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A Novel Mobile-Health Approach to Early Diagnosis of Oral Cancer

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Author contribution:

Praveen Birur N, Sanjana Patrick and Moni A Kuriakose were the Lead in designing and implementing the program. Suchitra Bajaj aided in program design. Sumsum P Sunny assisted in implementation of the program. Shubhasini AR prepared the first draft of the manuscript. Amritha Suresh, Radhika Chigurupati and Petra Wilder-Smith reviewed the manuscript. Keerthi G and Shubha G had a role in training and manuscript review. Pratima Rao took responsibility for overall administration of the program. All authors reviewed the results and edited the manuscript.

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Abstract

The incidence of oral cancer in India is high, which can be reduced by early detection. This paper summarizes the mobile-Health model, in which Frontline Healthcare providers (FHP) in rural areas were empowered for early detection and connected to specialist through mHealth.

We provided training to FHPs in examination of oral cavity, use of mobile phone for image capture and risk factor analysis. FHPs were selected from different cohorts in resource-constrained settings. The workflow involved screening of high-risk individuals in door-to-door and workplace settings, and capture of images of suspected lesions. Uploaded data was interpreted and recommendation was sent by specialist from a remote location. Their recommendation was intimated to FHPs who arranged for further action.

During the period 2010–18, 42754 subjects have been screened, 5406 subjects with oral potentially malignant disorders have been identified. The prevalence of potentially malignant disorders varied from 0.8 to 62% at different cohorts. 516 biopsies have been performed at remote locations.

Connecting specialists to rural population would not have been possible by conventional methods. Electronic data capture facilitated efficient follow-up. The program was very cost-effective with screening completed under \$1 per person. Some of the challenges we faced included securing participation of populace in screening, and in compliance for biopsies. Technological hurdles included poor connectivity in some areas.

The burden of non-communicable diseases is increasing in India. One among these is cancer, the cause of 15% of all deaths.¹ Worldwide, oral cancer is the 11th most common cancer among men, and 15th among women.² However, it is ranked first among men and third among women in India,³ where high incidence rates of 20 per 100,000 population have been reported.⁴

The public health care system in India consists of a three-tier system composed of subcenters, Primary Health Centers (PHC) and Community Health Centers (CHC). However, infrastructure and staffing are inadequate in these public health care centers.⁵ Public sector tertiary care institutions, consisting of government medical colleges and national educational institutes not only provide valuable specialized services, but also serve as primary care providers to compensate for weaknesses in the public health sector.⁶ However, these institutions function independently of the primary healthcare system.

The private health-care sector is extensive, heterogeneous and largely unregulated, including sophisticated hospitals with advanced investigatory and treatment facilities. However these may not be within reach of lower economic sectors of the population. The distribution of skilled manpower is exceedingly unequal in India, with only 3.3% of all allopathic doctors

working in public health facilities in rural areas. Informal care providers, with no formal medical training or government registration for medical practice are estimated to represent 55% of all providers⁷ and frequently act as the first point of contact for health-related issues especially in rural areas.⁶ Practitioners using indigenous systems of healing are also prevalent outside of urban centers.

Prognosis and treatment outcomes in terms of morbidity and mortality are excellent if oral cancer is detected early, before metastasis, with 82.8% surviving 5 years after diagnosis. However, most oral cancers are detected after metastasis, when 5 year survival is only 27.8%.⁸ Because oral cancer and associated conditions such as oral potentially malignant disorders (OPMDs) are asymptomatic, the majority of patients do not present for care until a late stage has been reached. Moreover, in spite of awareness about tobacco use and its side effects, patients are unsure of the symptoms that warrant an approach to a doctor. Many patients try out home remedies in favor of visit to doctors.

Clearly it is not effective to wait for patients to report to doctors at primary or tertiary levels. It is essential for doctors to reach out to patients, even in under-served areas. However, in view of the large population, low doctor-patient ratio, and geographic difficulties; it may not be possible for specialists to visit every patient. A more realistic concept is that of empowering health workers. Existing resources in the form of Frontline Healthcare Providers (FHPs) such as Accredited Social Health Activists (ASHA) can be utilized for health screening, and to provide linkage to specialist care.

Based on this concept of empowering FHPs through mobile health(mHealth), we conducted a pilot study in a targeted cohort (n=2000) screened by FHPs and an opportunistic cohort (n=1440) screened by dental professionals.⁹ The work flow involved the use of a mobile phone with oral cancer screening software, *Sana*. The outcomes measured were lesion detection and capture of interpretable images of oral lesions. 61% of images obtained by FHPs were deemed interpretable; and 45% of these were confirmed to be OPMDs. In the opportunistic cohort, all images captured (100%) were interpretable and all were confirmed as OPMDs.

This pilot study demonstrated that our mHealth-based approach can aid remote early detection of oral cancer in resource-constrained settings. It mapped out a novel approach that can provide the basis for a paradigm shift in cancer care and outcomes in low-resource settings, through networking FHPs with local community cancer screening service and a tertiary cancer center. The following conclusions were drawn (Flowchart 1):

1. At the community level, trained FHPs are capable of utilizing smart-phone-based technology for primary and secondary prevention of oral cancer. It was also suggested that further training of the FHP with newer technology that overcomes human error needs to be conducted.
2. Involvement of a dental school as a nodal center acted as a triage point for further specialist referral. This was also effective in creating awareness in the screened population at minimal cost. In view of the large number of dental

schools spread across India, involving other dental schools in future larger screening projects would be an excellent option.

3. Based on this study, a mobile-phone application for general dentists was designed and launched to assist them in managing oral cancer in diverse patient populations.

As the next action plan, the following screening programs were initiated:

1. Implementation in resource-constrained settings: As part of its community and social responsibility engagement, Biocon Foundation, has spearheaded the campaign against oral cancer through screening of rural populations using mHealth. For this project, a bifurcated screening approach is being used- door-to-door and workplace. Presently, screening has extended to multiple cohorts in rural geographic locations in four different states across the country in low-resource settings. To date, 42,754 subjects have been individually approached with the aid of technology. Of these, 20,462 subjects have been screened by door-to-door screening, and 2,650 subjects have been diagnosed with OPMDs. In various workplace settings, 22,292 subjects have been screened, and 2,756 subjects diagnosed with OPMDs. (Flowchart 2, Figure 1) The prevalence of OPMDs ranged from 0.8% to 62% at different cohorts. 67 and 449 biopsies have been performed in door-to-door and workplace settings respectively, underlining the challenges of performing invasive procedures in these settings.

The Biocon mHealth program was first implemented in 2011. We developed a standard 2-day training module for oral cancer screening and use of mobile phone application, through PowerPoints, videos and clinical cases. Oral Medicine specialists gave the training, and at the end FHPs' knowledge was tested. In 2011, door-to-door screening of high-risk persons was performed in two villages by four Biocon employees trained as FHPs. Mobile phones equipped with cameras for documentation as well as the decision supported algorithm, *Poi Mapper*, were issued to these FHPs.(Flowchart 3) While the screening program was generally effective in identifying at-risk patients and capturing quality intra-oral images, uploads were challenging in many locations due to poor connectivity, so that uploads were typically made from Biocon clinics in the villages.

During 2013–14, three additional villages and four workplace settings were added to the program. FHPs were proficient at identification of lesions and image captures. During 2014–15, a comparison of smokeless tobacco habits and oral lesions was performed at a workplace setting¹⁰ in conjunction with salivary analysis.¹¹ A follow up screening was carried out in two villages two years after the first visit. 21 new lesions were detected, however, there were no advanced lesions. During 2015–16, a scaled up model was implemented in multiple villages and workplace settings, and our reach was extended to North-East India. Here, students from the local community were trained and employed for screening. However, their involvement was not effective with regard to screening accuracy and image quality. Wired data transfer was attempted as a temporary measure, due to very poor connectivity in these areas. In our full-fledged program in North-East India, which involved population-based and screening at schools, 7202 subjects were covered, 311 OPMDs were identified and subjects were recalled for biopsy. The program is currently underway. 30 biopsies were performed in which one subject each with squamous cell carcinoma and microinvasive carcinoma were

detected. These two subjects were advised to undergo wide excision, as they were in T1 stage.

In India, it is critical to integrate any oral cancer control program with Government-run health initiatives. The ambitious 'screen and treat' program was initiated by Biocon Foundation in association with the Government of Karnataka. It is designed to reach out to rural populations through existing healthcare resources and ASHAs. ASHAs were trained in the standard format. Objective pre- and post-training tests were conducted to assess the learning of the ASHAs.

The 'screen and treat' program was conducted in two phases- in the first, persons served by a PHC aged 18+ underwent thorough door-to-door screening to identify at-risk individuals. Using electronic data capture (EDC) with digital sheets, data were automatically integrated into a database and tabulated. All subjects with high-risk habits as well as those with a positive family history of cancer were recalled to the PHC for further evaluation. In the second phase at the PHC, patients received a general health screening using a Multi-Parameter-Patient-Monitor device to assess their general health status. A local coordinator at the PHC examined the patients, identified oral lesions, and uploaded findings using the *Poi Mapper* application. The uploaded images were interpreted by an Oral Medicine specialist, (Figure 2) and results or requests for further investigations and treatment options were communicated to the FHP. They in turn would carry out the necessary actions. This program was conducted at two villages in Karnataka; and at Non-communicable Diseases (NCD) Desks at Rajasthan. In total, 4845 subjects have been screened and 1466 lesions have been identified.

2. Oncogrid: Another parallel program called 'Oncogrid' had the goal of assessing the routine 'standard of care' during screening carried out in dental schools compared to mHealth based screening. Screening was planned to be carried out in seven different dental schools spread out across the state of Karnataka. The schools acted as nodal centers, with surrounding villages targeted for screening. Students pursuing undergraduate programs and members of the Departments of Oral Medicine and Public Health were actively involved in screening. Four dental schools actively participated. 1444 subjects were screened. Intra-oral images were uploaded using the mobile application *Emocha*. In addition to collecting demographics, this app required the upload of ten images from each subject, covering the entire oral cavity irrespective of the presence of lesions. 234 smokers, 564 smokeless tobacco users were identified. 93 abnormal findings were identified by FHP.

3. Empowerment of general dentists: It was deemed necessary to reach out to general dental practitioners, and empower clinicians in diagnosing asymptomatic oral mucosal alterations. Several studies indicate that dentists lack knowledge in the area of oral cancer etiology and diagnosis.¹² An application termed '*Experteerz*' was downloaded onto the mobile phones of the dentists participating in this study. The application has a workflow of questions regarding adverse habits, with provision to record photographs of lesions. The dentists obtained this information and upload the data. Selected experts in the field of Oral Medicine with the same application on their phones received the data and provided their opinion regarding diagnosis, treatment options and referral. Thus there was direct communication

between two mobile phone users, rather than at the back-end. This real-time consultation saves chair-side time, provides immediate input about mucosal lesions and their management, and negates the need for further appointments. The application was launched at the International Conference of the Federation of Head and Neck Oncology in 2016. In the pilot study, 43 subjects were examined, and there was substantial agreement between experts. However, use of the application by private dentists has not met the expectation, in terms of low usage and the low number of uploads.

Role of the funding source: The funder of the study had no role in study design, data collection, interpretation of data, writing of the report or in the decision to submit the paper for publication. The corresponding author had full access to deidentified data and had final responsibility for the decision to submit the publication.

Discussion

Oral cancer and precancers are ideally suited to screening and early diagnosis as they are accessible to direct examination, and are associated with clearly identifiable risk factors.¹³ In spite of this, oral cancer is common in India. This is attributed to the high prevalence (about 35% of adults) of tobacco use in the country.¹⁴ There is a great opportunity to bring down prevalence rates through community screening, early detection & timely referral.

In recent years, there has been a tremendous growth in mobile phone usage in developing countries. Mobile phone subscribers in developing countries outnumber those in developed countries.¹⁵ There are several examples for the successful implementation of mobile health programs in various scenarios,^{16,17} and the authors have also conducted mHealth programs.^{9,10} It was considered opportune to share the experience & highlight the challenges faced in the actual implementation of these programs.

Implementation challenges:

One of the key factors in successfully implementing such programs at a grassroots level is to secure the active buy-in and involvement of local authorities who, in our experience, were predominantly keen to participate. FHPs selected were residents in the community where the screenings were conducted and fluent in that community's dominant language. ASHA's became involved through Government agencies and were generally effective in covering their respective populations.

A standard training module was developed to train the FHPs for measuring outcomes related to fieldwork performance. Post-training dropout of FHPs after program initiation caused unexpected delays in running the program. It was a challenge to identify new FHPs and train them in a timely fashion.

In the field, most subjects were cooperative, especially in rural populations. The participants were counseled on maintaining oral health and a toothpaste and antioxidants were given when required. Reasons for not participating varied from the absence of male members of the family, social stigmas, 'lack of time' in workplace settings to their 'perception of being healthy'. Some presumptions included 'absence of lesions even after years of chewing',

‘tobacco gives relief from toothache’, and ‘it’s a daily routine’. Many patients with lesions stated that they had used ‘more lime and that the lesion would regress by itself’. Screening within houses added the challenges of lack of clinic-like environment and poor lighting. Male-breadwinners were generally absent during door-to-door screening, and were recruited during evenings and weekends. It was noted that a recommendation to get themselves screened, by an authority they trusted, such as a PHC doctor, gave better results.

Any subject with an identifiable OPMD was recalled to a PHC or the nearest facility for a biopsy. However, there was poor compliance to the recall. We assessed the reasons for the same in one cohort. It was found that 459/1871 subjects were unwilling to travel the distance for a biopsy. Subjects did not consent to an invasive procedure, were fearful of injections, blood, and the resulting wound.

Technical challenges:

The success of this mHealth initiative to provide widespread screening of under-served population relied on technical aspects to a great extent.

Traditionally, field-based data collection or surveys use paper and pen-based methods in developing countries. Physical transportation of completed forms as well as consolidation, transfer, management and analysis of the data involve considerably greater time and cost than for electronically collected data.¹⁶ These limitations encouraged the development of electronic data collection approaches. Our mHealth initiatives were conducted to evaluate the feasibility and effectiveness of mobile application-based diagnosis. It ensured screening of thousands of persons in rapid turn-around time. It was also successful in terms of logistics, electronic data capture, and empowerment of local resources.

All uploaded subject data was de-identified and stored to a secure server at Biocon Foundation. It was desirable to keep the size of the uploads to a minimum and photos were limited to capture only the positive sites. The quality of images captured varied based on the distance from which the photograph was taken, zooming of the screen etc. The quality of photos obtained by FHP improved with training and were generally acceptable. The images obtained at workplace settings were better than those obtained from door-to-door screening.

Subjects were identified using multiple identifiers such as demographic details, phone number, and ID cards. In spite of these, some difficulty was encountered when subjects were not aware of their date of birth, or phone number, or when they lost their ID cards. In most cases, this was resolved through matching other identifiers.

The Oral Medicine specialist had to commit time for remote diagnosis. Complete subject data were not available at times. The remote specialist’s recommendation was transmitted to the FHP, who then recruited the subject for further steps. However, this transformation took time due to migration of subjects, or absence of contact numbers.

Administrative challenges:

It is advisable to prioritize geographic location of screening based on disease burden, local needs and consideration for social and cultural barriers. The budget outlay for preventive

oral cancer program should be designed such that screening is completed within \$1 per person. This is crucial to make the program cost-effective, so that it can be scaled-up. On an average, Biocon Foundation spends about Rs 59 per person; inclusive of screening, chemoprevention, creating awareness and providing patient education.

Detecting an OPMD early should be followed by monitoring and providing timely referral. Implementation of programs for monitoring of high-risk population is challenging and depends on the skill of the FHP. Recognizing the importance for follow-up, a surveillance module with biometric capture is being implemented.

Primary care physicians, ASHAs, dental schools, General Dental practitioners and tertiary care centers are all links in the chain of patient management. Hence, they need to be integrated and provided proper communication channels to monitor high risk groups. Biocon Foundation, a voluntary organization, is making an effort in this direction by creating awareness among the populace regarding the ill-effects of a traditionally accepted habit, providing guidance for self-mouth examination, an individualized approach and providing timely referral.

The shortcomings noted in our series of programs include a variable participation of dental schools in the Oncogrid trial, and a poor response to the use of *Experteez* app for general dentists. Both these case scenarios emphasize the need for a core administrative center to implement technology in health care. Thus, our future recommendation is to provide 'linkage to care' wherein rural population, nodal center, and tertiary center are interconnected to communicate. This will effectively reduce the burden at the tertiary center.

In this system, each individual has a predefined role to play in reducing the cancer burden. The FHP provides early detection, a general dental practitioner treats and provides referral, the dental school is responsible for performing a biopsy and surgical management, and the tertiary center provides advanced treatment and refers the patient back to the dental school for monitoring. This completes a linkage to care which ensures that a patient with an OPMD or Oral Cancer obtains optimal treatment and is not lost in the complex pathway of care.

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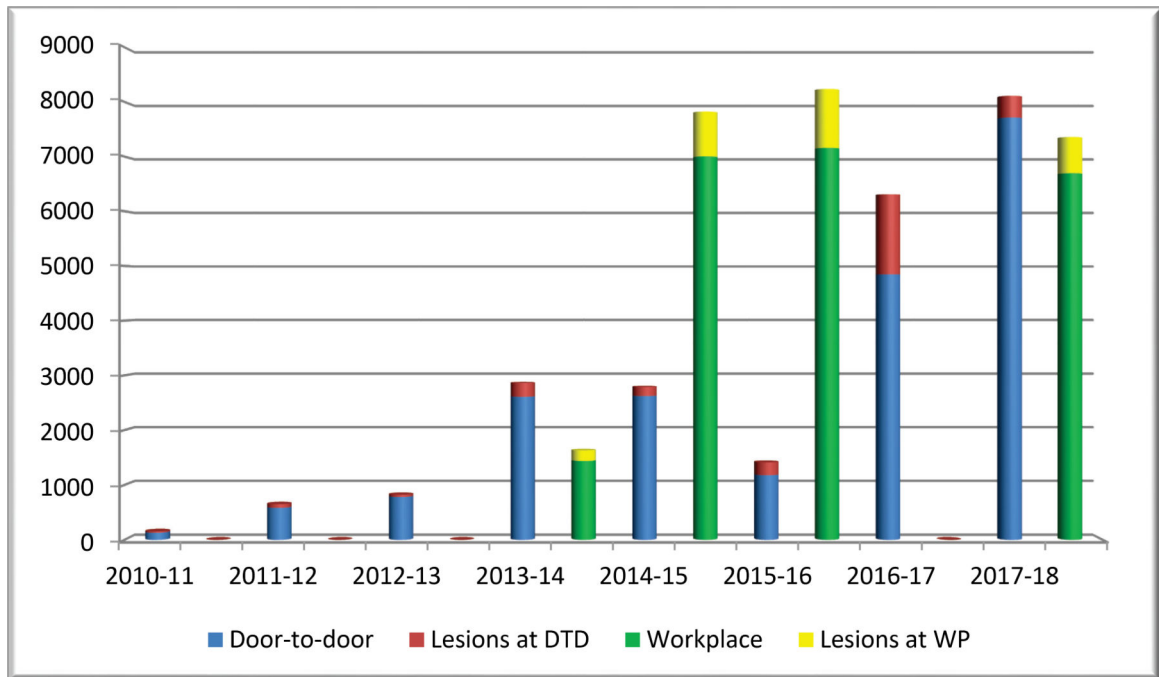


Fig 1:
Annual progress of mHealth program

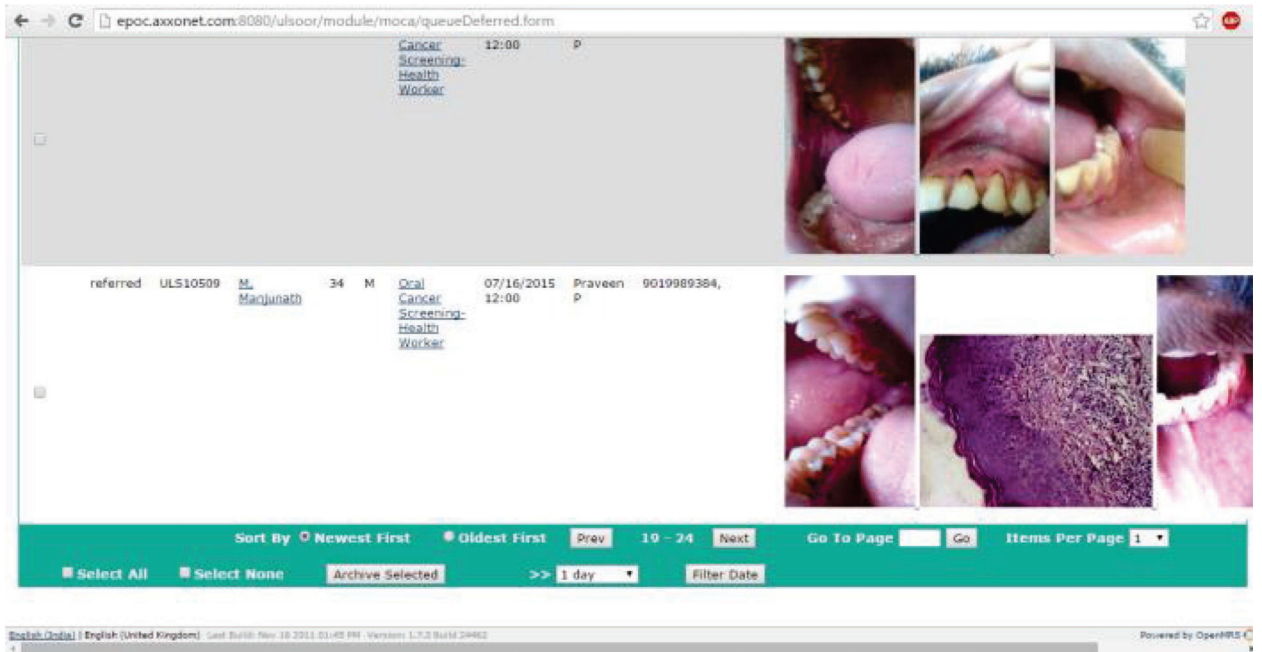
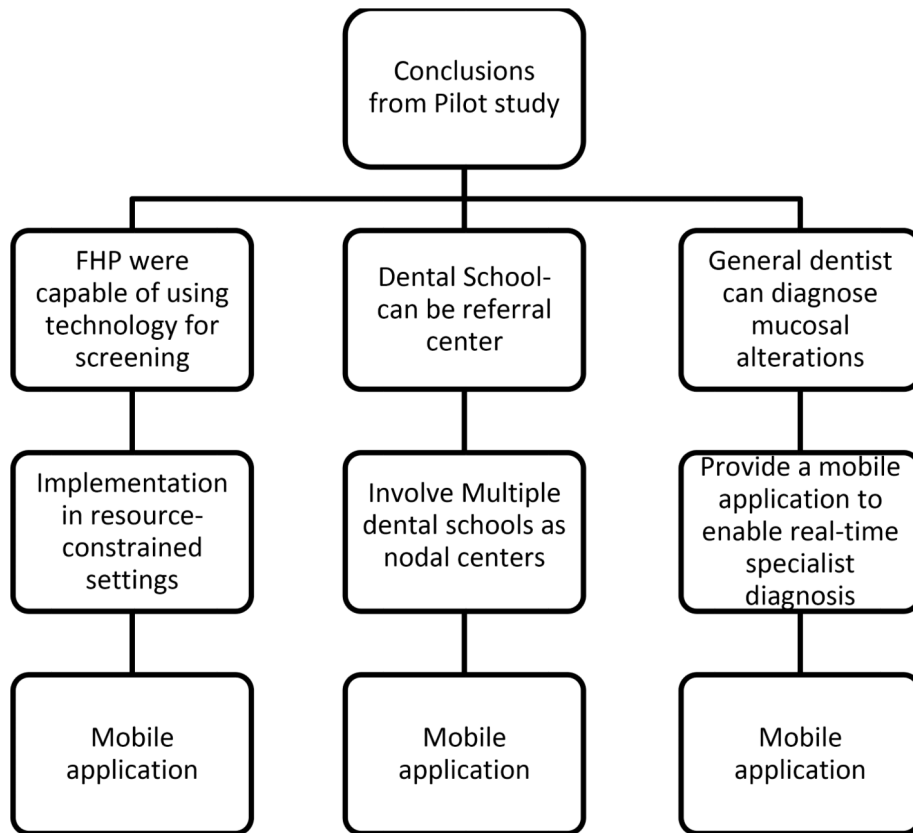
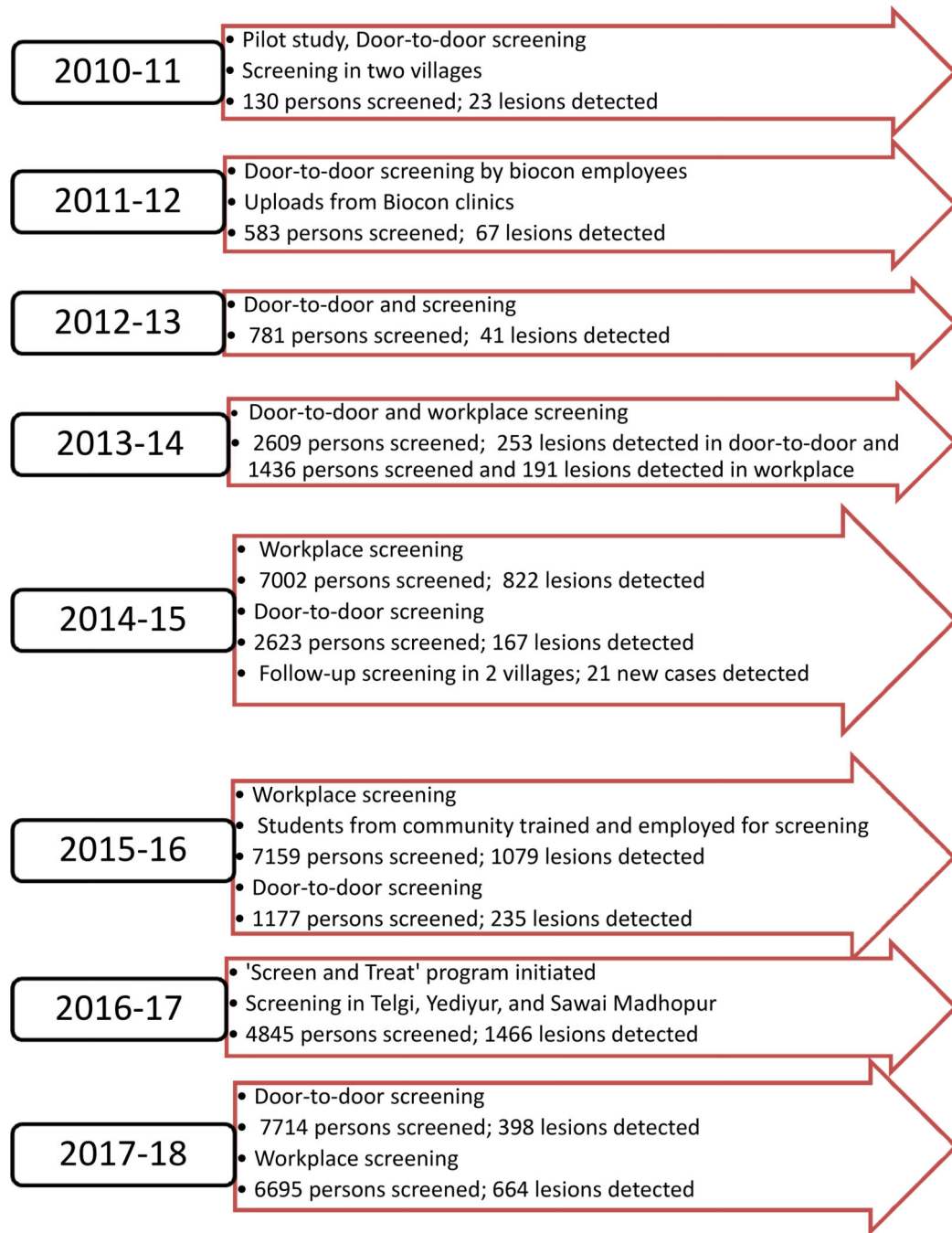


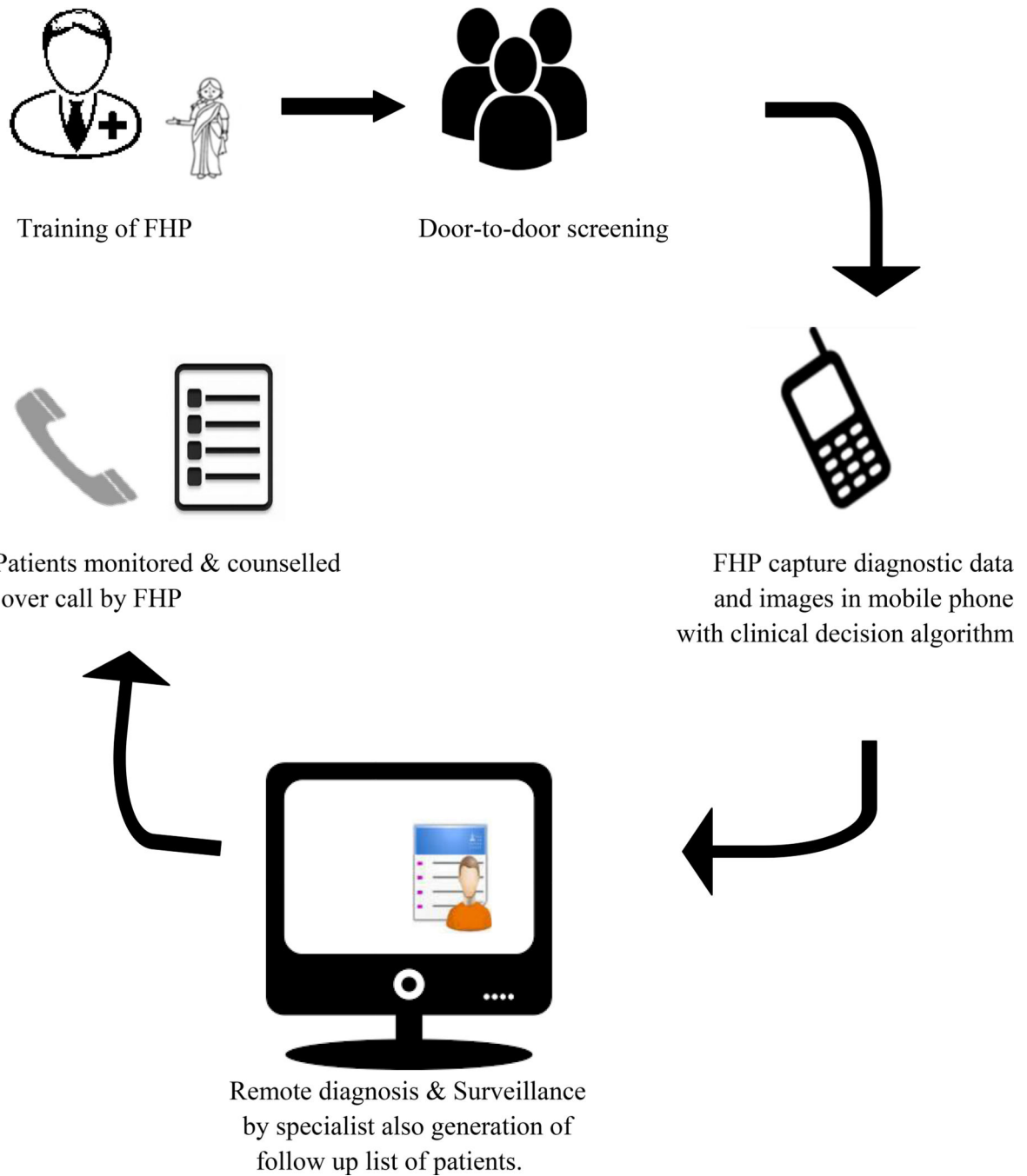
Fig 2:
User interface, Open MRS, for specialist recommendation



Flowchart 1:
Plan of action drawn following pilot study



Flowchart 2:
mHealth screening program outline



Flowchart 3:
Implementation in resource-constrained settings