

Field validation of smart phone-based portable Point-of-Care diagnostic tool with Artificial Neural Network for early detection of oral cancer

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Background: Early detection of oral cancer in low-resource-settings necessitates a robust, Point-of-Care screening tool that can empower Frontline-Health-Workers (FHW) for triaging high-risk populations. This study validated the accuracy of Artificial-Neural-Network (ANN) enabled m(mobile)-Health device deployed with FHWs. **Methods:** The dual- model imaging device capture white-light (WLI) as well as auto-fluorescence (AFI) images in wide FOV and focused view. Demographics and clinical details were documented in the device, and the subjects were screened independently by FHWs in addition to a remote evaluation by oral cancer specialists. ANN were built using the images for classification of oral-potentially-malignant/malignant lesions and integrated into the mobile phone/cloud. The specialist diagnosis were compared with the histopathology, FHW, and ANN-based diagnosis. **Findings:** 5025 subjects which were screened, 95% (n=4728) having tele-diagnosis. The onsite specialist diagnosis showed sensitivity of 94% and specificity of 72% when compared to histology diagnosis, while tele-diagnosis showed high accuracy when compared with onsite specialists (sensitivity: 95%; specificity: 84%). FHWs, when compared with tele-diagnosis showed less sensitivity (60%). The ANN (MobileNet) integrated with the phone for a real-time diagnosis could accurately delineate lesions (sensitivity: 82%), while the cloud-based ANN (VGG19) had higher accuracy (sensitivity: 87%) when compared to tele-diagnosis. **Interpretation:** mHealth-enabled dual-image system empowers FHWs towards accurate screening in low-resource settings.

Introduction

Clinical Problem: Lack of point-of-care (PoC) device to empower Frontline Health Workers (FHWs) for oral cancer screening

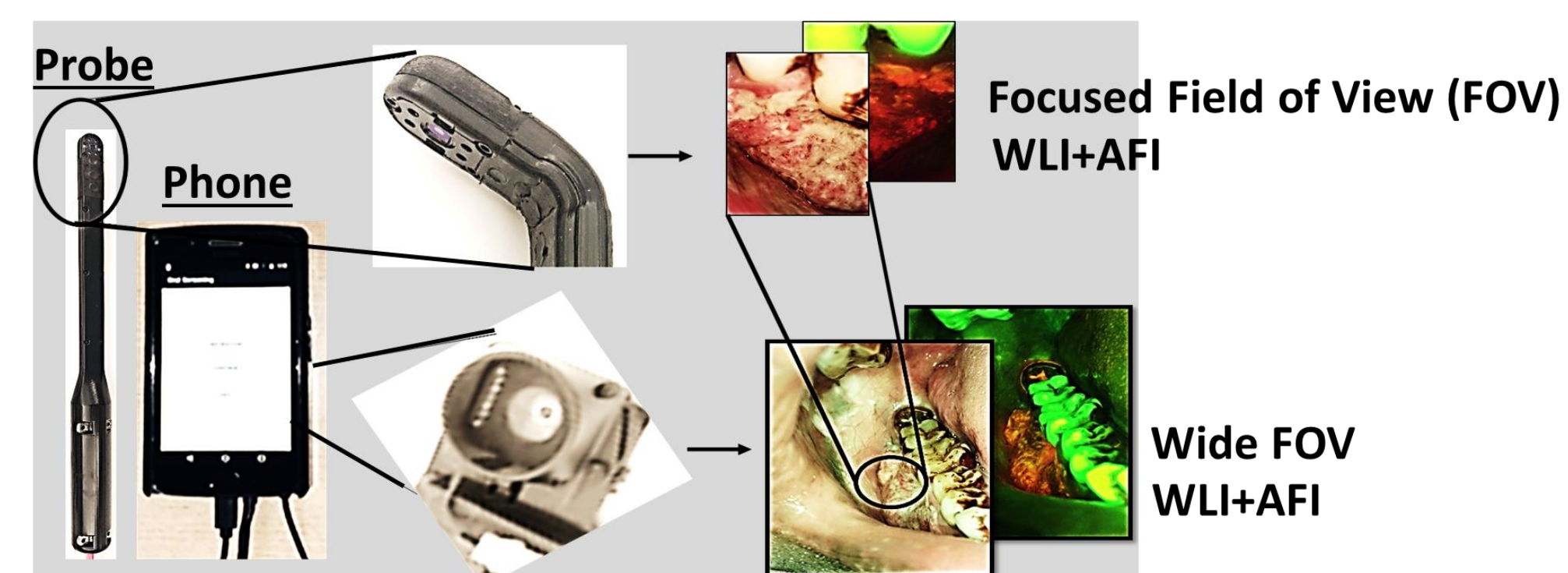
Hypothesis: Artificial-Intelligence (AI) enabled Dual-mode (White-light & Auto-fluorescence) imaging device can empower FHWs for detecting oral cancer and pre-cancer lesion

Aim: To validate diagnostic accuracy of dual-mode, AI-integrated PoC device deployed with FHWs for oral cancer screening

Objectives

- To evaluate tele-diagnostic capability of dual-mode device used by FHWs (tele-diagnosis of Remote specialist Vs onsite specialist diagnosis by direct visual examination)
- To determine diagnostic accuracy of trained-FHW in delineating oral cancer & pre-cancer (FHW diagnosis vs specialist diagnosis)
- To determine the diagnostic accuracy of AI-integrated PoC device (AI diagnosis Vs remote specialist diagnosis)

Dual-Mode Imaging device¹⁻⁴



Device captures White-light-(WLI) and Autofluorescence(AFI) images- in wide Field-of-View(FOV) using phone-camera and focused-view by probe-camera.

Every lesion, 4 images were recorded

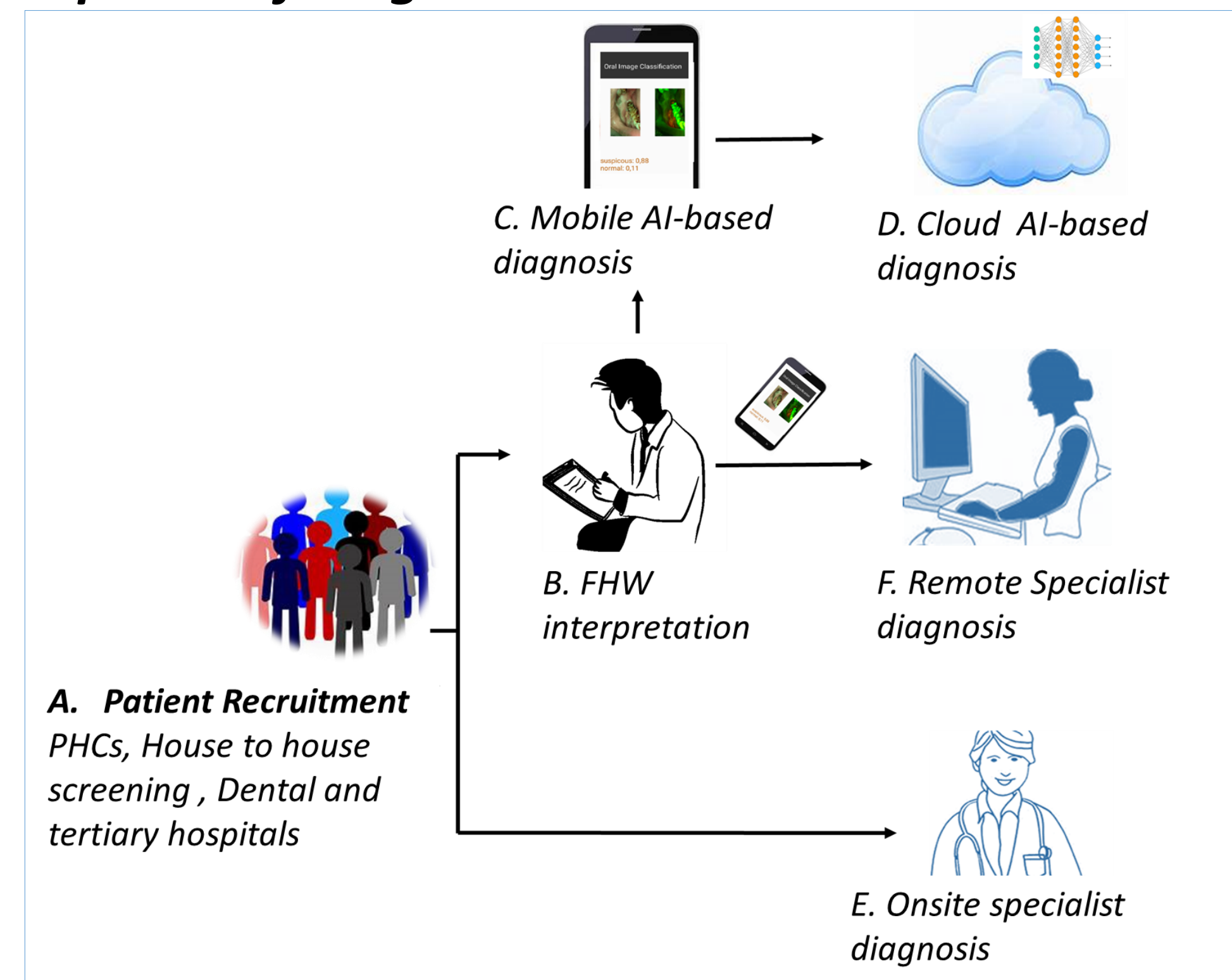
For details please contact: makuriakose@gmail.com, praveen.birur@gmail.com

Methodology

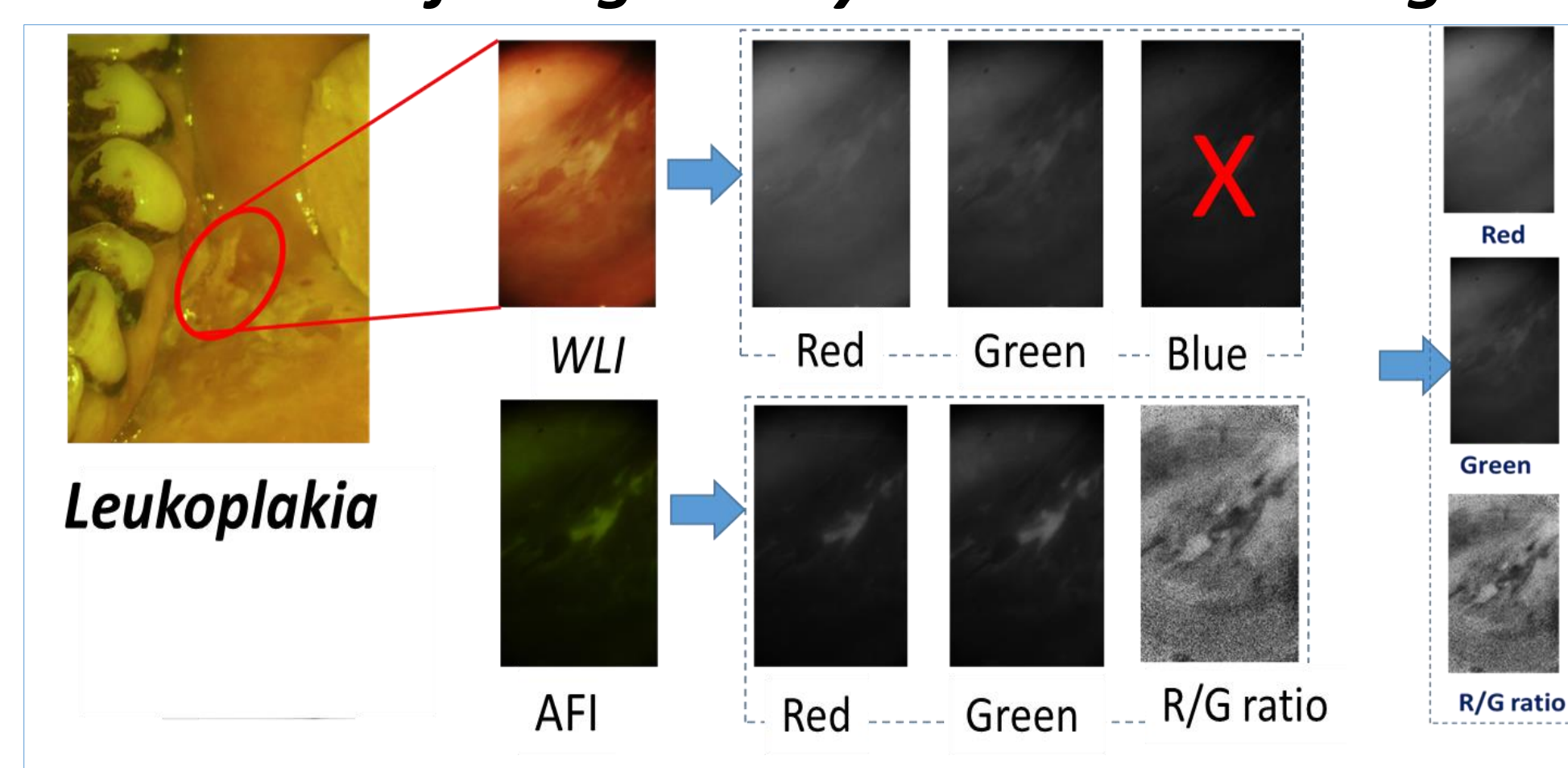
Study design



Pipeline of diagnosis



Work Flow of Image analysis and AI training¹⁻⁴

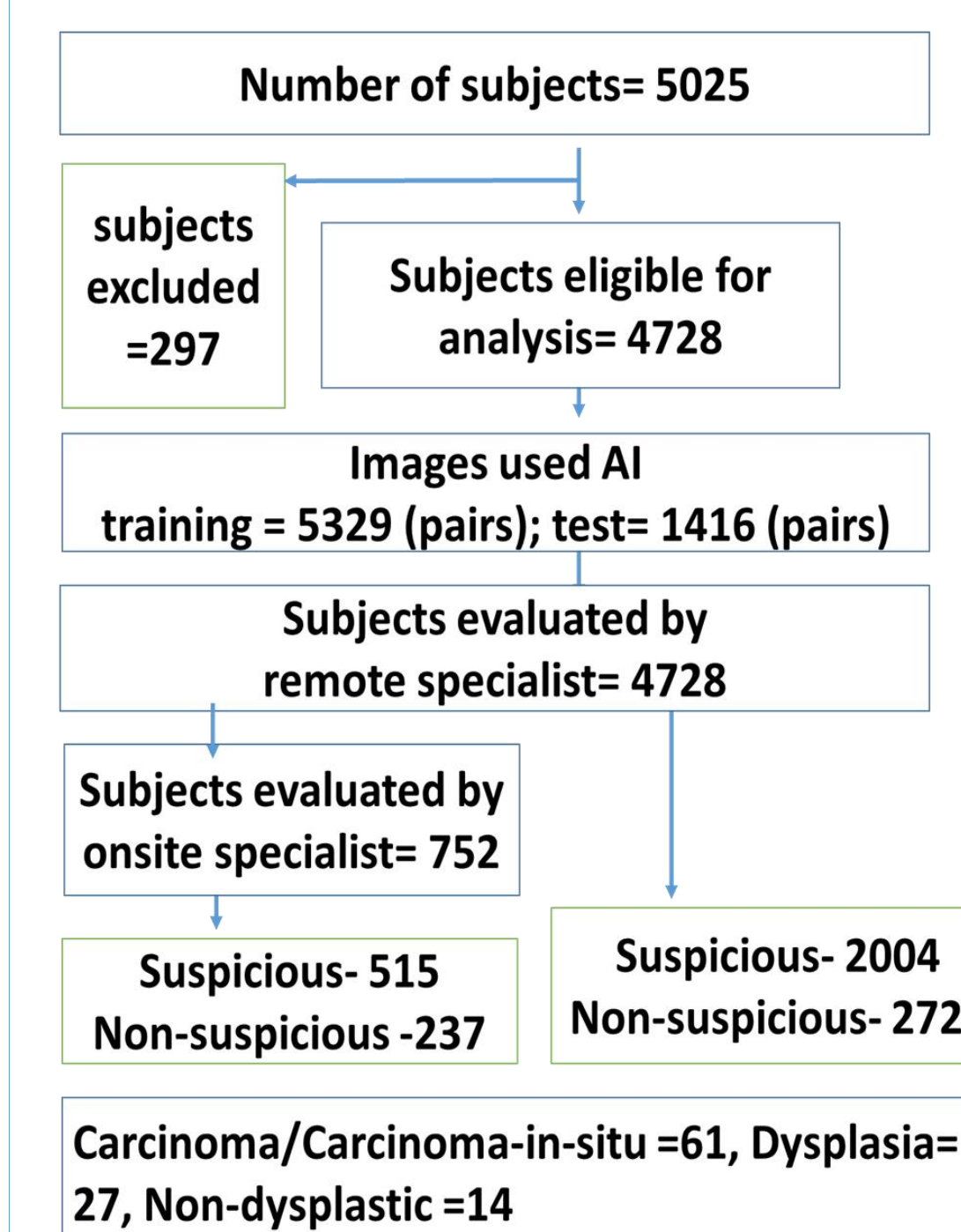


From WLI - Red & Green channels and AFI =Ratio of Red/green(R/G) were extracted for Neural network training (-MobileNet, VGG19)

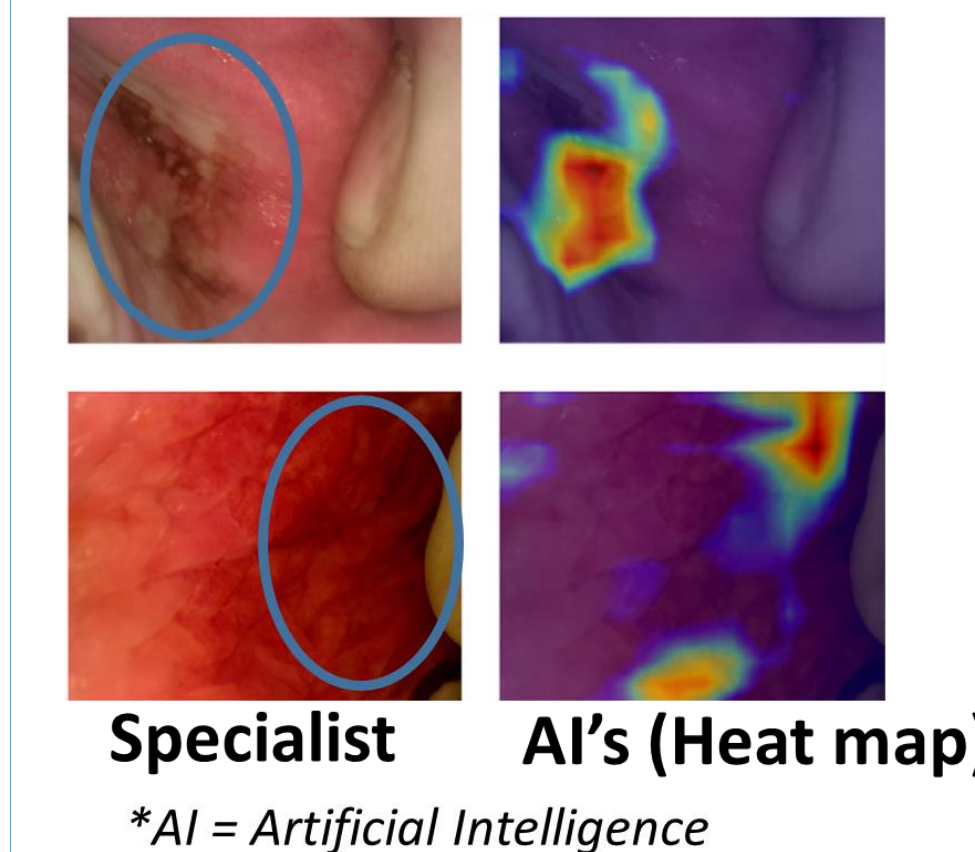
AI= Artificial Intelligence

Results and Discussion

Consort Chart

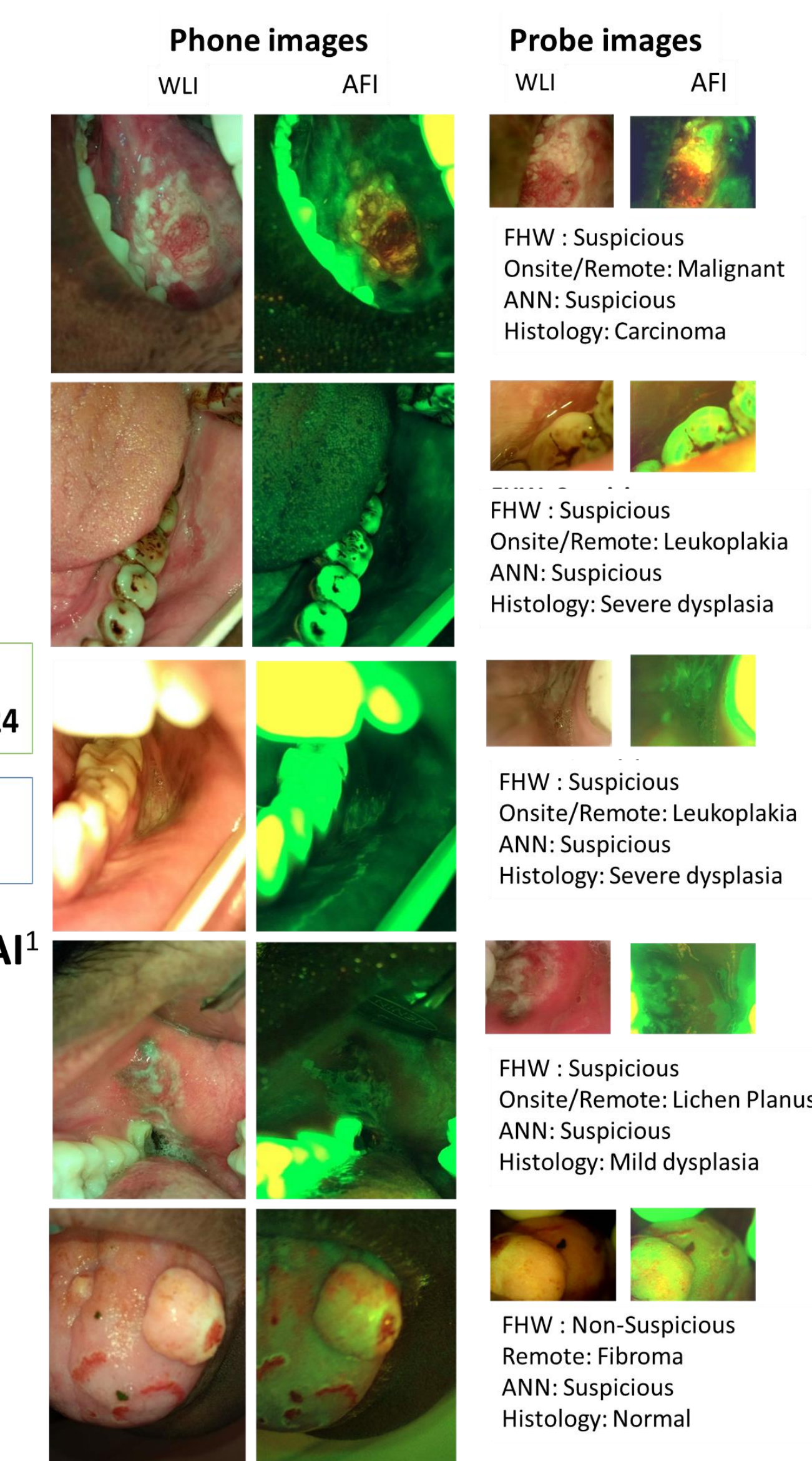


Lesion visualize by specialist and AI¹



*AI = Artificial Intelligence

Images and Diagnosis



- Artificial Intelligence integrated PoC device deployed with FHW is equivalent to remote specialist in detection of oral pre-cancer/ cancer
- Dual-mode device is robust and accurate which can empower the FHWs for early detection of oral cancer (Sensitivity = 82%)
- Frequent training of FHW for using device and identifying oral lesions is important (Sensitivity = 60%)
- PoC device can be deployed with FHWs for oral cancer screening in Large Volume High Risk Population

Conclusion

- Novelty : Validated robust, low cost, portable PoC device for oral cancer screening in Low-resource setting by FHW
- AI integrated device could delineate oral cancer/pre-cancer lesion with high sensitivity (Cloud NN sensitivity =87%)
- Accuracy of Phone-based AI has to be improved (Large data set needed)

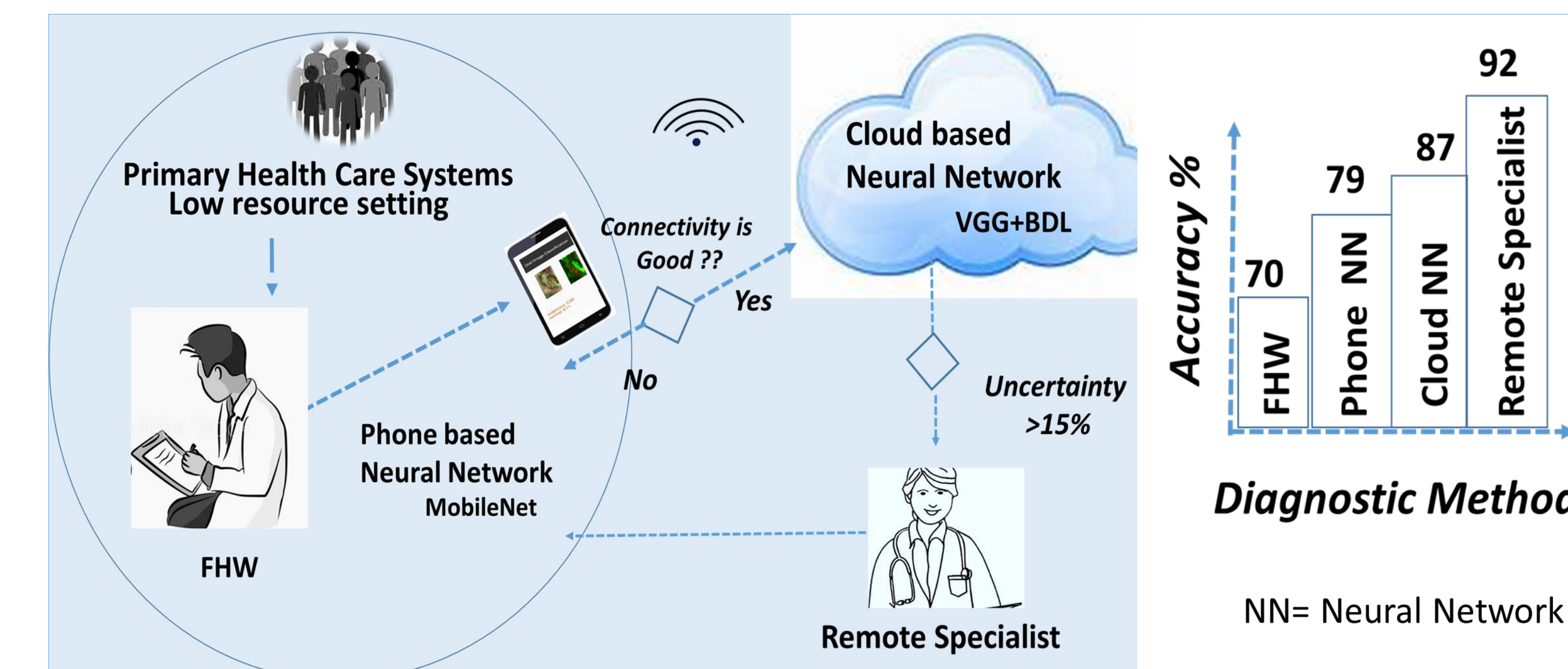
Publications

- Mobile-based oral cancer classification for point-of-care screening *J Biomed Opt* June 2021 **26(06)**
- Small form factor, flexible, dual-modality handheld probe for smartphone-based, point-of-care oral and oropharyngeal cancer screening. *J Biomed Opt* 2019 **Oct;24(10):1-8.**
- Point-of-care, smartphone-based, dual-modality, dual-view, oral cancer screening device with neural network classification for low-resource communities. *PLoS One* 2018 **Dec 5; 13 (12)**
- Development of a dual modality, dual-view smartphone-based imaging system for oral cancer detection," *Proc. SPIE 10486, Design and Quality for Biomedical Technologies XI, February 2018*

Differentiating oral cancer/pre-cancer from Benign/normal lesions

Test Vs Reference standard diagnosis	sensitivity (95%CI)	Specificity (95%CI)
Remote vs Onsite specialist	96.83% (95- 98)	83.53% (78-88)
FHW vs Remote specialist	60.03% (58-62)	77.83% (76-79)
MobileNET (Phone integrated AI) Vs Remote specialist	81.76% (78-85)	76.51% (74-79)
VGG19 (Cloud integrated AI) Vs Remote Specialist	87.14% (84-90)	86% (84-89)

Pipeline for using Point of Care diagnostic tool



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