Perspective

The ORNATE India project: Building research capacity and capability to tackle the burden of diabetic retinopathy-related blindness in India

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The ORNATE India project is an interdisciplinary, multifaceted United Kingdom (UK)–India collaborative study aimed to build research capacity and capability in India and the UK to tackle the burden of diabetes-related visual impairment. For 51 months (October 2017–December 2021), this project built collaboration between six institutions in the UK and seven in India, including the Government of Kerala. Diabetic retinopathy (DR) screening models were evaluated in the public system in Kerala. An epidemiological study of diabetes and its complications was conducted through 20 centers across India covering 10 states and one union territory. The statistical analysis is not yet complete. In the UK, risk models for diabetes and its complications and artificial intelligence-aided tools are being developed. These were complemented by joint studies on various aspects of diabetes between collaborators in the UK and India. This interdisciplinary team enabled increased capability in several workstreams, resulting in an increased number of publications, development of cost-effective risk models, algorithms for risk-based screening, and policy for state-wide implementation of sustainable DR screening and treatment programs in primary care in Kerala. The increase in research capacity included multiple disciplines from field workers, administrators, project managers, project leads, screeners, graders, optometrists, nurses, general practitioners, and research associates in various disciplines. Cross-fertilization of these disciplines enabled the development of several collaborations external to this project. This collaborative project has made a significant impact on research capacity development in both India and the UK.

Key words: Building research capacity, diabetic retinopathy, ORNATE-India project

The Global Challenges Research Fund (GCRF) was set up by the UK Government in 2015 to address complex global development challenges and support collaborative research that will improve the economic prosperity, welfare, and quality of life of people in low and middle-income countries (LMICs). The ORNATE India project, funded by GCRF and United Kingdom Research and Innovation (UKRI) in 2017, is a UK–India collaboration to build research capacity and capability to tackle the burden of diabetes-related visual impairment.[1] Six institutions in the UK and seven in India collaborated on this project, including the Government of Kerala.

Locally led health research in LMICs is critical for overcoming global health challenges. Sufficient research capacity in LMICs is essential to build a local evidence-based healthcare policy and improve the health of the population.[2] The UK Department of Health defines research capacity building as "a process of individual and institutional development which leads to higher levels of skills and greater ability to perform useful research."[3] Central to capacity building at the individual level is the training and mentoring of the investigators to ask the locally relevant research questions, design and conduct research, create or adapt research tools that address the research questions, and build collaborations with and outside the institutions, both nationally and internationally. An additional requirement is to train the investigators to work with the policy and program implementers for both bedside and community practice. Capacity building is vital at an institutional level to create new knowledge, enhance career opportunities for young investigators, and infrastructure development. A good research environment also needs the required processes and people for seamless grants management personnel, data management,

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financial management, procurement policies, and appropriate research governance.

The Enhancing Support for Strengthening Capacity and Effectiveness of National Capacity Efforts (ESSENCE) on Health Research initiative released a good practice document for capacity strengthening in LMICs with the following seven guiding principles:[4]

1. Network, collaborate, communicate, and share experiences
2. Understand the local context and accurately evaluate existing research capacity
3. Ensure local ownership and secure active support
4. Build in monitoring, evaluation, and learning from the start
5. Establish robust research governance and support structures, and promote effective leadership
6. Embed strong support, supervision, and mentorship structures
7. Think long-term, be flexible, and plan for continuity.

ORNATE India designed five work packages and used diverse approaches to build research capacity and capability, both in the UK and India. It broadly covered a multistate epidemiological investigation in India to study the prevalence of pre-diabetes, diabetes, and diabetic retinopathy (DR), diagnostic accuracy studies of laboratory and nonlaboratory tools to detect diabetes and its complications, process evaluation, and health economic assessment of a new DR care pathway in the public health system. The innovative approaches included artificial intelligence to grade retinal images, circulating biomarkers to predict DR and sensor to detect biomarkers in blood, predictive risk modeling studies, and developing research networks to support global translation. In addition, the project focused on developing population scientists and statisticians, health economics, public health, and computer scientists to use various UK and India datasets to answer research questions, especially risk models that can be applied globally.

Here we describe the capacity-building activities for two studies, namely the SMART-India study and the Nayanamritham study, undertaken in India to address the increasing burden of blindness due to DR so that it can be used as an example for translation to other LMICs.

Methods

ORNATE India embedded the abovementioned principles of the ESSENCE framework[4] to guide capacity building in this collaborative project between India and the UK. The governance structure was organized as an equal partnership, with joint leadership and joint development of study protocols, standard operating procedures, and publications. The local investigators from India were engaged in the design and conduct of all aspects of the studies done in India. A formal research collaboration agreement was signed by all collaborating institutions in the UK and India; it included the roles and responsibilities of each collaborator and an agreement for sharing any intellectual property. A set of measurable, feasible, and comprehensive indicators was developed to capture the complexities and evaluate the research capacity-building activities.

SMART-India study

The SMART-India (Translating research into clinical and community practice: a multicenter Statistical and economical Modelling of risk-based strAtified and peRsonalized screening for complications of diabetes in India) study is a cross-sectional community-based house-to-house study across 20 sites in India to provide data on the prevalence of diabetes, DR, and other complications of diabetes, as well as develop practical and affordable models to (a) diagnose people with diabetes and pre-diabetes and (b) identify those at risk of diabetes complications so that these models can be applied to the population in LMICs where laboratory tests are unaffordable.[5] The study sample covered urban and rural populations in different geographical regions (North, South, East, and West) and included 10 states and one union territory. Fig. 1 shows the 20 sites that participated in the SMART-India study.

Protocol. The study protocol was developed after a brainstorming session in Chennai, India, between UK and India co-applicants and collaborators. Study sites were confirmed for each region, and the principal investigator (PI) of each study site was trained to provide local leadership. The group also developed all the study documents, including the survey questionnaire. A project manager was appointed to coordinate the study. The study was approved by the Indian Council of Medical Research (ICMR)/Ministry of Health and Family Welfare Screening Committee and Institutional Ethics Committees of all the 20 participating institutions. The study obtained informed written consent from all participants and adhered to the tenets of the Declaration of Helsinki on human research. The methodology for the SMART-India study has already been published.[5]

Field workers conducted house-to-house surveys. They were trained in the SMART-India study protocol, filling and filing (cloud-based) of participant information sheets, data collection and entry into the cloud-based database, point-of-care blood tests (random blood glucose, HbA1c, and lipids), urine microalbuminuria, blood pressure, anthropometric measurements, vision test, and obtaining good quality retinal images using a nonmydriatic hand-held-based retinal camera (Zeiss Visuscout 100™). A teleophthalmology system was set up whereby the images captured by each fieldworker were uploaded to a cloud-based database.

Once recruited into the study, each participant was given a unique study identification number. The quality of the collected data was monitored by a data manager (UK), with queries sent to the field workers for addressing on a regular basis. In addition, virtual training was provided to the field workers if and when required.

Anonymized retinal images were graded by retinal graders optometrists and ophthalmologists (primary graders) at the local clinical center, as well as transferred to four central reading centers, where grading was done by a second ophthalmologist (secondary grader). A senior retinal consultant arbitrated in case of any discrepancies between primary and secondary graders. These graders were trained using study-specific standard operating procedures by using the International Clinical Classification of DR severity scale.[6] In the entire process, patient confidentiality was mainlined.

Center administrators were appointed, one for each study site, and were trained in the study protocol and study database at a 2-day workshop held in Chennai, India. They were responsible for setting up and maintaining the study master file and the study logistics, such as a seamless supply of point of care kits to the 20 sites, ensuring completion of retinal image grading, informing participants of the outcome of the retinal grading, and coordinating with the participants who were referred for sight-threatening DR (STDR) and other findings requiring referral. In addition to the initial training, three additional online training sessions were provided for the center administrators by the data manager and project manager.

The Nayanamritham study

The Nayanamritham study aimed to implement a pilot DR care pathway in the public system in the
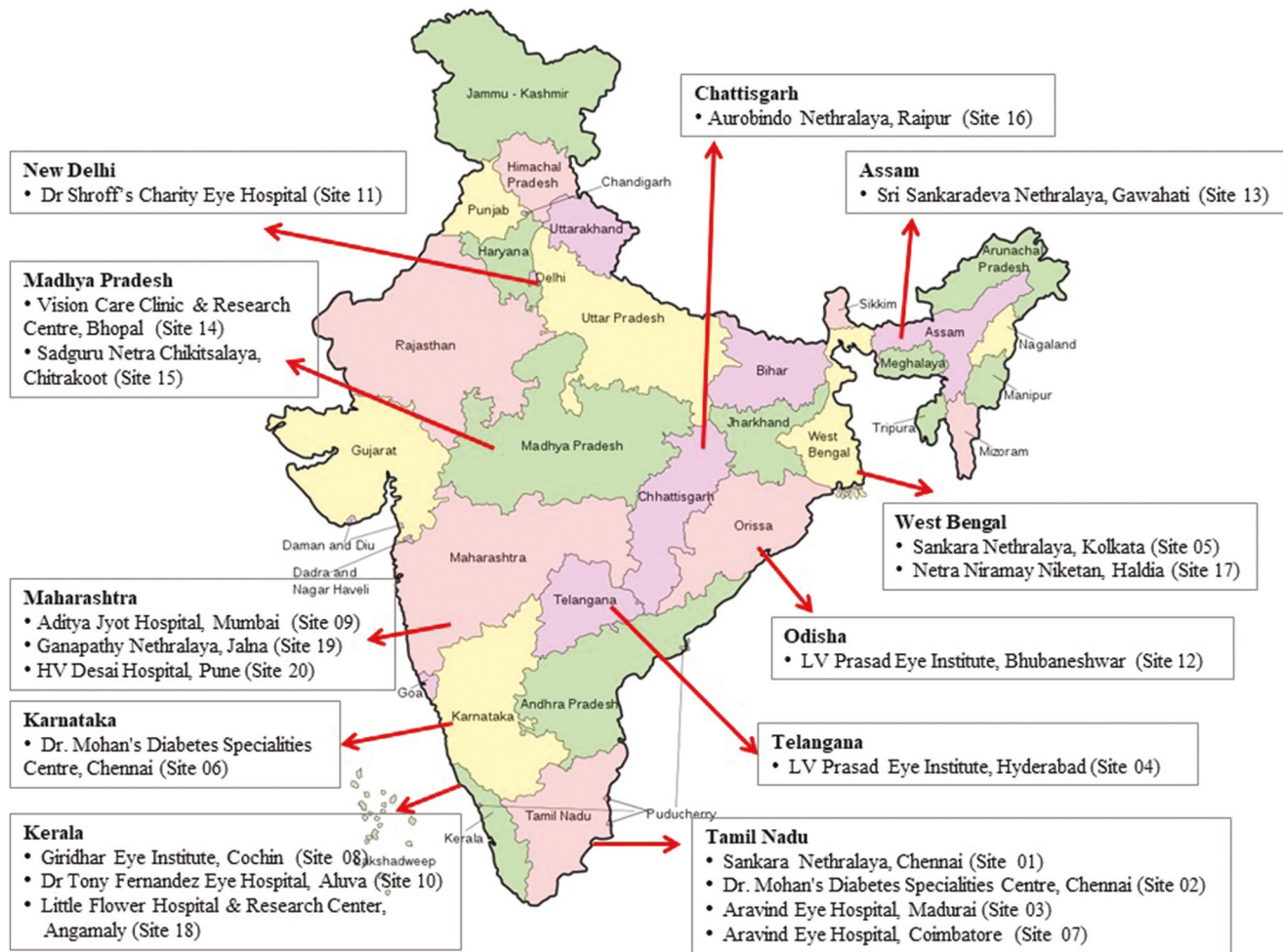
Figure 1: The 20 sites across India that participated in the SMART India study. Reproduced from S. Sivaprasad *et al.*, Protocol on a multicentre statistical and economic modelling study of risk-based stratified and personalised screening for diabetes and its complications in India (SMART India), BMJ Open 2020;10:e039657.[5] Permitted under https://creativecommons.org/licenses/by/4.0/

Thiruvananthapuram district in Kerala. It involved screening for DR in 16 family health centers (FHCs) (primary care), management of referred patients at four secondary care centers (district hospitals), and one tertiary care center at the Regional Institute of Ophthalmology (RIO).[7] The study protocol was developed by the Health Secretary in Kerala, noncommunicable disease (NCD) lead in Directorate of Health Services, other health and medical education service providers, technical and eHealth teams, local authorities, and the GCRF/UKRI-funded co-applicants from the UK. A project manager was appointed to manage the program under the supervision of the NCD lead. Capacity and capability building was initiated to implement DR screening in the FHCs, grading images at the reading center at RIO, and treatment for DR at secondary care. The Nayanamritham study was approved by the Indian Council of Medical Research (ICMR, Ref:2018-0551) and the RIO, Thiruvananthapuram. The study obtained informed written consent from all participants and adhered to the tenets of the Declaration of Helsinki on human research.

Project management: The collaborative team developed study protocols; patient information sheets and consent forms; study data collection forms; qualitative interview training, monitoring, and evaluation; and a monthly reporting system.

Smartphone-based retinal cameras (Remidio Innovative Solutions, Bengaluru, India) were procured for the 16 FHCs and RIO. The general physicians and nurses at the FHCs received training in diabetes and management of DR, developed by the University of East London; the university certified the successful candidates. Generalist nurses at the FHCs were trained to obtain good quality retinal images. Further training was imparted to the nurses who could not capture good quality retinal images.

Data-entry operators were employed (initially, the nurses were considered but changed to ease their burden) and trained on the different aspects of data collection and entry. The collected data included demographics, education, personal lifestyle (smoking, alcohol, and physical activity), family history, blood pressure, body mass index, and waist circumference.

Referral System: Patients identified with STDR were referred to four district hospitals. Laser equipment was purchased for each hospital, and the ophthalmologists were trained in laser surgery at RIO. More complex cases of DR were treated at the tertiary care center (RIO). All these events were duly captured.

Accredited social health activists (ASHAs) were trained in groups of 50–100 on diabetic eye disease and the need to treat vision-threatening complications to increase public awareness and encourage patients to participate in the DR screening

Table 1: Capacity/Capability building for the SMART-India study

SMART-India study set-up	
Study protocol developed collaboratively	
Ethics approval obtained from ethics review committees at each institution and ICMR	
Project manager appointed	
The study-based questionnaire developed and tested	
Cloud-based database for data entry and uploading of retinal images developed and tested	
Patient information sheets and patient informed consent forms prepared and translated into local languages	
Master file prepared for each site	
Hand-held retinal cameras (Zeiss Visuscout 100™) purchased and distributed to 20 sites for DR screening	
Point-of-care kits (e.g., HbA1c and lipids) and equipment (e.g., blood pressure monitors) bought and distributed to 20 sites	
Twenty tablets for data entry bought and distributed to field workers	
Set up of 4 main reading centers to grade retinal images	
Staff training for SMART-India study	**Numbers trained**
Principal investigators trained in the study protocol and database application	24
Field workers trained in the study protocol and database application	70
Center administrators trained in the study protocol and database application	42
Primary graders, secondary graders, and arbitration graders trained to access retinal images and report findings using the database application	35

program, in addition to promoting primary prevention of diabetes.

A comprehensive monitoring evaluation and learning framework with key outcome indicators were used to evaluate the effectiveness of the research capacity-building activities in the SMART-India and Nayanamritham studies.

Results

SMART-India study

The capacity and capability building under this study included procurement of hand-held retinal cameras, point-of-care kits and equipment, the establishment of retina image reading-grading centers, and training of healthcare personnel [Table 1]. Preliminary results show that 57,808 participants were recruited to the study, of which 22% had diabetes, based on HbA1c ≥ 6.5%. The retinal images of 12,832 participants with diabetes were sent for grading, of which 324 individuals (2.5%) were referred for STDR treatment. The study data analysis is ongoing.

A field worker capturing a retinal image from a participant in the SMART-India study using hand-held smartphone-based nonmydriatic retinal cameras (Zeiss Visuscout 100™) [Fig. 2].

Training field workers to conduct telephone surveys and conduct qualitative research

Recruitment to SMART-India study was discontinued in March 2020 due to the COVID-19 pandemic, and a questionnaire-based survey to evaluate the impact of COVID-19 lockdown on health and provision of healthcare services on participants in SMART-India was undertaken.[8] The collaborators developed the questionnaire and translated it into seven languages to address the non-English-speaking population. A total of 41 fieldworkers from the 20 centers in the SMART-India study received four online training sessions in the survey questionnaire, obtaining consent from participants and data entry into the cloud-based database explicitly developed for this study.

In addition, a qualitative study was undertaken to understand the barriers and enablers to access treatment for STDR for those identified with this condition in the SMART-India study. Ten field workers involved in the SMART-India study undertook a five-day online training

Figure 2: A field worker capturing a retinal image from a participant in the SMART-India study using a hand-held smartphone-based nonmydriatic retinal cameras (Zeiss Visuscout 100™)

in qualitative research techniques in collaboration with an NGO (Samarth). Additional online training was provided with the project manager and data manager in the UK for conducting in-depth interviews with patients who accessed and did not access treatment for STDR, as well as with health care professionals providing the treatments in eye hospitals.

India retinal disease study group

The ophthalmologists from across 20 clinical sites in the SMART-India study set up the India Retinal Disease Study Group to drive high-quality research to answer relevant questions related to diabetes and its complications in India. This group is working together with more clinical researchers to analyze several retrospective and longitudinal studies in diabetes and diabetic-related eye diseases. The model was driven mainly by regular virtual meetings discussing the research methodology, study protocols, and assistance in scientific writing, leading to several publications led by researchers in India. Other collaborations and partnerships include the Public Health Foundation of India (PHFI) and the All India Ophthalmological Society (AIOS).

Table 2: Capability/Capacity building for the Nayanamritham study

DR care pathway set-up	
DR care pathway developed by local leaders and UK collaborators	
Project manager appointed	
Study protocol developed collaboratively	
Ethics approval obtained	
Development of patient information sheets and consent forms, translated into Malayalam	
IT infrastructure developed to integrate DR screening at FHCs into eHealth and transfer retinal images from primary care to reading center for grading	
Retinal cameras purchased for each FHC (16) and tertiary center (1)	
Laser equipment for the treatment of DR in secondary care purchased (4)	
The reading center established to grade retinal images	
Training of staff involved in the DR care pathway implementation	**Numbers trained**
Optometrists trained and certified	20
General physicians in primary care trained in diabetes and DR management	38
Nurses in primary care trained in diabetes and DR management and retinal imaging following dilation	70
Data entry operators trained to collect patient data and enter into eHealth	20
Ophthalmologists in secondary care trained to do laser surgery	5
Doctors in FHCs trained on principles of laser application	50
ASHAs trained to increase public awareness of diabetes and its complications	411

A two-day research capacity building webinar was organized by the collaborators in India, with 16 speakers worldwide, exploring research funding for early career researchers, types of research needing funding, different funding bodies in India and internationally, and how to write a grant proposal. The webinars were attended by over 200 researchers, both basic and clinical, many of which are applying for grants for the first time.

Nayanamritham study

The capacity and capability building in this pilot study included the development of IT infrastructure, with significant contribution from the Government of Kerala, the establishment of Reading Grading Center at the RIO and certification of retinal image graders (https://drscreening.org/test-and-training), and training of a number of medical personnel at various levels and for a variety of activities of DR care [Table 2]. Joint training sessions between the camera manufacturers and project staff enabled group learning at each FHC. Cascading of training from the first group of trained staff to other staff that joined the project or participated in DR screening helped to ensure the sustainability of the screening at the FHCs.

During this pilot study, 5,307 people with diabetes, registered in the NCD registers at the 16 FHCs, were screened for DR; of these, 1,662 (31.3%) were referred to secondary centers either due to ungradable images or for treatment of STDR. The clinical and cost-effectiveness and process evaluation of the DR care pathway is ongoing.

Based on the successful implementation of this pilot DR care pathway in the public health system, the Government of Kerala is upscaling the screening to referral and treatment process across other districts in Kerala.

Discussion

India, home to over one-sixth of the world's population, is in the midst of a diabetes epidemic. The International Diabetes Federation (IDF) has estimated that 77 million adults (20–79 years) had diabetes in 2019, and this number is predicted to increase to 101 million in 2030 and 134.23 million in 2045.

In addition, an estimated further 43.9 million people have undiagnosed diabetes.[9,10]

Although cataract and refractive errors are the leading causes of visual impairment in LMIC, the diabetes epidemic is a global risk due to associated increased numbers of DR-associated visual impairment. Sight-threatening DR, which includes proliferative diabetic retinopathy and/or diabetic macular edema, is a common cause of visual impairment in people with diabetes. Timely detection and treatment of DR can prevent blindness, but many people with this condition are not diagnosed early enough to be treated effectively. Population-based studies in India over the last two decades report a prevalence of DR at approximately 18% in urban and 10% in rural areas.[11] However, there is a lack of contemporary data on DR prevalence in many regions in India.

To prepare for this emerging problem of visual impairment due to diabetes, India needs a systematic approach from screening to treatment, an effective public-private partnership, and a conducive public health policy for noncommunicable diseases, including diabetes. There are significant challenges in establishing a systematic screening program for DR with regular recall in India. First, the numbers of people with diabetes are too large to replicate successful DR screening programs from other smaller countries. To sustain DR screening programs, diabetes registers must be established to invite people with diabetes for regular screening. These registers must origin at primary care and diabetes centers. The current model of opportunistic screening in India is not sustainable; thus, new models of DR screening must be developed. In addition, new risk-based triage models are required to urgently identify the high-risk people for DR screening so that rates of blindness can be decreased relatively faster while systematic screening processes are being established.

Both the SMART-India study and the Nayanamritham study attempted to address some of these needs. By building research capacity and capability, it was possible to collect high-quality data in the SMART-India study, pertinent to understand the current prevalence of diabetes, DR, and other diabetes-related complications in 11 states and one union territory. We also evaluated the tests that could be used for holistic screening

for diabetes and its complications. In addition, a deep learning algorithm for DR detection using retinal images taken by the field workers using a low-cost nonmydriatic hand-held retinal camera is being developed.[12] This and the use of low-cost hand-held retinal cameras can significantly expand community screening for DR in LMICs.[13,14]

Kerala reports a high prevalence of diabetes—up to 1 in 5 adults aged 30 years or older may have the condition.[15] The Government of Kerala has prioritized screening for end-organ damage in people with diabetes within the public health system, but DR screening and management remains a challenge. Those with sight loss self-referred to tertiary care centers, resulting in over-burdened services with patients with irreversible visual loss, a situation seen in most LMICs. By partnering with the Government of Kerala, steps were developed to adapt the DR screening and treatment programs used in high-income countries to Kerala - the Nayanamritham study. This pilot study shows that building capacity and capability makes it possible to implement a DR care pathway in the public health system in Kerala, spanning primary, secondary, and tertiary care. Economic evaluation and outcome data from the study created evidence, which can inform policy on situating screening of DR in primary care setting and treating in secondary hospitals instead of tertiary centers. Integrating DR screening within the existing public system, without significant investment except for training and capital costs, ensured a smooth transition from research to a scalable and sustainable state-wide program, which has the potential to be replicated in other Indian states and LMIC settings.

Given the complexity and the number of challenges required to establish a DR care pathway for people with diabetes in India, it is necessary to integrate research into each of the components of the pathway. In these projects, the learnings from the scientific process and system of DR care used in the UK were used to guide the investigators in India. One of the important outcomes was the interdisciplinary collaboration and partnership with the Government of Kerala, who took ownership of the project to integrate the research findings into policy development.

Challenges

Our efforts to build research capacity to design and execute epidemiological and clinical studies were not without challenges. We underestimated the number of training sessions required to get field workers adequately trained for data collection, including retinal photography and data management. It was equally difficult to establish a link between screening at the primary level and treatment at the secondary/tertiary level. ORNATE India brought together many investigators for the first time to jointly design and conduct the SMART-India study across 20 clinical sites and to form the Indian Retinal Disease study group for collaborative research to analyze retrospective multicentric data on diabetic-related eye disease to inform clinical standards there. The daily workload was high for most staff members; thus, training had to be limited to the times that they were available.

Due to the unexpected COVID-19 pandemic and the ensuing lockdown, the SMART-India study was halted. However, prompt online data cleansing, resolution of queries by the field workers, prompt completion of retinal image grading by the graders across the 20 sites, and remote monitoring through regular virtual meetings enabled successful completion of the SMART-India study with the required sample size.

Shortfalls in DR screening implementation have also flagged the need for qualitative studies into attitudes and behavior that facilitate uptake of screening but hinder access to treatment. The scale-up of the DR pathway to the entire state is also an opportunity for the Government of Kerala to structure an implementation research proposal around it, using the capacity built by the Nayanamithram project.

Conclusion

The sustainability and scalability of research in diabetes and DR due to the ORNATE India project will be the lasting legacy of this grant and will be measured by the increase in scientific outputs, successful grants, and new partnerships in this field. The UK–India collaboration has created an enabling environment for the local researchers to set goals and tailor study protocols to local needs and opportunities. In addition to focusing on capacity building, ORNATE India has resulted in fruitful collaborative partnerships built on mutual trust and shared decision-making.

Conflicts of interest

There are no conflicts of interest.

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