



Screening for Oral and Oropharyngeal Cancer: A Comprehensive Solution for Better Outcomes

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Oral and Oropharyngeal Cancer (OC)

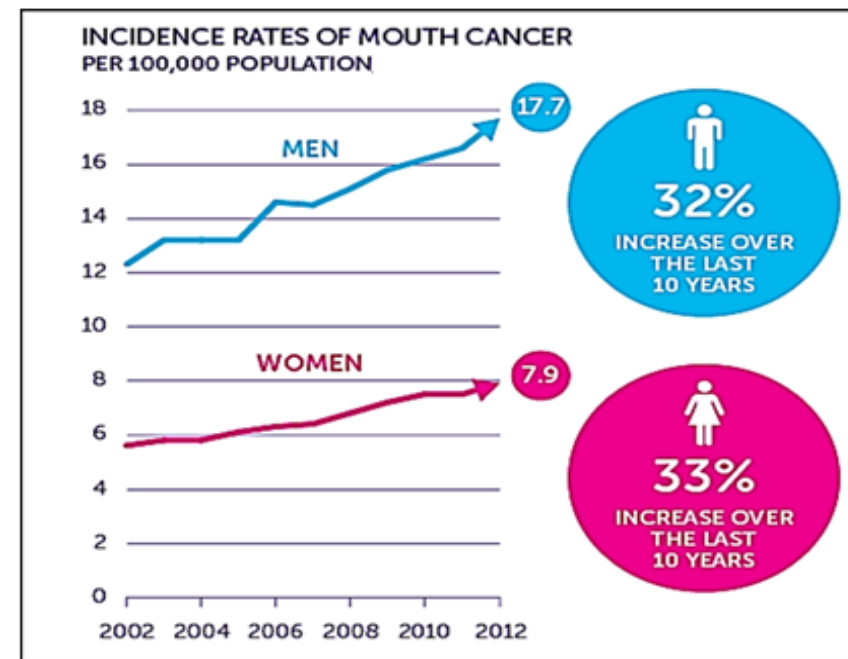
- Only major cancer whose outcome has not improved over past generation
- Tumors of mouth and oropharynx are some of the most frequent head & neck cancers
- HPV-related increase in OC incidence rates worldwide

In US¹

- 150,000 new cases annually
- 400,000 people living with OC
- 13,000 deaths annually

Worldwide²⁻⁴

- 600,000 new cases annually
- Estimated 2,000,000 people living with OC
- Estimated 220,000 deaths annually
- OC accounts for up to 40% of cancers in some regions



Problem

In High Income Countries

- 5-year survival:
 - 80% for early disease
 - 15 - 40% for cancer metastasis
- **More than 2/3 of all OCs are diagnosed at an advanced stage**
- High risk populations typically do not have access to early diagnosis

In Low/Middle Income Countries

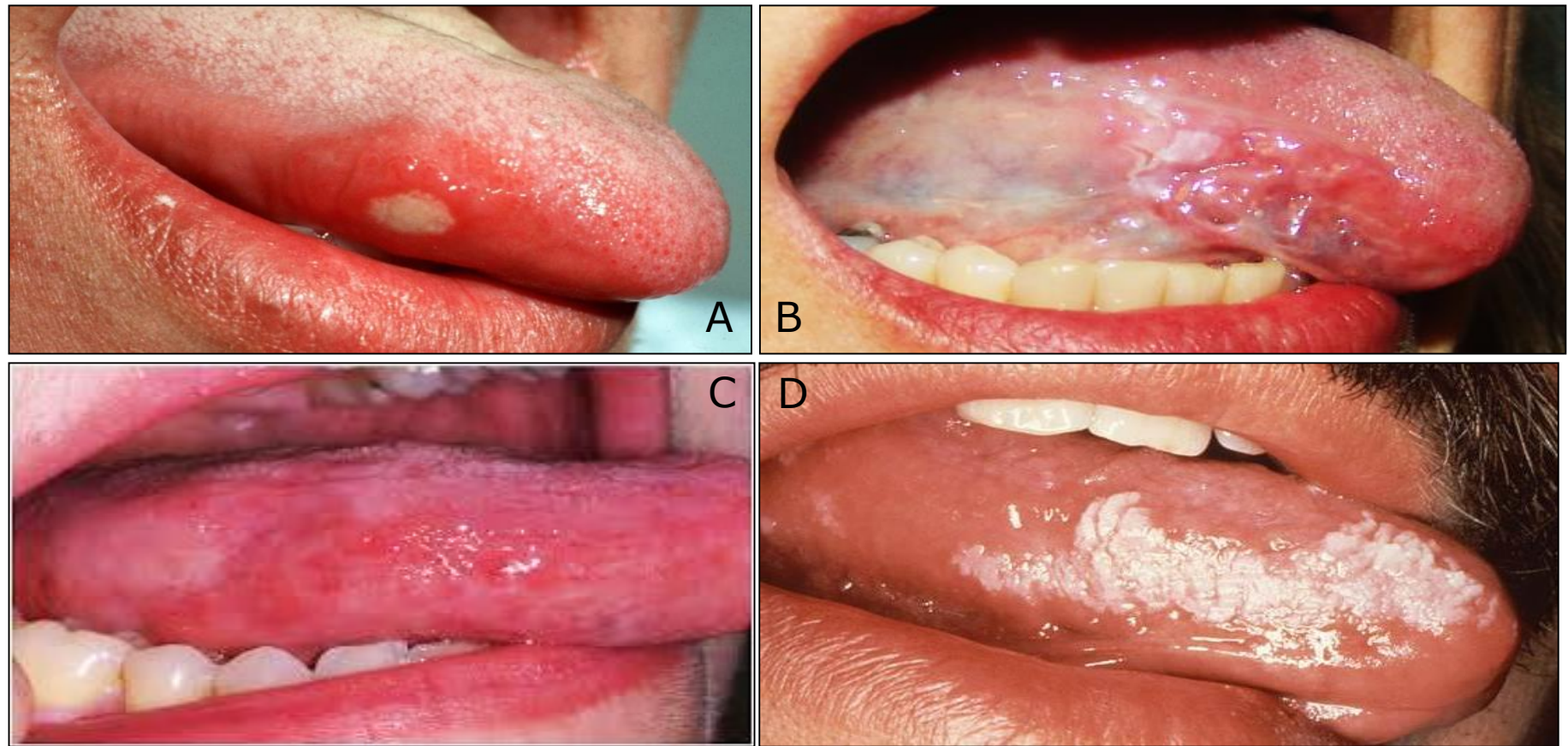
- 5-year survival is 10 - 40%
- **Over 90% of all OCs are detected at an advanced stage**
- In some developing countries, OC is #1 cause of death
- More than 90% of high risk individuals do not have access to early diagnosis

Current Path to OC Treatment

1. Positive screening outcome by hygienist/dentist/physician/nurse/screener
 - Typical screening accuracy 30-60%
2. Referral to specialist
 - History
 - Clinical exam
 - Biopsy
3. Biopsy to Pathology Lab
 - Processing
 - Pathologist evaluation and report
4. Repeat specialist visit
 - Diagnosis
 - Treatment planning and referral
 - Regular (biopsy-based) monitoring every 3, 6 or 12 months

Why is it so difficult to detect OC?

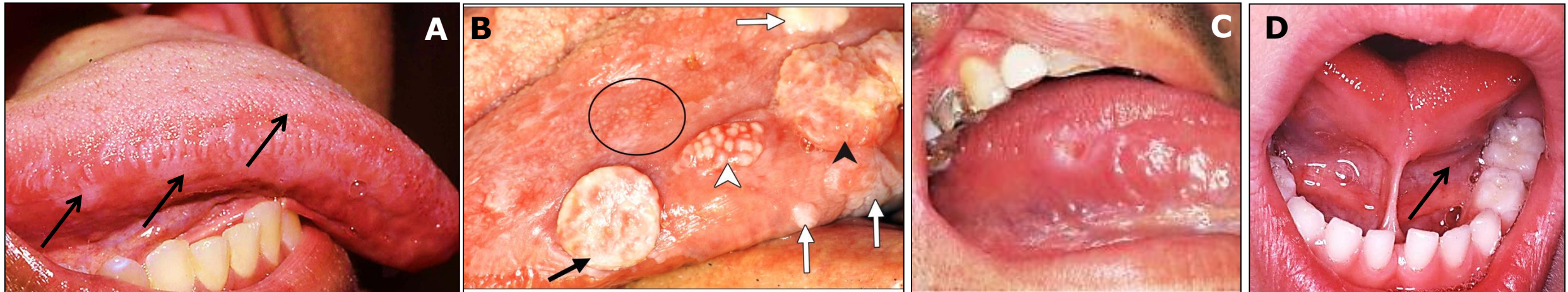
Can you determine which lesion depicts a malignancy and a premalignancy?



Why is it so difficult to detect OC?

Additional challenges in early detection and diagnosis

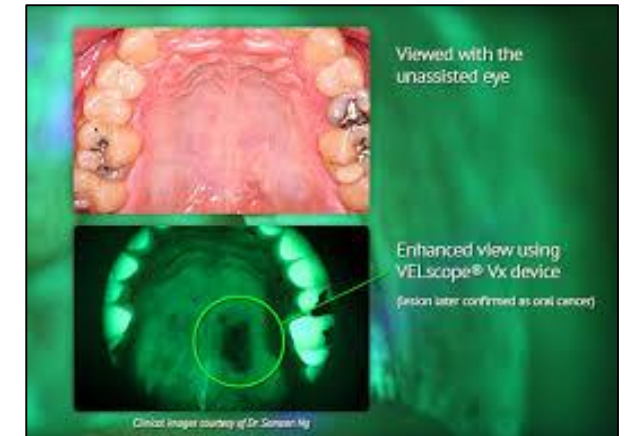
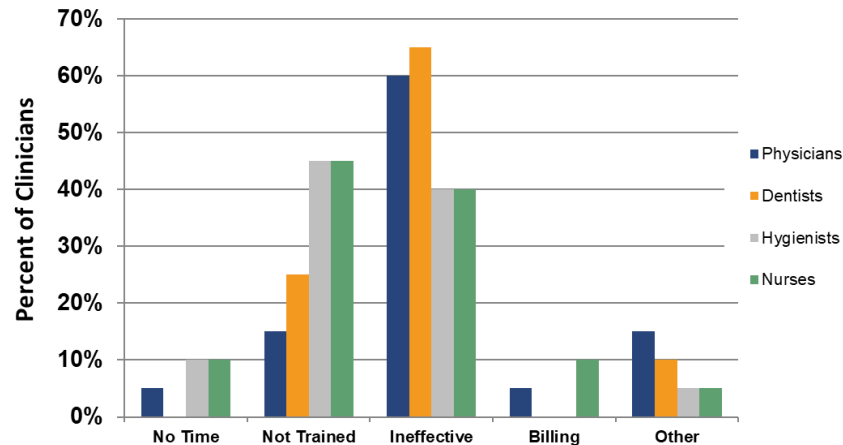
- Lesion monitoring (A)
- Field cancerization (B)
- Heterogeneity
- Recurrence (C)
- HPV (D)



Evaluation of Current Screening Practice

1. Hygienists, dentists, nurses, physicians mandated to examine for OC

- < 50% of clinicians feel competent
- Screening accuracy is poor: risk factor assessment, palpation, visual exam, cannot access all areas
- Surgical biopsy remains sole diagnostic and monitoring tool
- Adjunctive tools: costly, complex, specialist-oriented, no decision-making guidance, poor specificity, limited access



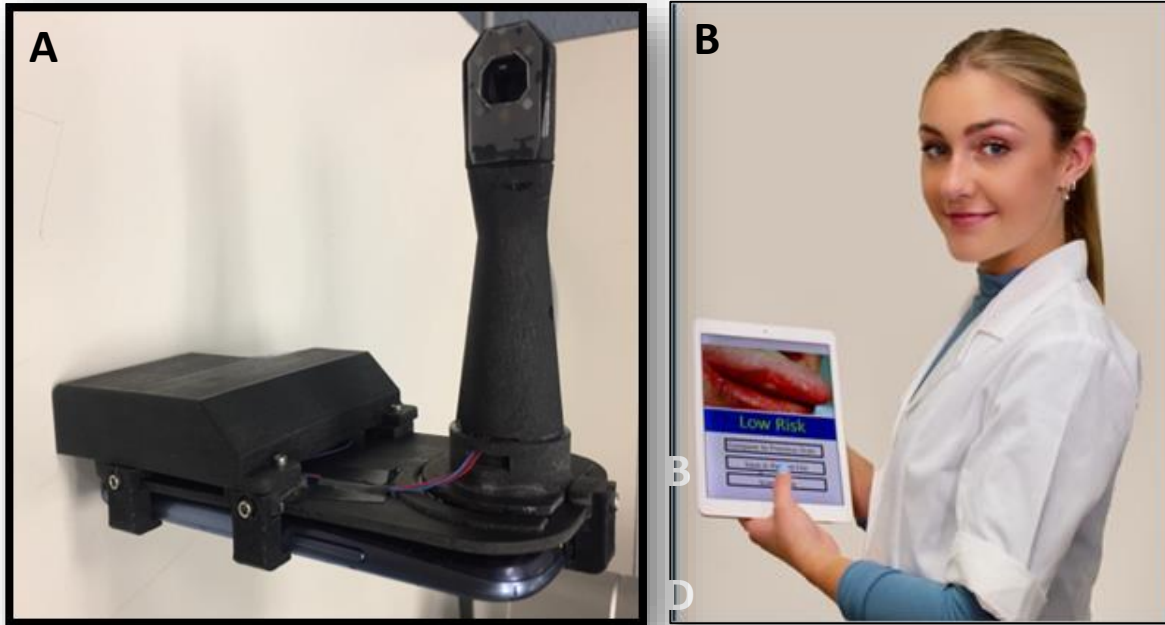
85% of clinicians cited “ineffective” (51.25%) or “inexpert” (32.5%) as primary reason for NOT screening

Solution

- **Novel smartphone-based solution for detecting and diagnosing OC**
- Images at any site in oral cavity, oropharynx
- Proprietary Artificial Intelligence (AI)
 - **Provides immediate screening outcome**
 - **Automatically measures lesion progression**
 - **Provides immediate decision-making guidance**
- Designed for use by community screeners, all clinicians
- Remote-enabled for real-time, off-site specialist input
- Very low cost, robust, compact and light



Oral Cancer Smartphone Probe



First (A) and third (B-D) generation oral cancer smartphone probe prototypes.

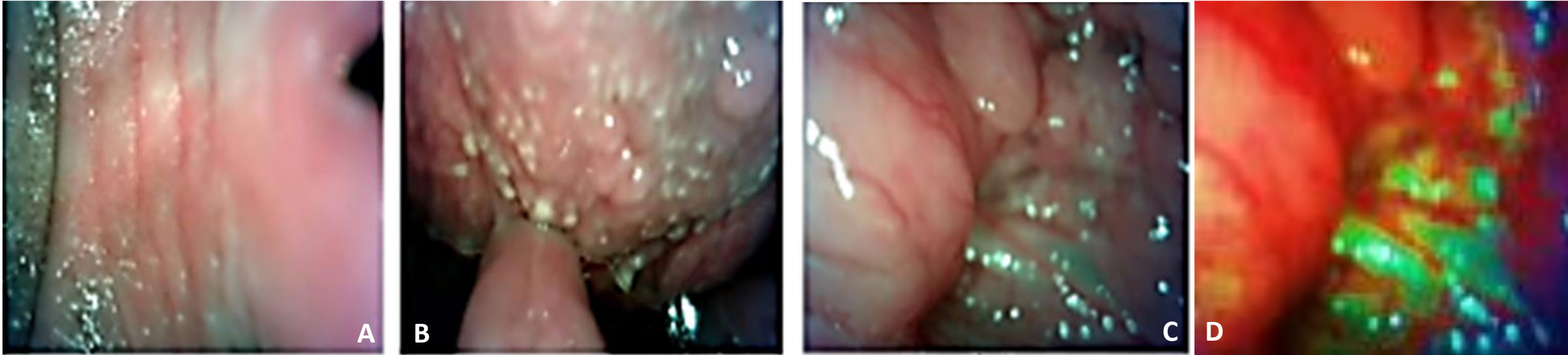
The third generation model provides imaging access to all areas of the oral cavity including the base of the tongue and oropharynx.



Oral Cancer Smartphone Probe

- One-step recording of images
- Probe provides easy access to high risk sites
- Large field of view (3cm x 3cm)
- Also functions as high-resolution dental intra-oral camera
- Diagnoses previously inaccessible areas (HPV-related base of tongue & oropharynx)
- High contrast & resolution in-focus images of all sites
- Images immediately visible on smartphone or tablet screen
- Proprietary Artificial Intelligence (AI) provides immediate screening outcome

Oral Cancer Smartphone Probe



Smart phone probe images

A: White Light Image (WLI) lower vestibule

B: WLI base of tongue

C,D: WLI and combined fluorescence image w pseudocolor of tonsillar region w green OSCC lesions

E,F: WLI and fluorescence image w pseudocolor of sublingual region w white ulcerated & hyperkeratinized lesions, no neoplasia

Sites

1. University of California, Irvine
2. Mazumdar Shaw Cancer Center, Bangalore, India
3. KLE Dental School, Bangalore, India
4. mhealth (Biocon Foundation), Kerala, India



Screening Performance in Remote Community Setting

9,468 subjects diagnosed as healthy, dysplastic, malignant or “other” by

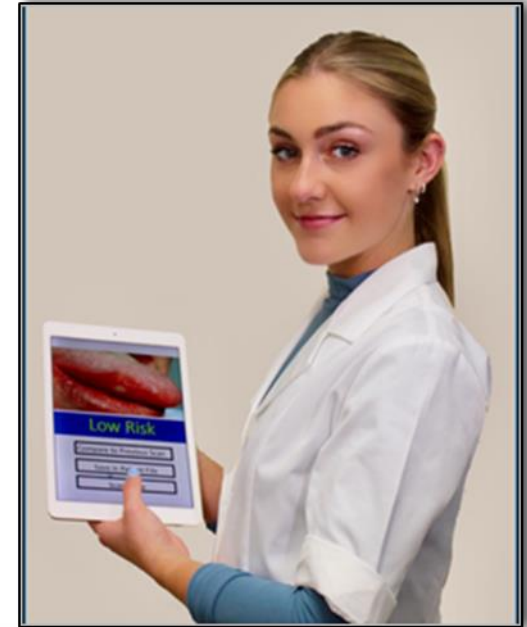
- Clinical assessment by community screener (CS) after oral cancer screening training
- Clinical assessment by CHW PLUS visual assessment of probe image by CS
- AI-driven diagnosis using images & convolutional neural networks

	CS: Clinical Evaluation + Risk Factors	CS: Clinical Evaluation + Risk Factors + Probe Image	Artificial Intelligence Diagnosis
Healthy	76.3%	71.7%	90.7%
Dysplastic	47.8%	58.8%	82.0%
Carcinoma	44.3%	62.3%	88.3%
<i>Other</i>	<i>56.3%</i>	<i>63.9%</i>	<i>85.9%</i>
MEAN	56.1%	64.3%	86.4%



Conclusion

- **Novel smartphone or tablet-based solution for oral cancer detection**
- **Proprietary AI-enabled** screening and triage guidance enables
 - earlier, more accurate referral
 - earlier care and better outcomes
- One-step automated process customized for ease of use
- Direct data, voice and video connect to off-site specialists
- HIPAA-compliant data protection
- Compatible with most smartphones and tablets



What's Next & the Big Picture:

A seamlessly integrated solution for OC

Low-cost non-specialist screening tool

screeener, physician, dentist, hygienist, nurse

*one-step triage
monitoring output
full mouth access incl HPV sites
specialist linkage
calendarng app links*

Security-compliant data share

High performance specialist tool

OM specialist, oncologist, surgeon

*maps heterogeneity
identifies biopsy sites & non-visible sites
delineates lesion margins in 3-D
treatment planning
intraoperative margins
early ID of recurrence*

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