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Evaluating Barriers to Clinical Trial Enrollment in Head and Neck Surgical Oncology

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Introduction

Nationwide, clinical trial enrollment is very low for eligible patients, averaging 3-5%, and this has a significant impact on both patient's health as well as medical research outcomes. The current paradigm is more focused enrollment of historically underrepresented groups, however, additional research is directed at potential clinic based solutions for how to more effectively recruit all patients. Studies are showing improved clinical efficiency when using medical scribes (Gidwani et al., 2017) as well as using artificial intelligence software to screen for eligible patients (Calaprice-Whitty el al., 2019). Jefferson's Otolaryngology department has recently transitioned to full-time scribe coverage for the Head and Neck cancer clinics in addition to increased patient volume over the past few years and is interested in determining what methods, if any, may be effective ways to enroll more patients on clinical trials. We are interested in exploring issues with recruitment from the patient and clinician perspectives and figuring out how to increase Jefferson's rate of enrollment into clinical trials.

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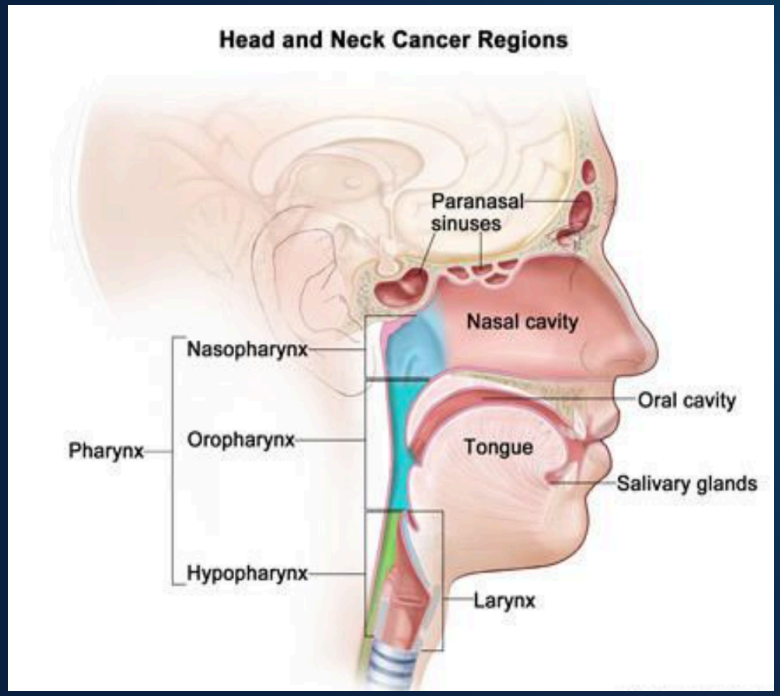
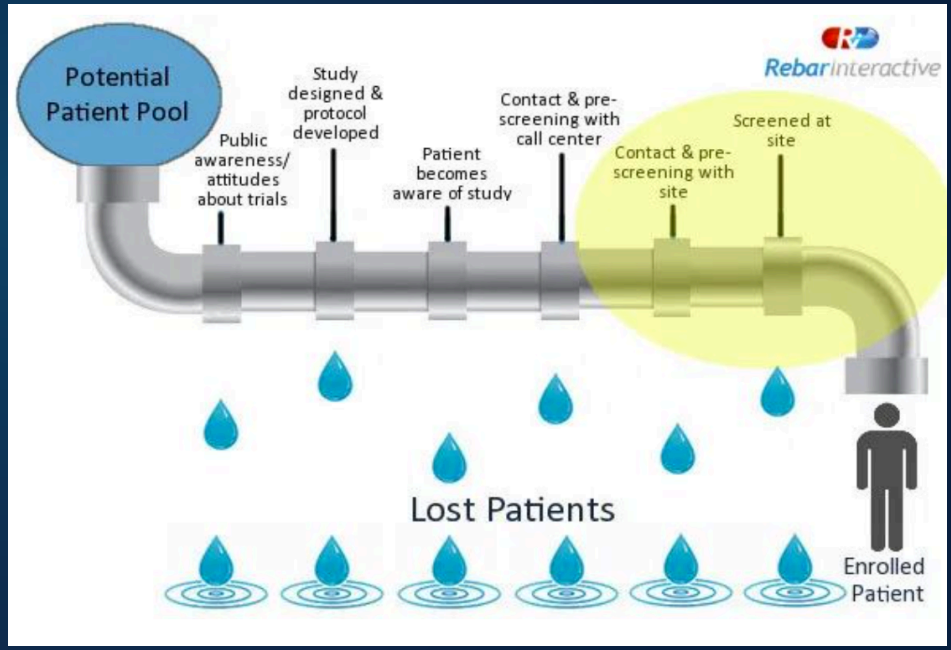
Introduction





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Objectives & Hypothesis

- Research Question
  - What are possible barriers to enrollment from the perspective of both surgical oncologists and their patients?
- Hypothesis
  - Use of an Epic SmartPhrase for evaluation of common barriers to clinical trial enrollment will allow further documentation for explanations of ineligibility or refusal to enroll.
  - Additionally, we anticipate that lowered wait times will lead to increased patient enrollment into clinical trials

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Approach & Results

- Study design: Prospective Observational
- Population / study sample: Patients who were eligible for any of the 8 clinical trials for H&N cancer offered at Jefferson between August and December 2020 were identified.
- Intervention: Pending, but a video to be played in the clinic waiting room with basic information regarding clinical trial enrollment.
- Data source and collection: Epic EMR and REDCap
- Rationale for Approach: We utilized an Epic EMR phrase to capture if a trial was offered or not and why, whether a patient refused enrollment and why, and patient wait time.

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Was the patient offered a clinical trial?

* must provide value

- ○ Yes, patient agreed to enroll
- ○ Yes, patient agreed to surgeon but declined to clinical trial staff
- ○ Yes, patient to make decision at future appointment
- ○ Yes, but patient declined
- ○ Discussed trial, trial to be offered after surgery
- ○ Biopsy ordered/results pending, trial TBD
- ○ Not offered, patient not eligible for open trials at Jefferson
- ○ Not offered, trial not appropriate treatment
- ○ Not offered, poor performance status
- ○ Not offered, poor clinical picture
- ○ Not offered, no trial available for patient's cancer
- ○ Not offered, not cancer
- ◉ Not offered, N/A (forgot)

reset

Why was patient ineligible or trial not offered? (optional)

Which trial was offered?

- ☐ Nivolumab + IDO Inhibitor
- ☐ Durvalumab + Metformin
- ☐ Nivolumab Induction (Carboplatin + Paclitaxel)
- ☐ Chemo/Surgery/Radiation vs. Surgery/Radiation Alone for Paranasal Sinus Squamous cell carcinoma)
- ☐ Nivolumab + Ipilimumab
- ☐ Photoimmunotherapy vs Standard of Care
- ☐ Thyroid + Metformin
- ☐ ETIP (Tobacco Cessation Protocol)
- ☐ Other

If trial was not listed, write here:

If patient refused, why?

- ☐ Time commitment
- ☐ Distance
- ☐ Wait time
- ☐ Concerns about clinical trial involvement
- ☐ Concern regarding perceived delays in treatment
- ☐ Generally uninterested

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Approach & Results

During the 4 month period, the clinic saw 45 new patients with a cancer diagnosis and the EMR SmartPhrase was used 32 times. For those offered a trial, 38.5% agreed to enroll and 15.3% deferred to make a final decision at a later appointment. Of patients that were eligible for a trial but declined, 60% were due to concerns about clinical trial enrollment and 40% because of general disinterest. Reasons for ineligibility were more difficult to track in the group where SmartPhrase was not used because the providers' thought processes were not declared. We will present average wait time data at a later time.

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Approach & Results

August 2020-December 2020

Patients offered trial	13
Said Yes	6
Deferred	2
Said No	5

Condition or disease	Intervention/treatment
Lip	Biological: Nivolumab
Oral Cavity Squamous Cell Carcinoma	Biological: IDO1 Inhibitor BMS-986205
Pharynx	Procedure: Therapeutic Conventional Surgery
Larynx	Other: Questionnaire Administration
Squamous Cell Carcinoma	

Condition or disease	Intervention/treatment
Lung Non-Small Cell Carcinoma	Drug: Nicotine Replacement
Head and Neck Squamous Cell Carcinoma	Drug: Bupropion Hydrochloride Controlled-release
	Drug: Varenicline
	Other: Tobacco Cessation Counseling
	Other: Questionnaire Administration
	Other: Quality of Life Assessment
	Other: Best Practice

Nivo + IDO trial and ETIP trial were the two most commonly enrolled trials

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Conclusions

- Our preliminary data shows an increased rate of patient enrollment (38.5%) into clinical trials compared to the national average (3-5%)
  - Likely this percentage will fall with increased patient volume but could be lower due to concerns about COVID
- Standardizing clinic note templates with the Epic SmartPhrase likely leads to increased patient enrollment
  - Consistent usage of SmartPhrase was complicated by scribe and departmental turnover during the 4 month period
- We are awaiting data regarding patient wait times, which may pose a major barrier in enrollment

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Future Directions

We are currently designing the intervention, which is a video with basic information and FAQ's regarding clinical trials, featuring the surgical and medical oncologists as well as the clinical trial coordinator for the cancer center. This will be shown in the waiting room of the clinic on repeat so that new patients are more comfortable with the topic of clinical trials before they are approached about it by the surgeons. By time of implementation, we will have approximately 6 months of pre-intervention data.

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