes are presented below:

Session #1: Opening of the meeting and arrangements for the session

Dorairaj Prabhakaran (DP) and Kavita Singh (KS) presented the welcome note and invited selected experts and those who are assisting the program delivery in India to make brief comments on the importance of this project.

Session #2: Introduction to the study and formative research findings

In this session, DP presented the introduction of the study and rationale for Quality Improvement (QI) strategies. His talk focused on the burden of cardiovascular disease (CVD), case-fatality rates, and relationship with use of CVD drugs. He also presented two case studies from India: SPREAD Trial⁴ and

PINNACLE QI registry⁵. Then, KS presented on how to bridge the knowledge-practice gap with the proposed study funded by the US National Institutes of Health, Fogarty International Centre. She briefly discussed the overall goals of the collaborative quality improvement study (C-QIP) in secondary prevention of CVD in India. The specific aims of C-QIP study are:

- 1. To describe *current practices, context, challenges, & opportunities* regarding chronic management of CVDs from patient and provider perspectives in India.
- 2. To assess the *transferability* of components of internationally successful multifaceted QI strategies to the Indian healthcare context.
- 3. To conduct a *pilot study* to assess the acceptability, feasibility, and fidelity of intervention in patients attending out-patient clinics in India.
- 4. Compared with usual care, to evaluate the *effect* of C-QIP intervention on processes of care and clinical outcomes, health-related quality of life, and costs and cost effectiveness at 1 year among CVD patients attending outpatient clinics in India.

KS then presented formative research results, which included: 1) a scoping review of 456 studies evaluating 186 interventions, 2) qualitative interviews with 71 key stakeholders (providers, patients, caregivers and health administrators), and 3) modified Delphi survey among experts. The following comments and questions were put by the experts (**Appendix II**).

- Daljit Singh Sethi (Hope Clinic, Assam): "For a long time we are teaching that diabetes is a cardiovascular disease equivalent. So, when we chart out a study as important as this study, I was just wondering that if you consider the presence of diabetes also as one of the components?"
- Rajeev Gupta (Eternal Hospital, Jaipur): "Is there effort to determine the cost-effectiveness of the whole exercise?"
- David Peiris (George Institute for Global Health, Sydney): "In scoping review, could you comment on the effect sizes of the various intervention strategies and any variability between intervention types or additive effects on multiple components?"
- Mohit Gupta (GB Pant Hospital, New Delhi): "From the Indian perspective, given the heterogeneity in the healthcare system that we are dealing with, there are very huge differences and huge gaps in care. So, it will be very pertinent to see that how we are using these quality improvement systems to apply in different settings?"
- Salim Virani (Baylor College of Medicine, Houston, Texas): "What percent of clinics in India actually have an EMR (electronic medical records), where decision support can be implemented?"

Response/Action plan:

- Diabetes as comorbidity as inclusion criteria for the study participants: Patients with established CVD and comorbid diabetes mellitus will be eligible to participate in this study, but not with diabetes alone.
- Effort to determine the cost-effectiveness: Yes, we will collect detailed costs from the patient, provider, and societal perspectives to perform a cost-effectiveness analysis at the trial end. In addition, overall costs to develop and deliver the intervention will also be reported.
- Scoping review: We have looked at the range of effect size for each of the interventions identified in this review and have not performed a meta-analysis at this stage because of the wide heterogeneity in terms of target patient population, intervention components, outcome measures, and measurement tools/scales used in the primary studies.

- Heterogeneity in the Indian healthcare system: Through this project by the introduction of an electronic health records-decision support system, we attempt to standardize and improve the care delivery systems across a range of hospitals in India. The C-QIP project will evaluate how contextual factors influence implementation and effectiveness across different sites.
- EMR status in India: India has a mixed system of healthcare consisting of a large number of hospitals run by the Central Government and State Government as well as the private sector. In general, the level of use of ICT (information communication technology) in the healthcare sector in India has been lower when compared to other countries. However, both central and state governments are working on several fronts to make use of the opportunities offered by ICT. Private sector hospitals are also in the process of implementing ICT projects, including EMR. Corporate hospitals in India, such as Max Health, Apollo, Sankara Nethralaya, and Fortis have implemented integrated ICT systems in place, covering all aspects--i.e., registration and billing as well as laboratory and clinical data.

Session #3: Collaborative quality improvement intervention for CVDs

Nikhil Tandon (NT) presented on the collaborative care model concept and framework and on the decade-long experience of developing and evaluating task-shifting and technology interventions for chronic conditions⁶⁻¹⁰. KS then presented how C-QIP study is different and/or similar to our team's prior work. Following comments or suggestions were made by the experts:

• Daljit Singh Sethi: His team has been using the EHR for the last 28 years. Initially the system was just storing medical records, but for the last 5 years they were using this as commercially developed record which talks to the patient. He said, "There is no doubt that EHR is really effective and particularly in rural areas EHR has made a difference". But he suggested to consider something like a hybrid model (EHR along with a non-physician health worker) as otherwise there could be language problem/ problem in explanation due to physician time constraints as not all patients are literate. So, it is important to have a person (equivalent to a community health worker) which is selected from the village to facilitate the use of EHR-DSS.

Response/Action plan: The concern around language barrier in this C-QIP study will be overcome by having a non-physician health worker who will be well versed in the local colloquial language to facilitate care for patients and to support patients for self-management.

Session #4: Breakout session on electronic health records

Session #5: Breakout session on non-physician health workers

Session #6: Breakout session on text messages

We conducted three parallel breakout sessions focused on:

- 1) Electronic health records and clinical decision-support system (EHR-DSS) to prompt physicians to adjust patient management plans to reach clinical targets and to store patient health records (e.g., labs, prescriptions)
- 2) Trained and supervised non-physician health workers (NPHWs) who facilitate care, perform follow-ups, including home visits, and empower patients for self-care
- 3) **Text messages** for lifestyle changes and follow-up visits to remind patients about lifestyle changes, clinic visit or lab appointments

In each breakout session, we presented with the evidence from scoping review on EHR-DSS, NPHWs, text messages, and key informants' views (positive/negative). At the end of the breakout sessions, we conducted an online Delphi survey to rate the strategy on a scale of 1-5 (1=high priority, 5=low priority) across 3 domains:

- Priority
- Relative advantage
- Implementation feasibility (technical complexity, resource requirement, reach, acceptability)

Session #7: Feedback from breakout sessions

EHR/DSS

- Experts suggested that we may need to consider whether the treatment algorithm or DSS will have a focus on acute patients versus those with stable conditions like stable heart failure patient's or recently hospitalized patients.
- Whether DSS will address the multi-morbidity or other co-morbid conditions, but we agreed that the EHR-DSS will not be like "one-size-fits-all" approach for all patients with CVD. The DSS needs to be tailored based on patients' primary diagnosis.
- Experts suggested that we need to focus on each co-morbid condition but not underestimate the key focus on atherosclerotic cardiovascular disease.
- We need to consider drug interactions, different doses, and dose tolerability of these dosages for different patients.
- Based on prior experience, providers will have flexibility and can override the DSS prompt.
 Providers can either accept or reject suggestions, and they can choose based on the patient condition and adherence.
- System which we can develop will need to be interoperable. Currently we do have a DSS which
 is Android based.
- It would be nice to lay out a plan for the lifestyle advice intensity, frequency etc.
- DP informed that our current mPower heart system¹⁰ is based on AI (artificial intelligence) / machine learning and already has 2,500 cases incorporated in the DSS algorithm.
- Usual care how this would look like; will the control group receive audit and feedback reports against the benchmark?

Response/Action plan: EHR-DSS will be applicable for stable CVD patients (i.e., not acute phase or in-hospitalization) who are seeking routine care at the out-patient clinic visit. CVD treatment algorithm will be based on most recent treatment guidelines and will provide specific recommendations for the care providers to manage coronary heart disease, stroke, and heart failure. Currently, the EHR-DSS will be able to manage only cardiovascular risk factors (blood pressure, glucose, and cholesterol) and will not provide specific treatment recommendations for other comorbidities. The EHR-DSS system will be adaptable as the providers will have the rights to override any DSS-based treatment recommendations (physicians can either accept or reject the DSS prompts, in case of rejection the system will ask the physician to provide a reason for rejecting the DSS prompt). Lastly, DSS developed in this study will be interoperable as it will be a standalone program having capabilities to be integrated with other existing EHRs at the hospital level.

NPHWs

• NPHW qualification is minimum 10th (secondary school) pass or graduate in any life sciences or related field.

- Fluent in the local language so that there will be no communication barriers between the health worker and patients.
- Team based care involving doctors, NPHWs, and patients would be crucial because trust among the team members is paramount for success.
- We have to clearly define the duties (roles and responsibilities) of NPHWs.
- There should be ongoing training and performance monitoring of NPHWs.
- Experts say that initially there could be 10-15 patients per day assigned to 1 NPHW but this can increase, when they get enough experience.
- Regarding patient follow ups, experts said that it entirely depends upon patients' diagnoses, as
 well as the situation for some conditions. They said the follow up would be required frequently
 but for stable patients it might be once a month or once in two months.
- Experts pegged the salary of NPHWs around INR 20-25K per month.

Response/Action plan: Above recommendations will be incorporated as we further develop the training manual for the NPHW to facilitate care for patients with CVD.

Text messages

- Experts suggested that the text messages should be related to the next clinical visit and lab test
 appointments, and for self-care management. Medication adherence and health behavior
 changes related text-messages were considered more important than other domains.
- One expert suggested having an app where users can modify text-message frequency.
- Text-messages should be in patient's local languages.
- Experts suggested that, in addition to text messages, we can also use voice messages as an option to be part of our intervention.
- Virtual coach can also be considered in places where NPHW calls are not possible.

Response/Action plan: Above recommendations will be incorporated as we further develop the template for text-messages. Text-messages will be made available in local languages —Hindi and Kannada, for the selected study sites —Delhi and Karnataka, respectively. We will also explore the possibility of having a virtual coach (voice messages), which might be particularly useful for patient who are uneducated.

Key attributes of a technologyenabled, NPHW-facilitated health care that are relevant across all domains and apply to all stakeholder groups are presented in this Figure 2. While it is important to focus on semantic interoperability, standards and large-scale implementation, access to data and so-called 'smart algorithms' are not sufficient to effect sustained change to practice. Paying close attention to

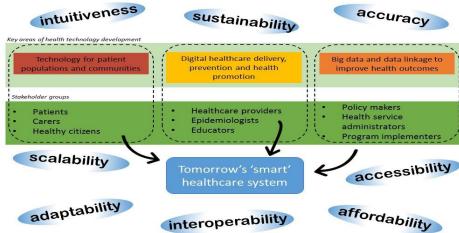


Figure 2. Key attributes of technology-enabled intervention

contextual, environmental, and behavioral factors is important to support the human angle, which is essential to high quality, proactive, and person-centered healthcare.

Session #8: Intervention flow and integration into the existing clinic flow

KS presented on how important it is to understand contextualization and integration of C-QIP strategy within the existing clinic flow. Further, she talked about the proposed C-QIP trial design and study flow. Then, 4 site investigators were invited to share their experiences and views on how the proposed C-QIP strategy can be adapted and integrated into the existing clinic flow:

1. All India Institute of Medical Sciences, New Delhi (Ambuj Roy)

- Currently, the project will be only implemented in the research mode and it has to be under supervision, and we will go by the protocols that will be implemented.
- Depending on what the results are, we can think of larger scale implementation but
 essentially these will be designed for outpatient tertiary care management of patients as
 most of these centres will have patients with multimorbidity and other issues where it may
 be challenging. To put it in place we have to implement the QI strategy as a part of project
 right now and see how it goes. Putting it in the tertiary care centre will be challenging, we
 have to work with the leadership, and consider its acceptability, feasibility and fidelity
 among various stakeholders.

2. G.B. Pant Hospital, New Delhi (Mohit Gupta and Girish MP)

- We are very excited to get started. The biggest challenge is the right selection of the
 patient and their attendant. We need patients who are concerned, motivated, have trust,
 are willing to follow up with us, and have reasonable understanding and knowledge of textmessaging and its interpretation.
- We have to respect patients' preferences because each patient's demands are different. We have to coordinate and integrate care within our own healthcare system, so we have to take our own staff into confidence, which is very important.
- Information and education of the patient about drugs and lifestyle measures are important aspects of self-management. Further, providing both emotional and physical comfort to patients should be an integral part of our system.
- Involvement of friends and family is important (i.e., care-giver involvement in patient education and self-care management).
- Since each patient requires different care, things will have to be customized. We can have simple, basic or some kind of 5-point application design for all patients: 1) what is the diagnosis, 2) when should the text-message be delivered to the patient, 3) where is the pharmacy located, 4) what are the requirements for the next clinic visit, 5) when is the next blood test or follow up scheduled.
- We can consider zoom calling feature in case the patient needs a drug dose adjustment, this would save time for the patient as well as for the doctor.

Response/Action plan: We will consider these comments and suggestions to finalize the intervention components.

3. Sir Ganga Ram Hospital, New Delhi (Kushal Madan)

- With this type of study, we cannot anticipate the problems at prior, but we have to take the problems the way they come and deal with them.
- Some questions or concerns were raised, for example, the kind of patients we get in our hospital, can we give them an opportunity to choose what kind of strategy they want? Like whether they want text messages or NPHW related services?
- As there is already an EHR system in the hospital, how will the C-QIP study's EHR-DSS be integrated into the existing EHR?

• For NPHWs, the important step is that we have to define the duties, level of qualification and awareness of hospital setting.

Response/Action plan: DP advised that in a research study or a clinical trial we would need to provide standardized treatment plan or intervention strategy to all patients who consent to participate in this study. We cannot provide an option to the patient to choose what features of the multicomponent strategy they want to opt for. Regarding the frequency of text messages or frequency of follow-up contacts by the NPHW can be customized as per the patient's preference. Participant information sheet will provide details on the intervention strategy and after the participant provides written informed consent, they will be registered in this study. Re: existing EHR at the hospital site: For this project we will have a separate study eCRFs, which will constitute as EHR while, DSS will be connected with the study eCRFs. In the future, if found to be successful, DSS will be a separate feature which can be linked with the existing EHR available at the site. We agree with the comments of the site investigator on the NPHW role and responsibilities. Research coordinating centre based at the Public Health Foundation of India will develop a training module for NPHWs which will guide them on how to perform their duties.

4. SDM Hospital, Dharwad (Kiran Aithal, Sathish Patil, Vithal Khoday)

- If we only enrol patients who are interested in the trial, then it may lead to a selection bias.
- Once the patient comes into the clinic and gets registered, then probably he/she may be offered to go to the NPHW, and then the patient can be directed to the physician (referring to the intervention flow at the clinic level).
- If we plan to give some patient education materials, then it can be distributed when the patient is waiting to consult the physician.

Response/Action plan: We would need to recruit willing participants to first understand whether feasibility and fidelity of proposed C-QIP. Further, we will use qualitative research to describe facilitators, barriers, and context, and to understand variability in feasibility and fidelity. Without having a clearer understanding of feasibility and fidelity of C-QIP strategy—including adaptations need to be made—it will not be useful to scale-up more broadly. We agree with the investigator's other comments. Further operational aspects of the intervention delivery will be customized in view of the local setting and available resources.

Session #9: Wrap-up session

In this session, we opened for further questions, comments, or suggestions from experts. **Daljit Singh Sethi** shared his experience on using the EHR. He said that with the EHR, he is currently managing records of 40,000 patients who are from remote areas. At the time of registration, patients selected options for various services offered, as per their preferences. For example, if the patient opted for the option SMS or emails, then they would receive only those. He further emphasized about privacy issues in using EHRs and how we must have robust systems to protect privacy of patients and confidentiality of medical reports. He further advised that EHR encryption should be explored while designing, in order to avoid its misuse.

Session #10: Study timelines, and next activities

The overall study timeline is presented in **Figure 3**. The project is well-positioned to be delivered over 5 years in 2 phases: <u>Phase 1</u> intervention development for 18 months and <u>Phase 2</u> evaluation (randomized trial) for 36 months. The last 6 months is earmarked for data analysis, reporting, and dissemination of study findings.

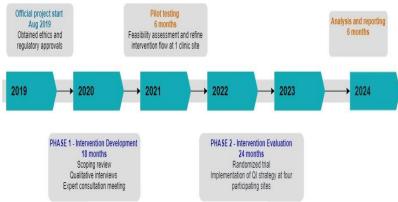


Figure 3. Study timelines

CONCLUSIONS

This first expert consultation meeting as part of the C-QIP study funded by the US National Institutes of Health involving 32 experts from different institutions across India, US, and Australia was a successful first step in developing new collaborations and engaging experts to inform the development of a collaborative QI strategy in secondary prevention of cardiovascular diseases in India. Important gains were made in understanding challenges that affect the cardiovascular health of Indians, as well as areas where the new proposed C-QIP study will help bridge the knowledge-practice gap for patients with CVD.

Key achievements of this expert consultation meeting were:

- Identification of how different technologies and task-sharing strategies are already being developed and researched for widespread use in cardiovascular risk reduction and CVD management in India.
- Identification of key evidence-practice gaps in this field and how these myriad factors can be addressed as part of the proposed C-QIP study
- Recognition of the importance of using a robust co-design approach and in-depth stakeholder engagement at all stages of program development and implementation.
- Identification of key attributes of a "collaborative quality improvement" strategy consisting of
 electronic health records-decision support system (EHR-DSS), NPHWs, and text messagesbased reminders for medication adherence and healthy lifestyle.
- Brainstorming how the C-QIP strategy can be adapted and integrated into the existing clinic flow at the 4 participating sites in India.

The final, take-away message from this expert meeting was that there is great enthusiasm to develop meaningful, productive, and long-term sustainable QI strategies to improve CVD patients' outcomes so that there are real societal benefits beyond the research and development phases. However, this will only be possible with a truly collaborative approach to research, development, funding, stakeholder engagement, and scale-up of proven strategies within India, and beyond.

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APPENDIX I: MEETING AGENDA

S.No.	Time	Session title	Speaker/Moderator
1.	2.30 – 2.45 pm	Opening of the meeting and arrangements for the	Kavita Singh
		session (15 mins)	
2.	2.45 – 3.00 pm	Introduction to the background, objectives, and expected	D. Prabhakaran/
		outcomes of the expert consultation meeting (15 mins)	Kavita Singh
3.	3.00 – 3.15 pm	Collaborative quality improvement intervention for the	Nikhil Tandon/
		purpose of chronic care of cardiovascular disease	Kavita Singh
		(15 mins)	
4.	3.15 – 3.45 pm	BREAK OUT SESSION 1: (30 mins)	Chair: D. Prabhakaran
		Role of electronic health records and decision-support	Facilitator: Kavita
		systems for providers	
5.	3.15 – 3.45 pm	BREAK OUT SESSION 2: (30 mins)	Chair: Nikhil Tandon
		Role of non-physician health workers to facilitate care for	Facilitator: Nikhil SV
		patients with cardiovascular disease	
6.	3.15 – 3.45 pm	BREAK OUT SESSION 3: (30 mins)	Chair: VS Ajay
		Adoption of text-messages for health lifestyle in patients	Facilitator: Dev Jindal
		with cardiovascular disease	
7.	3.45 – 4.00 pm	Reporting back to the main meeting	
		Feedback from break-out session 1 (5 mins)	
		Feedback from break-out session 2 (5 mins)	
		Feedback from break-out session 3 (5 mins)	
8.	4.00 – 4.30 pm	C-QIP Intervention flow and how it can be integrated	Kavita Singh
		within the existing care pathways (30 mins)	
		Procedural and institutional aspects	
		Infrastructure and resource requirements	
		Technical complexity	
		Cultural acceptability	
9.	4.30 – 4.45	Q&A, wrap up (15 mins)	D. Prabhakaran
10.	4.45 – 4.50	Vote of thanks and concluding remarks (5 mins)	Kavita Singh

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MEETING PHOTOS

