

# NATURAL HISTORY OF ORO-PHARYNGEAL CANCER PRECURSORS: A PILOT STUDY

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Canadian Association of Hospital Dentists Annual General Meeting

Halifax, NS

May 13, 2016

# MuCOSAL

Multi-Center Oro-pharyngeal Squamous Atypical Lesions

Natural history of oro-pharyngeal  
cancer precursors: a pilot study

# Overview of Study Design



- The MuCOSAL study is an international prospective cohort study
- Consist of pilot studies taking place in the U.S.A., Canada, Brazil
- In each site, 40 patients with leukoplakia or erythroplakia followed over 1 year for a total of 3 visits

# Objectives – long term

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- Among patients with potentially malignant oral lesions (leukoplakia and erythroplakia)
  - To study molecular, infectious, lifestyle factors, gene expression profiles and DNA methylation patterns
- ⇒ in relation to the risk of progression to oropharyngeal cancer

# Objectives – short term



- To describe the prevalence of risk factors and HPV infection, the progression of precursor lesions over one year
- To describe, for oral lesions and normal mucosa:
  - ▣ Gene expression profiles (high throughput DNA microarray analyses)
  - ▣ DNA methylation patterns

# Objectives – short term Canada



- To implement and evaluate the recruitment and data collection procedures, including:
  - ▣ the identification of potential participants
  - ▣ the recruitment & consent from eligible participants
  - ▣ the collection of biological specimens for molecular analysis
  - ▣ the conduct of in-person interviews
  - ▣ the compliance with follow-up return visits

# Eligibility criteria

- Presence of visible red or white plaques in the oral cavity or oropharynx
- Age 21 years or over
- Speak English or French

- No cognitive or mental disorders
- No treatment for oral lesions in previous 6 months
- No medical history of HIV infection, AIDS or OPC

# Study procedures

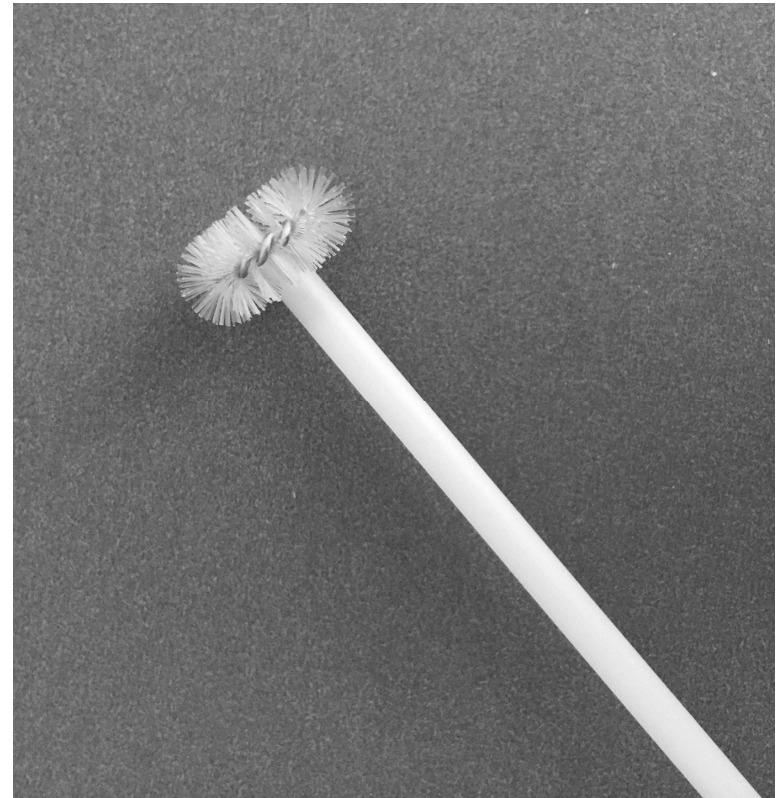


	Visit 1 (baseline)	Visit 2 (6 months)	Visit 3 (12 months)
Collection of oral cells	✓	✓	✓
Excision biopsy if clinically indicated	✓	✓	✓
Interview	✓	✓	✓



# Analyses conducted on oral cells

- Cytology
- HPV DNA detection
- Gene expression
- DNA methylation



# Questionnaires

	Visit 1	Visit 2	Visit 3
Socioeconomic position	✓	✓	✓
Smoking habits	✓	✓	✓
Nutritional aspects	✓	✓	✓
Sexual behavior	✓	✓	✓
Oral Health	✓		✓
Medical history	✓		✓
Family history of cancer	✓		✓

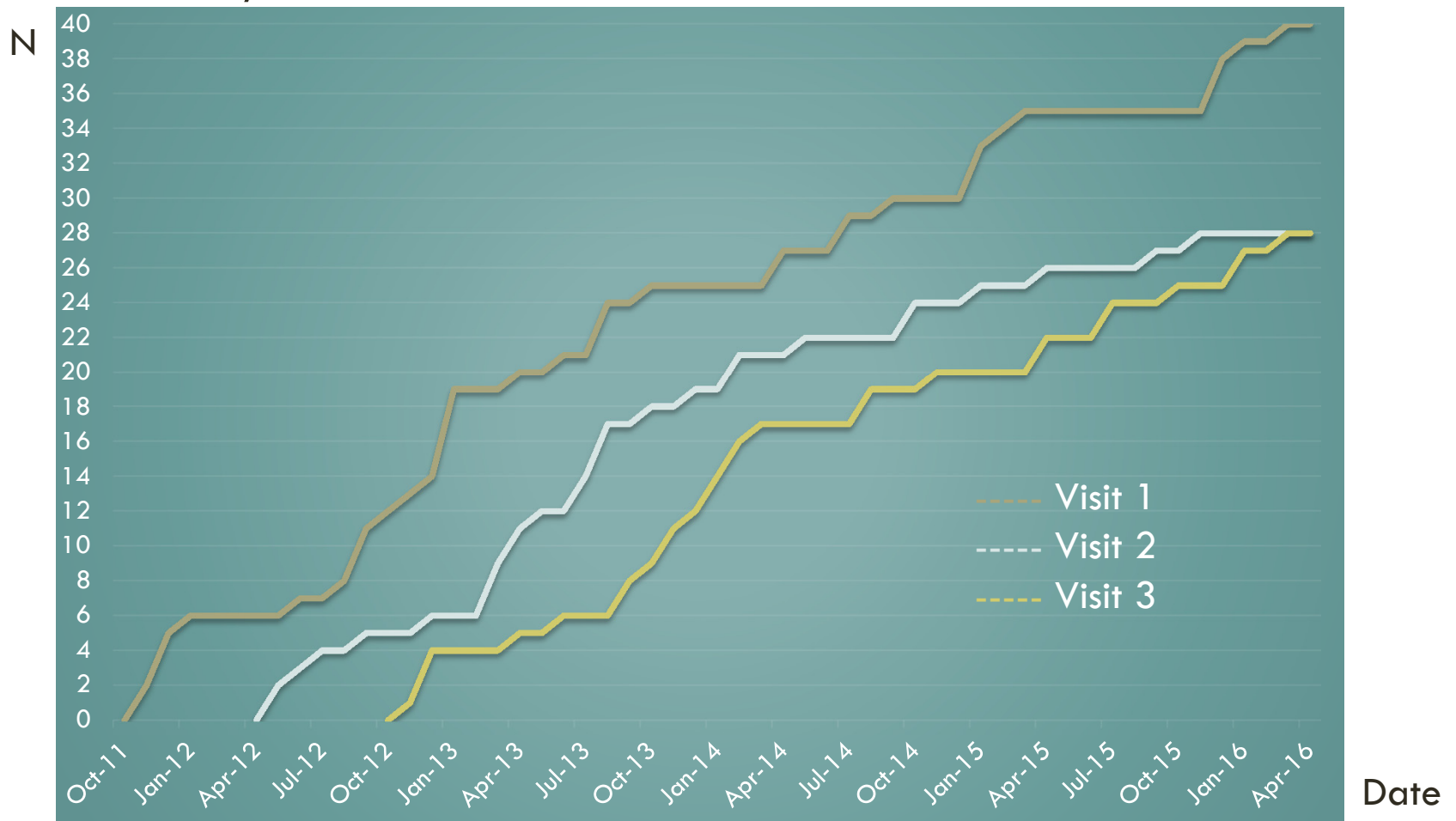
# Preliminary look at the data

- Recruitment completed in the 3 sites. Follow-up is completed in U.S.A. and Brazil, ongoing in Canada
- Canada site, n = 35:

Variable	
Age (average, years)	59
Male sex	43%
Lesion:	
Leukoplakia	85%
Proliferative verrucous leukoplakia	10%
Erythroplakia	5%
HPV positive	11%

# Recruitment and follow-up – Canada

■ 6 clinics/hospitals & 6 clinicians



# Methodological aspects

	Went well	Problematic
Identification of potential participants		✓
Recruitment & consent from eligible participants	✓	
Collection of biological specimens for molecular analysis	✓	
Conduct of in-person interviews	✓	
Compliance with follow-up return visits	✓	

# Issues / Solutions

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- There was more clinical information available during clinical exam than what the data collection form was able to capture
  - ⇒ Data collection form needs to be improved to provide a more detailed documentation of lesions and their evolution. E.g., adding digital pictures
  - ⇒ Importance of testing data collection forms before creating the final research/registry template

# Issues / Solutions

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- Identification of potential participants was more difficult and slower than anticipated:
  - ▣ No centralized clinic or reference database from which patients with these lesions can be reached
  - ▣ They are referred by various health professionals, (dentists, family physicians, etc.) to a variety of specialized clinics
- ⇒ **We added clinics/hospitals as only few participants could be identified in each one**

# Registry of potentially malignant oral lesions

- Dr. Makhoul obtained funding for establishing a registry of potentially malignant oral lesions
- REDCap software
- Initially, at Montreal General Hospital and Glen site of the McGill University Health Center
  - ▣ Medium term: provincial
  - ▣ Long term: national and international



# Registry in the context of patient recruitment for epidemiological studies

- Potential to impact
  - ▣ Our ability to do useful research with this patient population
  - ▣ The quality of care that they receive
- In the long term
  - ▣ Effective interventions to prevent the development of oral and oropharyngeal cancers at an early stage

# MUCOSAL STUDY TEAM

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