

**Working Collaboratively To  
Address Clinical Concerns  
Through Research –  
Pain and Mucositis in High-  
Dose Chemotherapy Patients  
as a Model**

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**Thank you to ASPMN for  
the research grant support  
for this study**

PS You too can apply for a grant –  
if you don't try you will never know

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**Disclaimer Notice**

- We do not have all of the answers
- We do want to hear from you
- We do want to learn together
- We do want this to be fun

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### Getting to Know You – Making This Meaningful

- Clinicians
  - Inpatient
  - Outpatient
- Educators
- Researchers
- Combined roles

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### Research Prompted by Clinical Issues of Importance

- Avoiding an us/them situation
- Working together to make a difference
- Listening and learning
- Articulating concerns
- Thinking creatively

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### Our Setting

- The Nebraska Medical Center
- Tertiary care center extensive medical research
- Two colleges of nursing on campus
- Clinical Nurse Researcher(s) in Nursing Department

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## Our Clinical Focus - Oncology

- Inpatient acute care including critical care management
- Focus on high-dose chemotherapy
  - Stem Cell Transplant
  - Acute Leukemia
- Adult and pediatrics

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## Mucositis

- Expected side-effect secondary to chemotherapy and radiation therapy

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## Mucositis ≠ Stomatitis

- Mucositis – inflammatory process involving the mucous membranes of the oral cavity and gastrointestinal tract.
- Stomatitis – inflammatory diseases of the mouth including:
  - Mucosa
  - Dentition
  - Periapices
  - Periodontium

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## Mucositis as a window

- Mucous membranes throughout the body
  - Throat
  - Esophagus
  - GI tract
  - Vagina
  
- We can see in the mouth

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## Mucositis - Cont

- Multi-phase process theoretically - Sonis

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## Patho-Physiology of Mucositis

- I. Initiation
- II. Up-regulation and message generation
- III. Amplification and signaling
- IV. Ulcerations
- V. Healing

Sonis 2004

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## Patho-Phys - Cont

### ➤ Phase I – Initiation

- Immediate effect on oral tissues
- Reactive oxygen species (ROS) injury to tissues & initiate series of biological events
- DNA damage results in death of cells

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## Patho-Phys - Cont

### ➤ Phase II - Up-regulation and message generation

- Damage to tissues causes biological switches to be turned on
- Send message to make different proteins or compounds in tissues of mucous membranes

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## Patho-Phys - Cont

### ➤ Phase III - Amplification and signaling

- Cytokines or messenger proteins produced target mucosal tissue
- Cause further injury and activate other messengers
- Damage and death at cellular level
- Mucosa become thin, reddened and painful
- Feedback system further activation

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## Patho-Phys - Cont

- Phase IV - Ulcerations
  - Reddened, painful mucosa thins
  - Normal healing restricted
  - Open breakdown occurs
  - Oral flora further damage
  - Inflammation

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## Patho-Phys - Cont

- Phase V - Healing
  - Growth of cells of mucosa resumes
  - Recovery occurs
  - Remains sensitive

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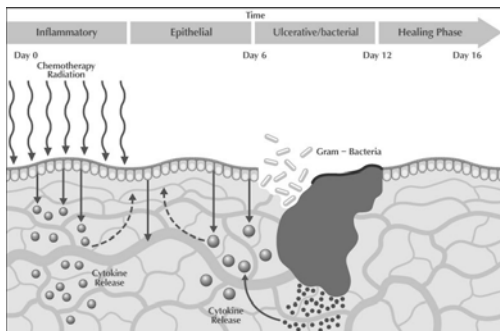
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## Phases of Mucositis



Sonis 2004

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## Mucositis – So What?

- Patients
  - Severe ***PAIN!!***
  - Difficulty eating, drinking, swallowing, speaking
- Professionals
  - Mucous membrane breakdown
    - Life-threatening infections
    - Pain

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## Significance – Why Are We Concerned?

- Mucous membrane breakdown
  - Portal for infection
  
  - Dose limiting side effect
  
  - Treatment delays
  
  - Dose reductions

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## Mucositis & Pain

- Coming together to examine the problem
  
- No universally applicable intervention to prevent mucositis
  
- Must focus on symptom control i.e. pain

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### Clinician Findings

- Evolving process – they feel it – we can't see it
- Most patients aren't prepared for how bad it might become
- Worse after all night without care
- Interferes with any movement in the mouth

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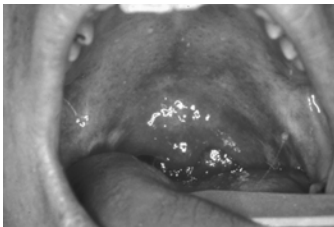
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### Erythema



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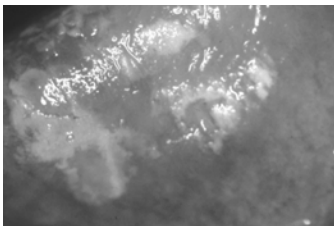
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### Ulceration



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**Severe Oral Mucositis in a Transplant Patient**



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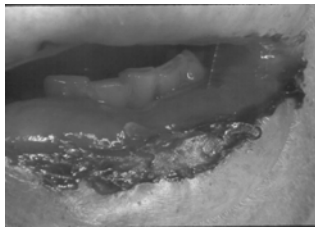
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**Grade 3-4 Mucositis (WHO Scale)**



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**Measurement Instruments**

- Clinical setting
  - Clear
  - Concise
  - Clinically useful
- Research
  - Validity
  - Reliability
  - Consistency

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## Bridging the Worlds for Research

- Oral Assessment Guide (OAG)
  - Developed at institution 1980s
  - Part of daily 24 hour flow record
  - Completed by nurse every shift
  - Clear, concise, clinically useful
  - Previously used in research studies

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## Pain Assessment

- Research tools
- Self report
- Clinical setting – Numerical Rating Scale
  - 0 to 10
  - Documentation

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## Clinical Concern

- Pain a major issue for patient care on unit
- Challenge of mucositis pain
  - Type(s) of pain
    - Inflammation
    - Neuropathic ?
  - More than visually apparent
- Rating by patient when worse than ever expected/imagined/experienced
- Knew we could do better

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## Research Plan

- Focus on mucositis severity and pain intensity
- Use of existing chart data
- Document current state
- Develop proposed algorithm for improved proactive approach to pain management
- IRB approval

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## Purpose

- To describe the patterns of mucositis-related pain and oral cavity changes to provide data for the development of an algorithm to guide mucositis-related pain management

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## Background

- GI tract rapidly dividing cells – mucotoxicity
- Mucositis dose limiting side-effect
- Pain with mucositis can be intense
- Management of acute persistent pain
- Pain with activity

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## Setting/Sample

- Oncology/Hematology Special Care Unit
- High-dose chemotherapy patients receiving stem cell transplant
- Retrospective 12 month time period

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## Design

- Retrospective chart review
- Regular documentation
  - Oral Assessment Guide scores
  - Pain scores
  - Narrative charting

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## Instruments

- Numeric Rating Scale for Pain
- OAG for mucositis

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## Pain Assessment

- Required every shift
- Pre and post intervention scores
- Increased frequency based on presence of pain
- Multiple sites/causes of pain

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## Oral Assessment Guide

- Categories
  - Voice
  - Swallow
  - Lips
  - Tongue
  - Mucous membranes
  - Gingiva
  - Teeth

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### Oral Assessment Guide

Developed by  
The University of Nebraska  
Medical Center

Category	Voice	Swallow	Lips	Tongue	Saliva	Mucous membranes	Gingiva	Teeth, Dentures, and Implants
Look for	Normal voice	Swallow	Normal lip function	Normal tongue function	Normal saliva	Normal mucous membranes	Normal gingiva	Normal teeth, dentures, and implants
Methods of Measurement	Visual observation	Visual observation	Visual observation	Visual observation	Visual observation	Visual observation	Visual observation	Visual observation
<b>1</b>	Normal voice	Normal swallow	Normal lip function	Normal tongue function	Normal saliva	Normal mucous membranes	Normal gingiva	Normal teeth, dentures, and implants
<b>2</b>	Hoarse voice	Swallow with difficulty	Lips not closed	Tongue not in mouth	Excessive saliva	Reddened mucous membranes	Gingiva with inflammation	Teeth with decay or damage
<b>3</b>	No voice	Swallow with difficulty	Lips not closed	Tongue not in mouth	Excessive saliva	Ulcerated mucous membranes	Gingiva with severe inflammation	Teeth with severe decay or damage

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## Sample – Cont

- Chemotherapy regimen
  - BEAM
  - CyTBI
  - Mini-MUD
  
- Type of transplant

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## Mucositis Data

- Massive number of scores
- Narrowed analysis focus – day 1 – 20
  - 2909 oral assessments
  - Capture critical time
  - Decrease wide variability in number of days

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**Highest Frequency of OAG Total Scores by BMT Day**

Day #	OAG Total Score						Total
	8	9	10	11	12	13	
1	83	58	37	21	15	7	225
2	50	60	50	34	13	15	232
3	47	46	44	24	26	15	223
4	21	46	59	30	22	20	226
5	14	50	29	31	26	27	217
6	12	39	35	36	29	30	225
7	16	27	40	42	21	39	223
8	17	28	36	41	24	38	225
9	19	25	33	31	25	29	192
10	20	24	24	29	27	25	190
11	19	23	21	30	22	21	168
12	12	8	33	26	18	8	130
13	15	17	17	13	13	9	106
14	8	15	14	16	7	5	83
15	3	10	8	14	9	4	63
16	1	5	10	13	9	8	55
17	0	3	7	10	6	2	37
18	2	7	6	6	4	1	34
19	3	2	9	2	5	6	29
20	4	3	7	3	4	3	26
Total	366	496	519	452	324	312	

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### Discussion - Pain

- Multiple sites/causes of pain
- Use of pain scores from clinical data
- We don't do as bad as we thought
- We want to do better

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### Discussion - Mucositis

- Wide variability in severity confirmed
- Usefulness of OAG clinical data
- Additional support for OAG as instrument
- Mouth as window

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### Clinical Implications - Pain

- Use of numeric scale when no previous experience with mucositis
  - No problem – no pain
  - Mucositis membrane changes – discomfort
  - Doesn't look bad, but hurts
  - How high can it go?
- Directions for use of pain scale???

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## Clinical Implications – Pain Cont

- Reality of multiple sites of pain
- Prevention of severe pain versus crisis management
- Mucositis related pain – most effective medication ???

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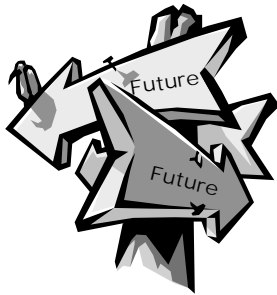
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## Future Direction



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## Next Step

- Additional analysis – growing number of questions
- Development and implementation of algorithm for pain management
- Plan clinical research study to evaluate algorithm

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## Immediate Next Steps

- What clinical issues can you study?
- Who are your potential partners in the effort?
- Can you seek funding to support your study?

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**Go Forward and  
Make a Difference!!**

Thank You  
Questions? ? ?

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