MOQC
JANUARY BIANNUAL MEETING
2023
Welcome

Keli DeVries, LMSW
## Morning Session | 9:00 – 11:45 am

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00</td>
<td>Welcome &amp; MOQC Updates</td>
<td>Keli DeVries, LMSW; POQC Member</td>
</tr>
<tr>
<td></td>
<td>MOQC Updates</td>
<td></td>
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<tr>
<td></td>
<td>POQC Update</td>
<td>Dawn M. Severson, MD; Taylor Wofford, MD</td>
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<tr>
<td></td>
<td>Steering Committee Report</td>
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<tr>
<td></td>
<td>Palliative and End-of-Life Care Task Force Update</td>
<td></td>
</tr>
<tr>
<td>9:30</td>
<td>MOQC Performance &amp; VBR Updates</td>
<td>Jennifer Griggs, MD, MPH, FASCO</td>
</tr>
<tr>
<td>10:15</td>
<td>Break — Mindfulness and Movement</td>
<td>Vanessa Aron, BA, RYT</td>
</tr>
<tr>
<td>10:25</td>
<td>The Voice of the Patient &amp; Caregiver</td>
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</tr>
<tr>
<td>10:35</td>
<td>Keynote Presentation</td>
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<tr>
<td></td>
<td>Oncology Stewardship: A Case-Based Discussion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lydia Benitez, PharmD, BCOP College of Pharmacy, University of Michigan</td>
<td></td>
</tr>
</tbody>
</table>

## Lunch | 11:35 am–12:05 pm

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:35</td>
<td>Break for lunch</td>
</tr>
</tbody>
</table>

## Afternoon Session | 12:05 – 2:25 pm

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:05</td>
<td>Presentation from Arbor Research — MOQCLink Demo</td>
<td>Keli DeVries, LMSW; Arbor Research</td>
</tr>
<tr>
<td>12:35</td>
<td>Patient-Reported Outcomes — Update</td>
<td>Chris Friese, PhD, RN, AOCN</td>
</tr>
<tr>
<td>12:55</td>
<td>Are We Delivering Equitable Care?</td>
<td>Jennifer Griggs, MD, MPH, FASCO</td>
</tr>
<tr>
<td>1:15</td>
<td>Break</td>
<td></td>
</tr>
<tr>
<td>1:25</td>
<td>The Language of Cancer Care</td>
<td>Tom Gribbin, MD</td>
</tr>
</tbody>
</table>

## Close | 2:25 – 2:30 pm

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:25</td>
<td>Closing Items</td>
<td>Keli DeVries, LMSW</td>
</tr>
</tbody>
</table>
Introductions

Please rename yourself to include your:

1) Full name
2) Organization
3) Pronouns
Reminder – How to Mute

To mute your microphone

To unmute your microphone

*6 to mute/unmute
Reminder – Chat

Use Chat to ask/answer questions
Add your reactions
Confidentiality Reminder

Taking pictures/videos of data slides is prohibited. This is a confidential professional peer review and quality assurance document of the Michigan Oncology Quality Collaborative.

Unauthorized disclosure or duplication is absolutely prohibited. It is protected from disclosure pursuant to the provisions of Michigan Statutes MCL 333.20175; MCL 333.21513; MCL 333.21515; MCL 331.531; MCL 331.532; MCL.331.533 or such other statutes as may be applicable.
MOQC Team Members

To learn more about our team, visit https://moqc.org/moqc/about-moqc/
MOQCLink
Our new database!

- Testing
- Broad release by the end of July
- Abstractor training November 2022
- LIVE! January 2023
Testimonials

There are aspects of MOQC that bring in other voices that we don’t, as clinicians, sometimes hear in that way because we see them in the patient exam room. But to have patient representation at MOQC also helps because it allows us to get some feedback, as clinicians, from the group that we need to address.

PHYSICIAN

Each meeting, we share, we collaborate, and we celebrate the success that’s being done around the state. I feel that MOQC really supports the practice, which then allows us to go back and support the patient.

SOCIAL WORKER

MOQC has given us the opportunity to benchmark our quality data against other cancer programs throughout the state. This helps us to identify opportunities for improvement.

PRACTICE MANAGER

https://umich.qualtrics.com/jfe/form/SV_06VDGWqXEExJExnM
Continuing Education Credits

This meeting has been approved for 4.75 CEU
Disclosure Statement

As a Jointly Accredited Provider of Interprofessional Continuing Education Credit, the National Center for Interprofessional Practice and Education Office of Interprofessional Continuing Professional Development (OICPD) complies with the ACCME and Joint Accreditors’ Standards for Integrity and Independence in Accredited Continuing Education. The National Center has a conflict of interest policy that requires all individuals involved in the development, planning, implementation, peer review and/or evaluation of an activity to disclose any financial relationships with ineligible companies. The National Center performs a thorough review of the content of the accredited activity to ensure that any financial relationships have no influence on the content of accredited activities. All potential conflicts of interest that arise based on these financial relationships are mitigated prior to the accredited activity.
Disclosures

There are no conflicts of interest or financial relationships with an ineligible company that have been disclosed by the planners and presenters of this learning activity.
In support of improving patient care, this activity is planned and implemented by The National Center for Interprofessional Practice and Education Office of Interprofessional Continuing Professional Development (OICPD) and The Michigan Oncology Quality Consortium. The National Center OICPD is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

Physicians: The National Center OICPD designates this activity for a maximum of 4.75 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with their participation.

Nurses: Participants will be awarded up to 4.75 contact hours of credit for attendance at this activity.

Nurse Practitioners: The American Academy of Nurse Practitioners Certification Program (AANPCP) accepts credit from organizations accredited by the ACCME and ANCC.

Pharmacists and Pharmacy Technicians: This activity is approved for 4.75 contact hours (.475 CEU)

Social Workers: As a Jointly Accredited Organization, the National Center OICPD is approved to offer social work continuing education by the Association of Social Work Boards (ASWB) Approved Continuing Education (ACE) program. Organizations, not individual courses, are approved under this program. State and provincial regulatory boards have the final authority to determine whether an individual course may be accepted for continuing education credit. The National Center OICPD maintains responsibility for this course. Social workers completing this course receive up to 4.75 continuing education credits.

Athletic Trainers: The National Center OICPD (JAA#: 4008105) is approved by the Board of Certification, Inc. to provide continuing education to Athletic Trainers (ATs). This program is eligible for a maximum of 4.75 Category A hours/CEUs. ATs should claim only those hours actually spent in the educational program.

IPCE: This activity was planned by and for the healthcare team, and learners will receive 4.75 Interprofessional Continuing Education (IPCE) credits for learning and change
POQC Update Video

https://youtu.be/YE0Tf2yeM7I
Steering Committee Report

Dawn Severson, MD
Steering Committee Report

• MOQC Certification Update
  ▪ Proposal is with BCBSM leadership
  ▪ We will be soliciting input from all MOQC practices

• June Med Onc Biannual Meeting
  ▪ Focus on palliative care
  ▪ Please invite your palliative care colleagues!
    Friday, June 16, 2023 in Midland
Steering Committee Report

• Generating Trusted Data
  ▪ MOQCLink, our new database and our relationship with Arbor Research will allow us to add & change measures
  ▪ Abstractors are undergoing training to increase accuracy of abstraction & to harmonize data collection
  ▪ We will collect feedback from our abstractors in real time

• Centering Equity
  ▪ New Equity Task Force will meet quarterly
  ▪ If you are interested in joining, please let anyone at the Coordinating Center know
Palliative Care and End-of-Life Task Force Update

Taylor Wofford, MD
Palliative Care and End-of-Life Task Force

• Palliative Radiation pathways

• Expanded questionnaire: https://umich.qualtrics.com/jfe/form/SV_bHDSah3bYGqCLUW

• June Biannual Meeting will focus on palliative care
  – June 16, 2023
  – Ideas? Please reach out to Natalia Simon nsimon@moqc.org
MOQC Practice Performance & VBR Updates

Jennifer J. Griggs, MD, MPH
## 2022 Medical Oncology Measures

<table>
<thead>
<tr>
<th>MOQC Pathway Measure</th>
<th>VBR Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completeness of race and ethnicity data</td>
<td>x</td>
</tr>
<tr>
<td>Complete family history documented for patients with invasive cancer</td>
<td></td>
</tr>
<tr>
<td>Smoking status recorded in medical record</td>
<td>x</td>
</tr>
<tr>
<td>Tobacco cessation counseling administered, or patient referred in past year</td>
<td>x</td>
</tr>
<tr>
<td>Chemotherapy intent (curative vs non-curative) documented before or within 2 weeks</td>
<td></td>
</tr>
<tr>
<td>GCSF administered to patients who received chemotherapy for non-curative intent</td>
<td></td>
</tr>
<tr>
<td>(lower score – better)</td>
<td></td>
</tr>
<tr>
<td>NK1RA &amp; olanzapine for high emetic risk chemotherapy</td>
<td>x</td>
</tr>
<tr>
<td>NK1RA for low or moderate emetic risk cycle 1 chemotherapy (lower score – better)</td>
<td>x</td>
</tr>
<tr>
<td>Hospice enrollment</td>
<td>x</td>
</tr>
<tr>
<td>Enrolled in Hospice for over 7 days</td>
<td></td>
</tr>
<tr>
<td>Enrolled in Hospice for over 30 days</td>
<td></td>
</tr>
<tr>
<td>Hospice enrollment within 7 days of death (lower score – better)</td>
<td></td>
</tr>
<tr>
<td>Chemotherapy administered within the last 2 weeks of life (lower score - better)</td>
<td>x</td>
</tr>
</tbody>
</table>
## 2022 Value-Based Reimbursement Summary

### Region-Level
**Meet 3 of 4**
- NK1RA & olanzapine given with high emetic risk chemotherapy: 25%
- NK1RA given for low or moderate emetic risk cycle 1 chemotherapy: 10%
- Hospice enrollment: 50%
- Hospice enrollment within 7 days of death: 30%

**3% Opportunity**

### Collaborative-Wide
**Meet 2 of 2**
- Tobacco cessation counseling administered or patient referred in past year: 75%
- Smoking status recorded in medical record: 90%

**2% Opportunity**

### Practice-Level
**Meet 2 of 2**
- Meet all 4 region-level measures
- Complete race and ethnicity data: 90%

**2% Opportunity**
## 2023 Medical Oncology Measures: Changes

### New VBR Measure

<table>
<thead>
<tr>
<th>Complete family history documented for patients with invasive cancer</th>
<th>VBR Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

### Measures Retiring from VBR

<table>
<thead>
<tr>
<th>Completeness of race and ethnicity data</th>
<th>VBR Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Smoking status recorded in medical record</th>
<th>VBR Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2023 Value-Based Reimbursement Summary

**Region-Level**
Meet 4 of the following 5

- NK1RA & olanzapine given with high emetic risk chemotherapy 30%
- NK1RA given for low or moderate emetic risk cycle 1 chemotherapy 10%
- Hospice enrollment 60%
- Hospice enrollment within 7 days of death 35%
- Complete family history documented 35%

3% Opportunity

**Collaborative-Wide**

- Tobacco cessation counseling administered or patient referred in past year 70%

2% Opportunity

**Practice-Level**

- Meet all 5 region-level measures

2% Opportunity
## Additional Criteria for Receiving VBR

<table>
<thead>
<tr>
<th>Level</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Practice Level</strong></td>
<td>At least one physician and one practice manager from the practice must attend both MOQC regional meetings and at least one biannual meeting during that year</td>
</tr>
<tr>
<td><strong>Physician Level</strong></td>
<td>Provider must be enrolled in PGIP for at least one year</td>
</tr>
</tbody>
</table>
# VBR Examples

## Collaborative Level (2%)
### Tobacco Cessation - Meet All + Attendance

<table>
<thead>
<tr>
<th>Attendance</th>
<th>Race &amp; Ethnicity</th>
<th>Hospice Enrollment</th>
<th>Hospice Enrollment 7 days</th>
<th>NK1RA for LEC</th>
<th>NK1RA for HEC</th>
<th>Tobacco Cessation Counseling</th>
<th>Smoking Status Recorded</th>
<th>Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>COLLABORATIVE</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Met</td>
<td>Met</td>
</tr>
</tbody>
</table>

## Region-Level (3%) VBR Measures - Meet 3 of 4 + Attendance

<table>
<thead>
<tr>
<th>Attendance</th>
<th>Race &amp; Ethnicity</th>
<th>Hospice Enrollment</th>
<th>Hospice Enrollment 7 days</th>
<th>NK1RA for LEC</th>
<th>NK1RA for HEC</th>
<th>Tobacco Cessation Counseling</th>
<th>Smoking Status Recorded</th>
<th>Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>REGION EXAMPLE</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Met</td>
<td>Not Met</td>
<td>Met</td>
<td>Met</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

## Practice-Level (2%) Race/Ethnicity - Meet All + Attendance

<table>
<thead>
<tr>
<th>Attendance</th>
<th>Race &amp; Ethnicity</th>
<th>Hospice Enrollment</th>
<th>Hospice Enrollment 7 days</th>
<th>NK1RA for LEC</th>
<th>NK1RA for HEC</th>
<th>Tobacco Cessation Counseling</th>
<th>Smoking Status Recorded</th>
<th>Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRACTICE EXAMPLE #1</td>
<td>Eligible</td>
<td>Met</td>
<td>Met</td>
<td>Met</td>
<td>Not Met</td>
<td>Not Met</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>PRACTICE EXAMPLE #2</td>
<td>Eligible</td>
<td>Met</td>
<td>Met</td>
<td>Met</td>
<td>Met</td>
<td>Met</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>PRACTICE EXAMPLE #3</td>
<td>Ineligible</td>
<td>Met</td>
<td>Met</td>
<td>Met</td>
<td>Met</td>
<td>Met</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
Measures

• ^ or ♦ indicates statistically significant improvement or worsening in performance between time periods (p< 0.05)

• Practices with no eligible cases in the denominator and/or missing data from one of the time periods are not shown
Completeness of Race and Ethnicity Data (N=7867)
Measure 108a: Complete Family History Documented for Patients with Invasive Cancer (N=6097)
Complete Family History

How is this measure constructed?

1\textsuperscript{st} degree relatives
- 1: Yes
- 0: No
- 9: Unobtainable

2\textsuperscript{nd} degree relatives
- 1: Yes
- 0: No
- 9: Unobtainable

Age at diagnosis
- 1: Yes
- 0: No
- 8: Requested but unknown
- 9: No blood relatives noted with cancer

In order to satisfy Complete Family History

1\textsuperscript{st} degree: 1 OR 9

2\textsuperscript{nd} degree: 1 OR 9

Age: 1 OR 8 OR 9

*No denominator exclusions
Complete Family History

How is this measure constructed?

1\textsuperscript{st} degree relatives’ cancer history documented? 82% complete

2\textsuperscript{nd} degree relatives’ cancer history documented? 58% complete

Age at diagnosis of each family member documented? 52% complete

Complete Family History documented? 28% complete

*2021 data shown*
Poll #1

Complete Family History
Poll | 1 question | 81 of 109 (74%) participated

1. How many cancer-affected family members must have age (or unknown age) documented? (Single Choice) *

81/81 (100%) answered

- Age is not part of complete family history | 2/81 (2%)
- 50% of family members with cancer | 7/81 (9%)
- 75% of family members with cancer | 1/81 (1%)
- All family members with cancer | 71/81 (88%)
The MiGHT Family History Project is now open to all MOQC practices
MiGHT Project

Project goal

• To improve collection of a complete family history

Participation includes:

• Access to an electronic family history collection tool
• Resources and support for collecting a complete family history
MiGHT Project

Family History Tool Example Output

Respondent Summary

<table>
<thead>
<tr>
<th>Ashkenazi</th>
<th>Both Parents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endometrial or Uterine Cancer</td>
<td>35</td>
</tr>
</tbody>
</table>

Cancer Summary

<table>
<thead>
<tr>
<th>Person</th>
<th>Cancer</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mother</td>
<td>Breast Cancer</td>
<td>63</td>
</tr>
<tr>
<td>Maternal Grandmother</td>
<td>Lung Cancer</td>
<td>88</td>
</tr>
<tr>
<td>Maternal Grandfather</td>
<td>Kidney renal cell Cancer</td>
<td>62</td>
</tr>
<tr>
<td>Maternal Grandfather</td>
<td>Prostate Cancer</td>
<td>60</td>
</tr>
<tr>
<td>Paternal Grandfather</td>
<td>Lymphoma</td>
<td>89</td>
</tr>
<tr>
<td>Paternal Grandfather</td>
<td>Non-Melanoma Skin Cancer</td>
<td>75</td>
</tr>
<tr>
<td>Paternal Aunt or Uncle 2</td>
<td>Non-Melanoma Skin Cancer</td>
<td>55</td>
</tr>
</tbody>
</table>

Premm 5 score

4.7%

The PREMM5 model is a clinical prediction algorithm that estimates the cumulative probability of an individual carrying a germline mutation in the MLH1, MSH2, MSH6, PMS2, or EPCAM genes. Mutations in these genes cause Lynch syndrome, an inherited cancer predisposition syndrome.

PREMM scores are based on initial patient survey input and for preliminary risk assessment purposes only.

Family history and PREMM scores should be confirmed (https://premm.dfci.harvard.edu) prior to use in clinical care.
MiGHT Project

• If interested in learning more or participating, email
  – Shayna Weiner at shaynaw@med.umich.edu
  – or moqc@moqc.org
Measure 101b: Tobacco Cessation Counseling Administered or Patient Referred in Past Year (N=1053)

Target 75%
Tobacco Cessation Resources

WE WANT TO MAKE OFFERING TOBACCO CESSTATION SUPPORT EASY
Explore resources to the right or scroll down to learn more about offering tobacco cessation support at your practice.

Tobacco Cessation Provider Box
Quit Smoking Resource Guide
Quit Smoking Medication Guide
Quit Smoking Resource Text line
Tobacco Cessation Posters

THE MICHIGAN TOBACCO QUITLINE
Website / Patient Referral / 1-800-QUIT-NOW

https://www.hbomich.org/
Measure 104: Chemotherapy Intent Documented before or within Two Weeks After Administration (N=4640)

Target 95%
Measure 111: GCSF Administered to Patients who Received Chemotherapy for Non-Curative Intent (lower score - better) (N=1205)
Poll #2

**Growth Factor**

Poll | 1 question | 85 of 109 (77%) participated

1. GCSF should not be given in patients receiving chemotherapy for non-curative intent because:
   (Single Choice) *

   85/85 (100%) answered

<table>
<thead>
<tr>
<th>Option</th>
<th>Votes</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is a low risk of side effects associated with GCSF administration</td>
<td>3/85</td>
<td>4%</td>
</tr>
<tr>
<td>The use of GCSF in a non-curative setting will not improve clinical outcomes</td>
<td>74/85</td>
<td>87%</td>
</tr>
<tr>
<td>GCSF administration lowers costs of care to the patient and healthcare system</td>
<td>8/85</td>
<td>9%</td>
</tr>
<tr>
<td>There is minimal impact on the patient/caregiver traveling to/from practices</td>
<td>0/85</td>
<td>0%</td>
</tr>
</tbody>
</table>
Measure 115: NK1RA & Olanzapine for High Emetic Risk Chemotherapy (N=1843)
### Antiemetics

Poll | 1 question | 71 of 110 (64%) participated

1. A goal of this measure includes: *(Single Choice)*

71/71 (100%) answered

<table>
<thead>
<tr>
<th>Goal</th>
<th>Votes</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreasing the use of olanzapine</td>
<td>8/71</td>
<td>11%</td>
</tr>
<tr>
<td>Assessing frequency of unplanned medical care and hospitalizations</td>
<td>10/71</td>
<td>14%</td>
</tr>
<tr>
<td>Assessing the use of guideline-concordant prescribing</td>
<td>46/71</td>
<td>63%</td>
</tr>
<tr>
<td>Decreasing the use of high emetic risk chemotherapy</td>
<td>7/71</td>
<td>10%</td>
</tr>
</tbody>
</table>
Measure 114: NK1RA for Low/Moderate Emetic Risk Cycle 1 Chemotherapy (Lower Score – Better) (N=2087)

Target 10%
EOL Measures
Measure 126a: Hospice enrollment (N=2679)

Target 50%
Measure 126b: Hospice Enrollment more than 7 Days Before Death (N=2603)

Target 60%
Measure 126c: Hospice Enrollment more than 30 Days Before Death (N=2603)
Hospice Enrollment within 7 Days of Death (Lower Score – Better) (N=1561)

Target 30%
Measure 127: Chemotherapy Administered within the Last 2 Weeks of Life (Lower Score - Better) (N=2690)

Target 10%
Discussion
The Voice of the Patient and Caregiver
ONCOLOGY STEWARDSHIP: A CASE-BASED DISCUSSION

Lydia Benitez, PharmD, BCOP
Clinical Assistant Professor & Leukemia Pharmacy Specialist
Michigan Medicine & University of Michigan College of Pharmacy
Learning Objectives

Describe oncology stewardship

Discuss new approvals in hematology space in the context of oncology stewardship

Develop a plan for applying oncology stewardship into your practice
Price of Cancer Therapy and Income

12,000
10,000
8,000
6,000
4,000
2,000


US Dollars per Month

Median monthly cost of new cancer therapies
Median monthly household income

This does not reflect 100+ new therapies since 2015!

Audience Poll Question #1

For drugs approved between Jan 2015 and Dec 2020, what is the median annual drug cost of a course of therapy? (across all tumor types)

A. $50,000
B. $100,000
C. $150,000
D. $200,000

Audience Poll Question #1

For drugs approved between Jan 2015 and Dec 2020, what is the median annual drug cost of a course of therapy? (across all tumor types)

A. $50,000
B. $100,000
C. $150,000
D. $200,000

Out-of-Pocket Costs of Cancer Treatment

- Total Cost Responsibility
- Inpatient
- Outpatient
- Physician visit
- Medical Equipment
- Medicare Part D

Symbols:
- Guideline-discordant
- Guideline-concordant
- * = significant (p < .05)

Impact of Financial Toxicity on Survival

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>HR (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>1.79 (1.64 – 1.96)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Breast</td>
<td>1.48 (1.15 – 1.91)</td>
<td>.003</td>
</tr>
<tr>
<td>Lung</td>
<td>1.55 (1.22 – 1.98)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Melanoma</td>
<td>1.50 (0.83 – 2.72)</td>
<td>.179</td>
</tr>
<tr>
<td>Thyroid</td>
<td>1.71 (0.69 – 4.27)</td>
<td>.249</td>
</tr>
<tr>
<td>Prostate</td>
<td>2.07 (1.56 – 2.74)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Leukemia/Lymphoma</td>
<td>1.22 (0.93 – 1.61)</td>
<td>.146</td>
</tr>
<tr>
<td>Uterine</td>
<td>1.09 (0.55 – 2.16)</td>
<td>.795</td>
</tr>
<tr>
<td>Colorectal</td>
<td>2.47 (1.85 – 3.31)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Other</td>
<td>1.49 (1.25 – 1.78)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>
Factors Influencing Cost in Oncology

- Market Exclusivity
- Therapeutic Monopolies
- Drug Discovery
- Price Inelasticity

Cost of new Therapies

What is Oncology Stewardship?

A set of coordinated strategies to improve the use of antineoplastic agents with the goal of enhancing patient health outcomes while reducing financial toxicity.

Developed with guidance from The Society of Healthcare Epidemiology of America
https://shea-online.org/index.php/practice-resources/priority-topics/antimicrobial-stewardship
New Approvals through Stewardship Lens

01. Efficacy
If there is a clear winner then this should become the standard of care

02. Toxicity
Efficacy is comparable thus we choose the treatment with less toxicities to improve quality of life and decrease unplanned hospitalizations

03. Cost
ONLY if efficacy and toxicities are comparable, choose the lowest cost treatment to the payer/patient

Adapted from Lancet.2016;388: 111-113 and ViaOncology, LLC.
## Incorporating Stewardship into your Practice

<table>
<thead>
<tr>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluate</td>
<td>Critically evaluate <strong>formulary additions</strong></td>
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<tr>
<td>Standardize</td>
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<td>Encourage <strong>rational use</strong> of medications &amp; palliative services</td>
</tr>
</tbody>
</table>
A New Therapy for Multiply-Refractory Multiple Myeloma

Outcomes that matter at end-of-life
Clinical Scenario #1 –

AP is a 75-year-old man with IgG κ multiple myeloma in fourth relapse

Relevant Disease Characteristics:

• PMH: hypertension, Type II diabetes mellitus, peripheral vascular disease
• Standard risk cytogenetics

Prior therapies:

• Bortezomib, lenalidomide, dexamethasone (RVD) → AutologousHCT → lenalidomide maintenance (18 months) → relapse after 40 months
• Carfilzomib, lenalidomide, dexamethasone → VGPR lasting 22 months complicated by intermittent neutropenia
• Daratumumab, pomalidomide, dexamethasone → VGPR lasting 10 months

AP is not able to travel to a site where clinical trials are available and is not a candidate for CAR-T cell therapy.
Timeline of Advances in Multiple Myeloma

- 2020: Isatuximab
- 2020: Belantamab mafodotin
- 2022: Ciltacabtagene autoleucel
- 2019: Idecabtagene vicleucel
- 2018: Denosumab
- 2013: Pomalidomide
- 2012: Carfilzomib
- 2019: Selinexor
- 2007: Doxorubicin
- 2006: Thalidomide
- 2003: Bortezomib
- 1986: High-Dose Dex
- 1983: Auto Transplantation
- 1962: Prednisone
- 1958: Melphalan

Auto = autologous; Dex = dexamethasone.

https://www.myeloma.org/multiple-myeloma-drugs
Simplified Therapeutic Pathway for MM

Newly Diagnosed

- Transplant Eligible
  - Proteasome Inhibitor (PI)
  - IMiDs
  - Steroids
  - Autologous HCT (AutoHCT)

- Transplant Ineligible
  - High-Risk Features?
    - Add daratumumab
    - Maintenance

Relapse(s)

- Lenalidomide sensitive?
  - Len based combinations

- Lenalidomide refractory?
  - Intensify PI based therapy
  - Second gen IMiDs
Options in Triple-Class Relapse

- Depth of response and length of remission decrease with subsequent lines of therapy
- Challenging subsets
  - Ineligible for autologous hematopoietic cell transplant
  - Adverse disease characteristics (e.g., del(17)(p))
- Patients with “penta-refractory” myeloma or more have dismal prognosis (median survival ~1-3 months)
- Options include
  - Non-CAR-T BCMA-based therapies
  - CAR-T cell (BCMA directed)
  - XPO1-inhibitor (Selinexor)
Selinexor

STORM trial

Patients with triple class refractory Multiple Myeloma*
- ECOG 0-1
- Adequate renal, hepatic and hematopoietic function

Selinexor 80 mg and dexamethasone 20 mg
days 1 and 3, weekly in 4-week cycles until progression/death or discontinuation

$n = 122$

*Measurable MM after therapy with PI (bortezomib and carfilzomib), iMiDs (lenalidomide and pomalidomide), steroids, and an alkylating agent AND most refractory to at least one drug in each class of PI, IMiD, daratumumab, glucocorticoid and last therapy received.

Phase II Open-label single arm trial
Primary Outcome: Overall Response Rate

For drugs approved between Jan 2015 and Dec 2020, agents approved through comparative studies were associated with higher price-tag than those approved via single-arm trials?

A. True
B. False

For drugs approved between Jan 2015 and Dec 2020, agents approved through comparative studies were associated with higher price-tag than those approved via single-arm trials?

A. True

B. False

## STORM Efficacy Outcomes

<table>
<thead>
<tr>
<th>Demographics &amp; Disease Characteristics</th>
<th>(n=122)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong>, median (range)</td>
<td>65 yrs (40-86)</td>
</tr>
<tr>
<td><strong>Disease duration</strong>, median (range)</td>
<td>6.6 yrs (1-23.4)</td>
</tr>
<tr>
<td><strong>Prior therapies</strong>, median (range)</td>
<td></td>
</tr>
<tr>
<td>Daratumumab combinations, n(%)</td>
<td>7 (3-18)</td>
</tr>
<tr>
<td>Stem-cell transplantation, n(%)</td>
<td>86 (70)</td>
</tr>
<tr>
<td>CAR-T, n(%)</td>
<td>102 (84)</td>
</tr>
<tr>
<td>2 (2)</td>
<td></td>
</tr>
<tr>
<td><strong>High-risk features, n (%)</strong></td>
<td>65 (53)</td>
</tr>
<tr>
<td><strong>Refractory (DOES NOT imply combination), n(%)</strong></td>
<td></td>
</tr>
<tr>
<td>Carfilzomib, pomalidomide, and dara</td>
<td>117 (96)</td>
</tr>
<tr>
<td>Carfilzomib, lenalidomide, pomalidomide, dara</td>
<td>101 (83)</td>
</tr>
<tr>
<td>Bortezomib, carfilzomib, pomalidomide, dara</td>
<td>94 (77)</td>
</tr>
<tr>
<td>Bortezomib, carfilzomib, lenalidomide, pomalidomide, dara</td>
<td>83 (68)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Response, %</th>
<th>N=122</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall Response Rate</strong></td>
<td>26.2</td>
</tr>
<tr>
<td>Stringent Complete Response</td>
<td>1.6</td>
</tr>
<tr>
<td>Very Good Partial Response</td>
<td>4.9</td>
</tr>
<tr>
<td>Partial Response</td>
<td>19.7</td>
</tr>
</tbody>
</table>

**Duration of Response**        4.4 months

**Median Overall Survival**      8.6 months
STORM Safety

- Thrombocytopenia
- Fatigue
- Nausea
- Anemia
- Decreased appetite
- Weight loss
- Diarrhea
- Hyponatremia
- Neutropenia
- Lymphopenia
- Dyspnea
- Constipation
- URTI
- Pyrexia
- Mental status changes
- Cough
- Dehydration
- Pneumonia

- Grades 1-2
- Grades 3-5

Discontinuation due to adverse effects in 33%
Grade 3+ hematologic events in > 50%
Fatal adverse events in 9% of patients

Includes fatal event(s)
Quality of Life Assessments & Supportive Care

Clinically Significant Changes in FACT-MM Score

Toxicity management recommendations
- Hematologic Toxicity
  - Antimicrobial prophylaxis ($)
  - Consideration for myeloid growth factor ($$$)
  - Consideration of TPO mimetic! ($$$$
- Gastrointestinal Toxicities
  - High Emesis protocol antiemetics ($-$)
  - Intravenous fluids in select patients ($$)


Selinexor 80 mg =
$26,859 per 4-week cycle*
*Wholesale Acquisition Cost

REDBOOK. Micromedex. © Copyright Merative 2023
Summarizing What We Know

01. Efficacy
- No data with regards to overall survival improvement in any setting
- No comparative data for penta-refractory patients (against dex alone?)
- Suboptimal comparator in 1-3 prior lines of therapy

02. Toxicity
- Significant toxicities leading to discontinuation/death in large % patients
- Toxicities associated with large healthcare utilization near end of life
- Quality of life worsened in a large % of patients receiving therapy

03. Cost
- Expensive oral therapy with potential to result in high co-pays for patients without access to grants/manufacturer funding support
- Significant expenses expected from supportive care measures.
Parallels in other Tumor Types?

Monjuvi (tafasitamab-cxix)
Relapsed/Refractory Large B-cell Lymphoma

Marjenza (Margertuximab-cmkb)
Metastatic HER2+ Breast Cancer
<table>
<thead>
<tr>
<th>Stewardship in End-of-Life Therapy Decisions</th>
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Chimeric Antigen Receptor T-cell therapy for Diffuse Large B-cell Lymphoma

One size does not fit all
Clinical Scenario #3 –

TH 59-year-old man with a history of high grade diffuse large B-cell lymphoma (DLBCL) being considered for CD-19 directed CAR-T cell therapy.

Relevant Patient Disease Characteristics:

- Biopsy reveals: Germinal Center lymphoma, MYC translocation and t(8;14)
- Treatment History: Dose Adjusted (R-EPOCH) with a CR in 2/2019 → Relapse in 7/2021 treated with RDHAP in CR after 2 cycles, receipt 3 total cycles → Patient relapsed while awaiting AutoHCT (10/7)
- PMH: none ECOG= 1

Plan: Bridge with Polatuzumab, Bendamustine, Rituximab then proceed to CAR-T cell therapy.

What outcomes can we expect from these interventions?
Lymphoma Drugs: Approval Timeline

Median Monthly Cost ($K)

- Nitrogen Mustard
- Methotrexate
- MOPP
- Vincristine Doxorubicin
- Autologous SCT
- Cisplatin
- Rituximab
- Etoposide
- CHOP
- R-CHOP
- 2-CDA
- Radioimmunotherapy
- Bortezomib
- Bortezomib vedotin
- Temsirolimus
- Pralatrexate Romadepsin
- Ibrutinib
- Lenalidomide
- Belinostat
- Idelalisib
- Nivolumab
- Pembrolizumab
- Venetoclax
- CAR T Cells

Thanarajasingham et al, *Lancet Haematology* 2018
Simplified Pathway in Relapsed B-cell Lymphoma

Relapsed DLBCL

- Transplant Eligible
  - Intensive chemotherapy
    - Chemo sensitive
      - Autologous HCT
        - Subsequent relapses
    - Chemo refractory
      - Therapy bridge?
        - CAR-T cell therapy
- Transplant Ineligible
  - Non-intensive chemotherapy

Subsequent relapses
CD19+ CAR T Cell Therapy for R/R DLBCL

Axicabtagene ciloleucel (Yescarta)

ZUMA-1
Phase II, multicenter, open-label
Primary endpoint: ORR (CR + PR)

Tisagenlecleucel (Kymria)

JULIET
Phase II, multicenter, open-label
Primary endpoint: ORR (CR + PR)

Schuster et al, NEJM 2019; 380:45-56
Neelapu et al, NEJM 2017; 377:2531-2544
Axicabtagene Ciloleucel (Yescarta)  
ZUMA-1 Efficacy

Overall CR

<table>
<thead>
<tr>
<th>Duration of Response (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
</tr>
<tr>
<td>80</td>
</tr>
<tr>
<td>60</td>
</tr>
<tr>
<td>40</td>
</tr>
<tr>
<td>20</td>
</tr>
<tr>
<td>0</td>
</tr>
</tbody>
</table>

ORR 82% 83%

CR rate 55% 58%

PFS (12 month, 24 month) 44% ** 72% **

OS (12 month, 24 month) 59% 50.5%

Neelapu et al, NEJM 2017; 377:2531-2544
Locke et al, Lancet Oncol 2019; 20:31-42
Tisagenlecleucel (Kymriah)

**JULIET Efficacy**

Schuster et al, *NEJM* 2019; 380:45-56

- **ORR**: 52%
- **CR rate**: 40%
- **PFS (12 month)**: **83%**
- **OS (12 month)**: 49%
Meta-Analysis of Outcome Reporting in CD-19 CAR-T Trials

- Patients included: 77%
- Excluded: 23%
- Patients did not receive CAR-T product: 16%
- Excluded despite receiving CAR-T: 7%

Patients Excluded from Efficacy Analyses

52 studies with CD19 targeting CAR-Ts were evaluated for efficacy across intent to treat population

- 266/1649 (16%) patients were excluded from efficacy analyses due to not being treated

Reason for Exclusion

- Insufficient follow-up
- Progression/disease complications
- Response to bridging therapy
- Difficulty manufacturing CAR-T
- Death
- Not reported/Other

More Patients Excluded from Efficacy Analyses

Across 52 studies with CD19 targeted CAR-Ts, 113 patients were excluded from efficacy analyses DESPITE being treated.

<table>
<thead>
<tr>
<th>Reason for Exclusion</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lost to follow-up</td>
<td>0%</td>
</tr>
<tr>
<td>CAR-T greater than max dose</td>
<td>5%</td>
</tr>
<tr>
<td>MRD(-) prior to CAR-T</td>
<td>10%</td>
</tr>
<tr>
<td>No PET before treatment</td>
<td>15%</td>
</tr>
<tr>
<td>Death</td>
<td>20%</td>
</tr>
<tr>
<td>Non-comforming product</td>
<td>25%</td>
</tr>
<tr>
<td>Not yet evaluable</td>
<td>30%</td>
</tr>
<tr>
<td>Not reported/Other</td>
<td>35%</td>
</tr>
</tbody>
</table>

Intent to Treat versus modified Intent to Treat

Modified ITT:
ORR 0.707 (95% CI 0.639-0.775)

ITT:
ORR 0.587 (95% CI 0.497-0.677)

Real-World CAR T Cell Data from the U.K

Kuhnl et al, ASH Annual Meeting 2019; session 627, abstract 767

CD-19 CART (N=80)

- Early progression 63% (N=50)
- Partial Response 15% (N=12)
- Complete Response 20% (N=16)
- Death 2% (N=2)

Event-Free Survival (proportion)

Time (Months)

Median EFS 3.1 months (95% CI 2.7-3.4)
Real-World Outcomes in Germany

Progression Free Survival

- Axi-cel 12-month PFS = 35%
- Tisa-cel 12-month PFS = 24%
- Overall, 12-month PFS = 30%

Overall Survival

- 12-month OS = 53%

## CD19+ CAR T Cell Therapy Safety

<table>
<thead>
<tr>
<th>Adverse reaction</th>
<th>AxiCel (ZUMA-1, n = 101)</th>
<th>TisaCel (JULIET, n = 111)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any</td>
<td>Grade 3</td>
</tr>
<tr>
<td>Any AE (worst grade)</td>
<td>100%</td>
<td>26%</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>87%</td>
<td>14%</td>
</tr>
<tr>
<td>Hypotension</td>
<td>58%</td>
<td>13%</td>
</tr>
<tr>
<td>Chills</td>
<td>37%</td>
<td>0%</td>
</tr>
<tr>
<td>Anemia</td>
<td>68%</td>
<td>43%</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>44%</td>
<td>9%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>53%</td>
<td>3%</td>
</tr>
<tr>
<td>Headache</td>
<td>46%</td>
<td>1%</td>
</tr>
<tr>
<td>Encephalopathy</td>
<td>37%</td>
<td>21%</td>
</tr>
<tr>
<td>Tremor</td>
<td>31%</td>
<td>2%</td>
</tr>
<tr>
<td>Nausea</td>
<td>58%</td>
<td>0%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>44%</td>
<td>5%</td>
</tr>
</tbody>
</table>

Schuster et al, *NEJM* 2019; 380:45-56
CD19+ CAR T Cell Therapy

Value

Cost = $373,000 for a 1x infusion (for both)
* Does not factor in admission, other clinical management*

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Cost, 2018 US$</th>
<th>Proportion of Simulations Cost Effective at Various WTP Thresholds</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>$50,000</td>
</tr>
<tr>
<td><strong>Axicabtagene ciloleucel</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40% 5-year PFS*</td>
<td>651,000 (602,000-700,000)</td>
<td>0</td>
</tr>
<tr>
<td>30% 5-year PFS*</td>
<td>638,000 (584,000-694,000)</td>
<td>0</td>
</tr>
<tr>
<td>20% 5-year PFS*</td>
<td>655,000 (597,000-712,000)</td>
<td>0</td>
</tr>
<tr>
<td><strong>Tisagenlecleucel</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35% 5-year PFS*</td>
<td>529,000 (481,000-579,000)</td>
<td>0</td>
</tr>
<tr>
<td>25% 5-year PFS*</td>
<td>523,000 (474,000-577,000)</td>
<td>0</td>
</tr>
<tr>
<td>15% 5-year PFS*</td>
<td>521,000 (470,000-578,000)</td>
<td>0</td>
</tr>
<tr>
<td><strong>Non-CAR-T</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemoimmunotherapy and stem-cell transplantation†</td>
<td>169,000 (145,000-195,000)</td>
<td>—</td>
</tr>
</tbody>
</table>

Closing the Gaps in Knowledge- Update from UK

Changes in Management

• Less patients with elevated LDH pre lymphodepletion
• Increased use of bridging therapy
• Decreased Grade III+ CRS/ICANS
  • Increased use of tocilizumab and steroids

Risk factors for worse overall survival

• 3+ extranodal sites: HR 2.0 (95% CI 1.1-3.7)
• Elevated LDH prior to lymphodepletion: HR 1.7 (95% CI 1.1-2.8)
• ECOG 2+: HR: 2.0 (95% CI 1.2-3.7)

Stewardship when considering CAR-T cell therapy

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</table>
Parallel in Other Tumor Types?

Keytruda (pembrolizumab)

Pembrolizumab improved survival compared to platinum doublet in PD-L1 >50%
(KEYNOTE 024 trial)

Consistent with other PD-1/PDL-1 targeting products, when expanded to a larger population (ie PD-L1 >1%), pembrolizumab still showed an OS benefit, but clearly driven by the PD-L1 >50% subgroup

<table>
<thead>
<tr>
<th>Study</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>KEYNOTE 042</td>
<td>PD-L1 1-49%, no OS benefit</td>
</tr>
<tr>
<td>IMPOWER 110</td>
<td>Atezolizumab showed no OS benefit when expanded to &gt;5%, &gt;1%</td>
</tr>
<tr>
<td>Checkmate 026:</td>
<td>Nivolumab no OS benefit in PD-L1 population &gt;1%</td>
</tr>
</tbody>
</table>

However, based on the OS benefit in the entire population, FDA approved pembrolizumab for any metastatic NSCLC with PD-L1 >1%
Audience Poll Question #3

The intent of a randomized controlled clinical trial is to establish the best standard of care

A. True
B. False

Audience Poll Question #3

The intent of a randomized controlled clinical trial is to establish the best standard of care

A. True
B. False

Recognizing Barriers to Stewardship

- Incorrect perception of national guideline role in care
- Incomplete understanding/access to data prior to drug approvals
- Subjective nature of drug use requests
- False belief that providers cannot impact cost of care
- Novel is better mentality
Proposed Stewardship Model

- Evidence for new drugs reviewed by Stewardship Committee

Committee:
- Hematologists
- Trainees
- APPs
- H/O PharmD

- Restrictions and place in therapy defined

Focus:
1. Efficacy
2. Safety
3. Cost

- Request for approval for specific patient submitted

Goals:
- Review under context of restrictions
- Serve to review new evidence
Audience Poll Question #4

Which of the following is the biggest barrier to implementation of oncology stewardship in your practice?

A. Lack of clear guidance on best practice by national guidelines
B. Incomplete understanding/access to data prior to drug approvals
C. Subjective nature of drug use requests (patient progressing in front of me)
D. Other
QUESTIONS?
ADDITIONAL SLIDES
Therapeutic Monopolies

**MRSA Bacteremia**

- Treat with vancomycin
- Drug induced AKI, change to linezolid

**Result:** Drug companies compete to produce the most effective antibiotic with less ADRs at the best cost

**Metastatic Colon Cancer**

- FOLFOX +/- bev
- FOLFIRI +/- bev
- Capecitabine
- Trifluridine + tipiracil
- Regorafenib

**Result:** Less competition because patient will likely need their drug eventually

Phase III randomized open label comparison of Selinexor+bortezomib+dex to bortezomib and dex

402 patients previously treated with 1 (51%), 2 (33%), or 3 (16%) lines of therapy

“Additional supportive measures were provided at the discretion of the investigator and could include use of olanzapine, megestrol acetate, intravenous fluids, methylphenidate, thrombopoietin stimulating agents, or transfusions.”
Chemotherapy for Secondary Acute Myeloid Leukemia

*Let’s talk about external validity*
Clinical Scenario #2 –

TS is a 62-year-old woman with a prior history of breast cancer and a new diagnosis of acute myeloid leukemia

Relevant Disease Characteristics:

- PMH: ER (+)/ HER (+) stage III invasive ductal carcinoma of right breast 2016 s/p neoadjuvant AC; taxol/Herceptin weekly x12 followed by herceptin to complete one year; right mastectomy 2016; tamoxifen x4 days; and aromasin
- Bone marrow biopsy reveals del 5(q)
- ECOG = 1; Ejection fraction > 50% and allogeneic HCT transplant candidate

What induction therapy would you recommend for TS?
Acute Myeloid Leukemia - Timeline of Drug Approvals

- **1969**: Daunorubicin
- **1979**: Idarubicin
- **1990**: Cytarabine, Mitoxantrone
- **2000**: Gemtuzumab Ozogamicin (GO) (2000-2010)
- **2017**: Midostaurin
- **2018**: Enasidenib, Ivosidenib
- **2022**: CPX-351, Olutasidenib, Glasdegib, Gilteritinib
Approval of CPX-351 for sAML

Phase III multicenter randomized controlled trial

Patients with treatment naïve sAML (N = 309)

- Related to prior chemotherapy/radiation (t-AML)
- Arising from antecedent hematologic disorder (AML-AHD)

Induction (1-2 cycles)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Patients (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPX-351*</td>
<td>153</td>
</tr>
<tr>
<td>7+3†</td>
<td>156</td>
</tr>
</tbody>
</table>

Consolidation (1-2 cycles)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Patients (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPX-351*</td>
<td>49</td>
</tr>
<tr>
<td>5+2‡</td>
<td>33</td>
</tr>
</tbody>
</table>

Allogeneic HCT if eligible

*CPX351: (liposomal daunorubicin-cytarabine in a 5:1 molar ratio) 44mg/m² – 100mg/m² Days 1, 2, 3 induction and 29mg/m²-65mg/m² Days 1 and 3 consolidation
†7+3: daunorubicin 60 mg/m² and cytarabine 100 mg/m²2 and reinduction with 5+2 (daunorubicin 60 mg/m² and cytarabine 100 mg/m²) if needed

Complete Remission (%)

- CPX-351: CR 42, CRi 3
- 7+3: CR 28, CRi 3

Median OS 9.56 vs. 5.95 mo (HR 0.69, 95% CI 0.52-0.90) P = 0.003

Primary Outcome: Overall Survival

Limitations of Study

- 7+3 may not be best comparator
- Unconventional consolidation strategy

Comparing HIDAC-based therapy to CPX-351

Patients with treatment naïve sAML (N = 169)

<table>
<thead>
<tr>
<th>CPX-351 (n = 94)</th>
<th>CPX-351 (n = 49)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIDAC-based† (n = 75)</td>
<td>HIDAC-based (n = 33)</td>
</tr>
</tbody>
</table>

AlloHCT if eligible

Secondary Endpoints:
- Efficacy
  - CR, CRi, MLFS
  - Overall survival (OS)
  - Event-free Survival (EFS)
- Safety
  - 30 and 60-day mortality
  - Neutropenic fever and confirmed infections
  - Chemotherapy related complications

Primary Endpoint:
Complete response/Complete response with incomplete count recovery (CR/CRi)

Non-inferiority design
- CR+CRi for CPX-351: 47.7%
- CR+CRi for FLAG: 63%
- Margin of non-inferiority: 7.5%
  - \( \alpha = 2.5\% \) (one-sided)
  - Power: 80%

†HIDAC based regimen: Regimen containing cytarabine at 1,000 mg/m² or greater dose.

Multi-center Retrospective Cohort Study

Participating Centers and Patient Screening

**210 Patients with sAML screened**

**41 Patients Excluded:**
- 22, prior AML treatment
- 14, targeted therapies
- 3, diagnosis by morphology only
- 2, incomplete records

**HIDAC-based cohort**
- N=75

**CPX-351 cohort**
- N=94

**Participating Centers**

<table>
<thead>
<tr>
<th>Participating Center</th>
<th>Participants (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Michigan Health System</td>
<td>73</td>
</tr>
<tr>
<td>MD Anderson Cancer Center</td>
<td>27</td>
</tr>
<tr>
<td><strong>Lead Investigator:</strong> Caitlin Rausch, PharmD</td>
<td></td>
</tr>
<tr>
<td>Barnes Jewish Hospital</td>
<td>22</td>
</tr>
<tr>
<td><strong>Lead Investigator:</strong> Jeff Klaus, PharmD</td>
<td></td>
</tr>
<tr>
<td>University of North Carolina</td>
<td>11</td>
</tr>
<tr>
<td><strong>Lead Investigator:</strong> Stephen Clark, PharmD</td>
<td></td>
</tr>
<tr>
<td>Huntsman Cancer Center</td>
<td>9</td>
</tr>
<tr>
<td><strong>Lead Investigator:</strong> Kelley Ratermann, PharmD</td>
<td></td>
</tr>
<tr>
<td>University of Rochester</td>
<td>9</td>
</tr>
<tr>
<td><strong>Lead Investigator:</strong> Carissa Treptow, PharmD</td>
<td></td>
</tr>
<tr>
<td>Indiana University</td>
<td>8</td>
</tr>
<tr>
<td><strong>Lead Investigator:</strong> Shawn Griffin, PharmD</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient and Disease Characteristics</th>
<th>HIDAC-based (n=75)</th>
<th>CPX-351 (n=94)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs¹</td>
<td>67 (27-82)</td>
<td>66.5 (31-80)</td>
<td>0.919</td>
</tr>
<tr>
<td>Gender, female²</td>
<td>31 (41.3)</td>
<td>32 (34)</td>
<td>0.330</td>
</tr>
<tr>
<td>sAML Etiology²</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AHD</td>
<td>42 (56)</td>
<td>50 (53.2)</td>
<td>0.716</td>
</tr>
<tr>
<td>t-AML</td>
<td>24 (32)</td>
<td>27 (28.7)</td>
<td>0.645</td>
</tr>
<tr>
<td>AML-MRC without AHD</td>
<td>9 (12)</td>
<td>17 (18)</td>
<td>0.276</td>
</tr>
<tr>
<td>Cytogenetic Risk²</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Favorable</td>
<td>1/73 (1.4)</td>
<td>3/92 (3.3)</td>
<td>0.631</td>
</tr>
<tr>
<td>Intermediate</td>
<td>19/73 (26)</td>
<td>30/92 (32.6)</td>
<td>0.394</td>
</tr>
<tr>
<td>High</td>
<td>53/73 (72.6)</td>
<td>59/92 (64.1)</td>
<td>0.314</td>
</tr>
<tr>
<td>HIDAC-based regimen</td>
<td>FLA/G n=73</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CLA/G n=2</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

¹median (range) ²n (%)  *n=71 **n=72  †if received for AHD

Rates consistent with previously reported data in Phase III trial

Long Term Outcomes: Overall Survival

Survival in all Patients

Median Survival (95% CI), months
HIDAC-based: 9.8 (6.87 – 12.73)
CPX-351: 9.14 (6.32 – 11.96)
P = 0.88

Median Survival (95% CI), months
HIDAC-based: 28.1 (8.1 – 47.2)
CPX-351: NR (NR)
P = 0.65

Survival consistent with previously reported data in Phase III trial

Safety Outcomes

<table>
<thead>
<tr>
<th></th>
<th>HIDAC-based (n= 75)</th>
<th>CPX-351 (n = 94)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days to ANC recovery (1000) in CR/CRi²</td>
<td>18 (9-67)</td>
<td>35.5 (25-95)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Days to PLT recovery (100) in CR/CRi²</td>
<td>23 (17-112)</td>
<td>37.5 (25-95)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ICU admission in induction²</td>
<td>11 (14.7)</td>
<td>23 (24.5)</td>
<td>0.114</td>
</tr>
<tr>
<td>Mortality During Induction²</td>
<td>5 (6.7)</td>
<td>11 (11.7)</td>
<td>0.267</td>
</tr>
<tr>
<td>30-day mortality²</td>
<td>1 (1.3)</td>
<td>8 (8.5)</td>
<td>0.039</td>
</tr>
<tr>
<td>60-day mortality²</td>
<td>8 (10.7)</td>
<td>13 (13.8)</td>
<td>0.536</td>
</tr>
<tr>
<td>Neutropenic Fever during induction²</td>
<td>64 (85.3)</td>
<td>87 (92.6)</td>
<td>0.131</td>
</tr>
<tr>
<td>Confirmed Infection in Induction²</td>
<td>42 (56)</td>
<td>70 (74.5)</td>
<td>0.012</td>
</tr>
<tr>
<td>New onset LVEF &lt; 50%²</td>
<td>4 (5.3)</td>
<td>11 (11.7)</td>
<td>0.148</td>
</tr>
<tr>
<td>AKI²</td>
<td>9 (12)</td>
<td>13 (13.8)</td>
<td>0.750</td>
</tr>
<tr>
<td>Other Complications²</td>
<td>4 (5.3)</td>
<td>3 (3.2)</td>
<td>0.488</td>
</tr>
</tbody>
</table>

²median (range)  n (%)
Summarizing What We Know

01. Efficacy
- Non-inferior CR/CRi rates with HIDAC-based therapy
- Similar long-term outcomes (EFS and OS)
- No benefit signal for CPX in any subgroup analyzed

02. Toxicity
- Longer time to hematologic recovery with CPX-351
- Higher rate of death in first 30-days with CPX-351
- Higher rate of confirmed infections with CPX-351

“Normal markets wouldn’t behave like this, you couldn’t introduce something twice eight times! as expensive and no better and still sell it.”

-Adapted from Dr. Peter Bach ziv-aflivercept commentary

03. Cost

Drug Cost of Induction (BSA ≤2 m²)

- CPX-351
- HIDAC-based

Market Exclusivity
Therapeutic Monopolies
Drug Discovery
Price Inelasticity

High Cost of Therapeutics
# Stewardship in sAML -

<table>
<thead>
<tr>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluate</td>
<td>Critically evaluate formulary additions</td>
</tr>
<tr>
<td>Standardize</td>
<td>Facilitate standardization of treatment plans for diseases</td>
</tr>
<tr>
<td>Do not shy away</td>
<td>Discuss financial toxicity regularly with providers</td>
</tr>
<tr>
<td>Promote</td>
<td>Promote interventions that optimize quality of life</td>
</tr>
<tr>
<td>Encourage</td>
<td>Encourage rational use of medications &amp; palliative services</td>
</tr>
</tbody>
</table>
Parallels in other Tumor Types?

Onivyde
(irinotecan liposome)

- Suboptimal efficacy comparator leading to approval
- Increased toxicity due to liposomal design
- Premium price tag for non-entirely novel therapy

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>Yescarta (ZUMA-1)</th>
<th>Kymriah (JULIET)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>58 (23 – 76)</td>
<td>56 (22 – 76)</td>
</tr>
<tr>
<td>% ≥ 65 yo</td>
<td>24 (24%)</td>
<td>25 (23%)</td>
</tr>
<tr>
<td>Disease subtype</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DLBCL</td>
<td>77 (76%)</td>
<td>88 (79%)</td>
</tr>
<tr>
<td>FL or PMBCL</td>
<td>24 (24%)</td>
<td>23 (21%)</td>
</tr>
<tr>
<td>ECOG score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>42 (42%)</td>
<td>61 (55%)</td>
</tr>
<tr>
<td>1</td>
<td>59 (58%)</td>
<td>50 (45%)</td>
</tr>
<tr>
<td>Disease stage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I/II</td>
<td>15 (15%)</td>
<td>27 (24%)</td>
</tr>
<tr>
<td>III/IV</td>
<td>86 (85%)</td>
<td>84 (76%)</td>
</tr>
<tr>
<td>≥ 3 prior therapies</td>
<td>70 (69%)</td>
<td>57 (52%)</td>
</tr>
<tr>
<td>Refractory to 2nd line</td>
<td>78 (77%)</td>
<td>61 (55%)</td>
</tr>
<tr>
<td>Relapse after ASCT</td>
<td>21 (21%)</td>
<td>54 (49%)</td>
</tr>
<tr>
<td>CD19(+) status</td>
<td>74/82 (90%)</td>
<td>-</td>
</tr>
<tr>
<td>Bridging therapy?</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Most patients (~84%) received bridging therapy prior to CAR T infusion
- Median time to CAR T cell infusion = 63 days
MOQCLink Launch
Data Reporting

David Dickinson
Shannon Li
Sonia John
Arbor Research Collaborative for Health
Arbor Research Team supporting MOQC

David Dickinson  Shannon Li  Sonia John  Shengqian Li  Michael Lipham  Brandon Rogers
MOQCLink - Login

- Single login per person
- Access control for all “authorized sites”
Building the Chart Roster

- **Round calculated:** based on chart abstraction date
- **Visit date valid range** based on round number
- **Cohort (GynOnc vs MedOnc)** based on Dx code

**Future: import of chart abstraction lists per site**
## Chart Abstraction Grid

<table>
<thead>
<tr>
<th>Edit</th>
<th>Chart ID</th>
<th>Round Number</th>
<th>Diagnosis Code</th>
<th>Site Name</th>
<th>MRN</th>
<th>Patient First Name</th>
<th>Patient Last Name</th>
<th>Chart Abstraction Form</th>
<th>Created By</th>
<th>Created Date</th>
<th>Modified By</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HNK-30000-177</td>
<td>R22022</td>
<td>C00</td>
<td>Malignant neoplasm of lip</td>
<td>Muskegon</td>
<td>1312213</td>
<td>Sonia</td>
<td>1220</td>
<td>Edit</td>
<td>sjohn</td>
<td>12/20/202</td>
<td>ddickinson</td>
</tr>
<tr>
<td></td>
<td>HNK-30000-176</td>
<td>R22022</td>
<td>--</td>
<td></td>
<td>Lemmen Holton Cancer Pavilion</td>
<td>432423</td>
<td>test</td>
<td>1219</td>
<td>Edit</td>
<td>sjohn</td>
<td>12/19/202</td>
<td>ddickinson</td>
</tr>
<tr>
<td></td>
<td>HNK-30000-141</td>
<td>R22022</td>
<td>C00.9</td>
<td>Malignant neoplasm of lip, unspecified</td>
<td>Muskegon</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **PII Encrypted**
- **Delete/edit links**
- **Filter/search**
- **Sort (default to newest)**
- **Print/Export**
Chart Abstraction Navigation

- Progress indicators
- Page/section navigator
  - Profile, Encounter, Staging, Therapy, etc.
- Detailed instructions (i)
- Display calculations
  - e.g., BMI, BSA, Age
Data Quality and Suppression

- Date validations
- Range Checks
- Cross checks
- Hard stop (error) and Soft stop (warning/confirm)
- Suppress unneeded fields

When possible, identify errors in real time while chart is available

MOQCLink (arborresearch.org)
• Staging options specific to MedOnc or GynOnc
• Suppression logic limits combination options
# Race/Ethnicity

## Family History

**Cohort: MEDONC**

<table>
<thead>
<tr>
<th>1</th>
<th>CA Diagnosis in 1st Degree Relative Documented</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Documentation that family history is unobtainable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2</th>
<th>CA Diagnosis in 2nd Degree Relative Documented</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Documentation that family history is unobtainable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3</th>
<th>Age of Diagnosis Documented</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>No blood relatives noted with cancer</td>
</tr>
<tr>
<td></td>
<td>Requested but unknown by family</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4</th>
<th>Patient Referred for cancer genetic testing or counseling</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
</tr>
</tbody>
</table>

[Continue button]
Drug Therapy and Chemo Treatment Plan
### Roles and Information Access

<table>
<thead>
<tr>
<th>Role</th>
<th>Create, Edit, Delete Charts</th>
<th>Add, Edit, Delete MOQCLink Users</th>
<th>View Charts</th>
<th>(Reports) View calculated measures, with patient detail</th>
<th>(Reports) View calculated measures, aggregated to provider/site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstractors</td>
<td>Yes</td>
<td></td>
<td></td>
<td>Yes (for their practices)</td>
<td>Yes (other practice names blinded)</td>
</tr>
<tr>
<td>Practice Managers</td>
<td></td>
<td>Yes</td>
<td></td>
<td>Yes (for their practices)</td>
<td>Yes (other practice names blinded)</td>
</tr>
<tr>
<td>Physicians</td>
<td>(no Link Access)</td>
<td></td>
<td></td>
<td>Yes (for their cases)</td>
<td>Yes (blinded of other practices &amp; physicians)</td>
</tr>
<tr>
<td>Physician Champions</td>
<td>(no Link Access)</td>
<td></td>
<td></td>
<td>Yes (for their practices)</td>
<td>Yes (other practice names blinded)</td>
</tr>
</tbody>
</table>
2022 Round 2:
Our first MOQC Link Abstraction!

- Chart abstractions: 574
- Practices: 7
- Abstractors: 9
- Total data fields: 51,559
- Both QOPI and MOQC link –
  – some overlap for data validity checks
Tableau Reporting!

- Consortium/abstraction progress
- Calculation of measure attainment
- Track how the consortium is reaching measures, over time; also by
  - Provider/site
  - Physician
- Available to all stakeholders
  - Physicians, Champions, Practice Managers, DCC
- Permissions reflect appropriate aggregation/deidentification
Trends over time; Aggregate Consortium or Provider
MOQC Tableau

- Reports being designed now
- As data aggregates, more possibilities...
- Abstraction progress by practice, abstractor
- Individual listings available to abstractors
Performance Measure Calculations by Practice, Physician (drill-in available for own data)
## Measure Performance Over Time Heat Map

Select a dimension:
- By Practice

Select a measure:
- Med 2

### Med 2 Rate

<table>
<thead>
<tr>
<th></th>
<th>2020R2</th>
<th>2021R1</th>
<th>2021R2</th>
<th>2022R</th>
<th>2022R2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>41.67%</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>31.20%</td>
<td>38.13%</td>
<td>51.61%</td>
<td>50.00%</td>
<td>42.37%</td>
</tr>
<tr>
<td>2</td>
<td>32.44%</td>
<td>23.81%</td>
<td>21.61%</td>
<td>100.00%</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>42.75%</td>
<td>17.19%</td>
<td>4.38%</td>
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### Denominator

<table>
<thead>
<tr>
<th></th>
<th>2021R1</th>
<th>2021R2</th>
<th>2022R</th>
<th>2022R2</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>257</td>
<td>279</td>
<td>118</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>273</td>
<td>310</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>221</td>
<td>274</td>
<td>136</td>
<td></td>
</tr>
</tbody>
</table>
Views Across Multiple Measures
(visual dashboards to come)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Performance</th>
<th>Other Practice</th>
<th>Performance</th>
<th>Other Practice</th>
<th>Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core10Rate</td>
<td>97.22%</td>
<td>100.00%</td>
<td>82.98%</td>
<td>100.00%</td>
<td>100.00%</td>
</tr>
<tr>
<td>Core10Hbp</td>
<td>35.00%</td>
<td>100.00%</td>
<td>35.00%</td>
<td>100.00%</td>
<td>100.00%</td>
</tr>
<tr>
<td>Core10Ben.</td>
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Live Demonstration/Q&A
Patient-Reported Outcomes (PROs) Project

Chris Friese, PhD, RN
Why PROs?

Systematic PRO collection, reporting and analysis:

- Helps focus clinical interventions
- Prioritizes improvement efforts
- Centers care on patient + family needs
- Must be done with care to avoid burdens
QUESTION In patients undergoing treatment for metastatic cancer, does electronic symptom monitoring improve patient-reported outcomes?

CONCLUSION Use of weekly electronic patient-reported outcome (PRO) surveys to monitor symptoms resulted in statistically significant improvements in physical function, symptom control, and health-related quality of life (HRQOL) at 3 months vs usual care among patients with metastatic cancer.

POPULATION
694 Women
496 Men
Adults receiving treatment for metastatic cancer
Mean age: 62 years

LOCATIONS
52 Community oncology practices in the US

INTERVENTION
1197 Patients randomized
1191 Patients analyzed

PRO intervention
Weekly electronic patient survey asking about symptoms, performance status, and falls

Control
Usual care

FINDINGS
Change in physical function, symptom control, and HRQOL (score range, 0-100 points) from baseline to 3 months

<table>
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<tr>
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<th>PRO intervention</th>
<th>Control</th>
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</thead>
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<tr>
<td>Physical function</td>
<td>74.27 ➤ 75.81</td>
<td>73.54 ➤ 72.61</td>
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<tr>
<td>Symptom control</td>
<td>77.67 ➤ 80.03</td>
<td>76.75 ➤ 76.55</td>
</tr>
<tr>
<td>HRQOL</td>
<td>78.11 ➤ 80.03</td>
<td>77.00 ➤ 76.50</td>
</tr>
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</table>

Mean differences were significant:
Physical function, 2.47 points (95% CI, 0.41 to 4.53); P = .02
Symptom control, 2.56 points (95% CI, 0.95 to 4.17); P = .002
HRQOL, 2.43 points (95% CI, 0.90 to 3.96); P = .002

How will we collect PROs?

• 2-week data collection; twice per year
• MOQC-provided tablets in clinic; check-in desk hands to patient to complete. Paper back up.
• PRO-CTCAE and Health Leaders social needs screen. If + → prompt guides patient to talk to clinician
• English and Spanish versions, caregiver can help
What will it entail?

- 12 practices to participate in 2023
- All practices participate in 2024
- Questionnaires – preparation in progress (Arbor Research)
- Spring 2023: user testing and intake meetings
- Summer 2023: 3 pilot sites
- Fall 2023: ~10 practices
What will it entail?

• On-site training and support

• Intake meetings to understand:
  – Preferred location(s) in practice (waiting room, infusion)
  – How to best get MRNs to patients to link to patient data
  – Other logistical concerns and questions
  – Site-specific IRB and DUA concerns

• Data from your site, region, & MOQC shared at regional & biannual meetings
A Phased Approach

Early State
• Meet practices where they are
• Four measures, one-time
• Tablet platform, paper backup
• Reports generated by MOQC
• Shared at regular intervals
• Data inform QI efforts

Future State
• 100% digital reporting
• Fully-integrated into EHR
• Scored & shared in real-time
• Can adjust timing, questions
• Longitudinal monitoring
• Subgroup analyses
• Caregiver-specific instrument
• Grants and papers
Thank You to our Task Force Members

• Megan Beaudrie
• Tracey Cargill-Smith
• Diane Drago
• Jacklyn Griffin
• Mike Harrison
• Amanda Itliong
• Pat Keigher

• Kathy LaRaia
• Cindy Michelin
• Lindsey Ranstadler
• Jerome Seid
• Dawn Severson
• Patrice Tims
Contact us to learn more:

• Shayna Weiner: shaynaw@med.umich.edu
• Ashley Bowen: asbowen@med.umich.edu
• Robin Voisine: rvoisine@med.umich.edu
• Chris Friese: cfriese@umich.edu
Are We Delivering Equitable Care?

Jennifer Griggs
MD, MPH, FACP, FASCO
Equity in Cancer Care

Why is MOQC focused on equity?

• Disparities in cancer care and outcomes have been seen across
  – Race
  – Ethnicity
  – Language of care
  – Immigration status
  – Age
  – Gender
  – Other non-clinical factors

• Advances in treatments have led to a widening in some disparities
• Equity issues cannot be addressed until they are identified
Equity Work at MOQC

- **Measure Selection**
- **POQC Representation**
- **Equity Task Force**
- **Selection of Initiatives**
- **Increasing Number of Records**
- **Equity Dashboard**
Equity Task Force

• Founding Group:
  – Tracey Cargill-Smith
  – Michael Dudley
  – Beth Fisher-Polasky
  – Zachary Hector-Word
  – Beth Sieloff
  – Diane Smith
  – Elena Stoffel
What is Included in Equity?

- Race
- Ethnicity
- Rural/Urban
- Sex
- Area-level deprivation
- Cancer diagnosis
- Sexual and gender minority status
- Language of care

Future:
Disparities in Performance on MOQC Measures

• Multivariate analysis was performed for 4 MOQC measures to identify disparities in care
  – Complete Family History
  – Hospice Enrollment
  – Chemotherapy Given in the Last 2 Weeks of Life
  – Days in Hospice

• Variables analyzed included:
  – Age
  – Sex
  – Race
  – Ethnicity
  – Cancer diagnosis
  – Year
Disparities in Performance on MOQC Measures

Complete Family History, Multivariate Analysis (N = 24,505)

- **Decreased** odds of having a complete family history documented
- **Increased** odds of having a complete family history documented

*Axes range from -0.5 to 0.5, indicating the magnitude of the effect.*
Disparities in Performance on MOQC Measures

Hospice Enrollment, Multivariate Analysis (N = 13,153)

Age
Female
Black Race
Race Not Reported
Race Unknown
Lymphoma
Pancreas Cancer
Year

Decreased odds of being enrolled in hospice
Increased odds of being enrolled in hospice
Disparities in Performance on MOQC Measures

Chemotherapy Given in the Last 2 Weeks of Life, Multivariate Analysis (N = 13,153)

- Decreased odds of receiving chemotherapy in the last 2 weeks of life
- Increased odds of receiving chemotherapy in the last 2 weeks of life
Disparities in Performance on MOQC Measures

Days in Hospice, Multivariate Analysis (N = 6,705)

- Decreased odds of being in hospice for more time
- Increased odds of being in hospice for more time
Site Effects

What are site effects?

- Patients with similar characteristics receive care at specific hospitals/practices with fewer resources

- Patients receive varying quality of care at the same hospital/practice

Excellent care

Good care

Moderate care
The Language of Cancer Care: Reframing our work in 5 words
(Changes in my time)

Thomas Gribbin, MD
Vice President, Cancer and Hematology
Centers of Western Michigan

Founding Director, Lacks Cancer Center,
Trinity Health Grand Rapids
From 1985-2023:

- Understand how our **words** have changed
- Understand how our **goals** have changed
- Understand how our **outcomes** have changed
- Speculation: **What’s next?**
• No conflicts of interest to declare
Why we are talking today

How did we identify cancer patients at high risk of high-cost complications?

• ER visits
• Avoidable hospitalization
• ICU utilization
• Futile end-of-life care

Look at the words we use.
1. The Words
Five words with evolving meanings

• Cure
• Palliate
• Response
• Survivor
• Value
Cure: to cure (verb), the cure (noun)

The Latin noun ‘cura,’ meaning ‘care,’ became the verb ‘curare,’ meaning ‘take care of,’ and then the Old French ‘curer,’ meaning ‘cure’

- To attend to, to be responsible, to take trouble
- To heal, to make whole
- To mend: to repair, to make good, to restore completeness or usability

Accurate: executed with care
Amend: to heal, to make good, to restore, to change
Cure is given/done to you by someone who cares
Palliate

- From the Latin *pallativus*, Middle English “cloak”
  - A garment worn by Christians instead of a Roman toga
  - Under a cloak, cover
  - A cloth spread over a coffin, a pall (pallbearer)
  - That which relieves the symptoms of a disease without dealing with the underlying cause

“Covering it over”
Response: an action and an answer

• **Respondere**: something offered in return
  - **Spondere**: a surety, guarantee, pledge, a sponsor
  - **re**: an answer back

• Antiphon: a musical response
  (like a Bach fugue or “dueling banjos”)
Value

• **Valere: “be worth”**
  - The regard that something is held to deserve the importance, worth, or usefulness of something
  - A person’s principles or standards of behavior
  - Value based care vs fee-for-service (value vs volume)
Survivor

• **Super** (above or beyond) and **vivere** (to live)
• Continuing to live typically in spite of accident, ordeal, or difficult circumstance
• A continuation of life despite difficult conditions
2. Cure And Its Meaning Over Time
What cancer is curable in advanced stages?

1985
• ALL
• AML
• Hodgkin Disease
• Diffuse Large Cell Lymphoma
• Testicular Cancer

2023
• Lung Cancer
• Breast Cancer
• Ovarian Cancer
• Head and Neck Cancer
• ?Colon Cancer
• ?Melanoma
• ?Myeloma
What cannot be cured in advanced stages in 2023?

- Glioblastoma
- Pancreatic Cancer
- Carcinoid Tumors
- Prostate Cancer
- CLL
- Alzheimer’s
- Multiple Sclerosis
- Cirrhosis
- Emphysema
- Advanced CHF
- CAD
- HIV
Oncologist’s meaning of cure comes from a surgical paradigm

- Surgeons resect to negative margins
- “No touch”
- Remove an organ, not a tumor

You cannot be cured if you have residual disease
Changing definitions and minimal residual disease

- Negative physical exam
- Negative pathologic exam
- Negative CT scan
- Negative PET scan
- Negative PCR
- Negative circulating tumor cells
- Negative status maintained for meaningful duration (5 years) = cure
A Pooled Analysis of Bone Marrow Micrometastasis in Breast Cancer

Stephan Braun, M.D., Florian D. Vogl, M.D., Bjørn Naume, M.D., Wolfgang Janni, M.D., Michael P. Osborne, M.D., R. Charles Coombes, M.D., Günter Schlimok, M.D., Ingo J. Diel, M.D., Bernd Gerber, M.D., Gerhard Gebauer, M.D., Jean-Yves Pierga, M.D., Christian Marth, M.D., Daniel Oruzio, M.D., Gro Wiedswang, M.D., Erich-Franz Solomayer, M.D., Günther Kundt, M.D., Barbara Strobl, M.D., Tanja Fehm, M.D., George Y.C. Wong, Ph.D., Judith Bliss, M.Sc., Anne Vincent-Salomon, M.D., and Klaus Pantel, M.D.*
Predicting systemic relapse from breast cancer by bone marrow involvement at presentation

• Pooled patient data from 9 studies involving 4703 patients evaluated for micro-metastatic bone marrow involvement by bone marrow sampling at the time of diagnosis, with detection by H and E and IHC

• 30.6% of patients had detectable breast cells in bone marrow at presentation

• Involvement predicted worse outcome but...
Survivor

- The majority of women with micro-metastatic involvement of the bone marrow did not relapse in this study.
- You can be a survivor and have residual disease.
- You can be a survivor and not cured.
From: Personalized Detection of Circulating Tumor DNA Antedates Breast Cancer Metastatic Recurrence

So, what does it mean to be cured?

You’re Cured Till You’re Not: Should Disease-Free Survival Be Used as a Regulatory or Clinical End Point for Adjuvant Therapy of Cancer?

Alberto F. Sobrero, MD; Alessandro Pastorino, MD; John R Zalcberg, PhD
For the sake of cure
- Unlimited cost
- Unlimited toxicity

For the sake of palliation
- Limited cost
- Limited toxicity

For the sake of cure
- Unlimited cost
- Managed Toxicity

For the sake of palliation
- Unlimited cost
- Limited toxicity
Today, our language for curing and palliating is overlapping (confused)
And the source of value has become confused

- Medicare daily rate for hospice in home care (2022): $203.40, average length of stay = 18 days
  - $3,661 per patient
- Per day cost for nivolumab $534 x median duration of response in lung cancer = 696 days
  - $371,664 per patient
- Is the value in the time extended, is it in the suffering avoided, the possibility for cure?
3. Cure Meets Value
Oncology Care Model - Cancer on a Budget

• Care was provided on a stipend calculated for each patient

• Provider is incented to provide care “on or under budget”

• Encourages identifying and avoiding “high-cost interventions”:
  ▪ ER utilization
  ▪ Hospitalization
  ▪ ICU stay
Our Pen and Paper Solutions

• Patient survey instruments
• High risk huddles
• Patient reported outcomes
## HIGH-RISK PATIENT MANAGEMENT

- Discussion at multidisciplinary huddle when initiating a new treatment, or when there is significant change in performance status/recent admission
- Immediate screening for community-based program
- RN Care Coordinator visits every cycle. phone calls in between as warranted (as frequently as 1-2x per week, if needed)
- Social Work visits every month, phone calls in between as warranted (as frequently as 1-2x per week, if needed)
- Comment in chart that patient is considered “high risk” as reminder to MD and support staff

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<th>Metric</th>
<th>0-Low Risk</th>
<th>1– Moderate Risk</th>
<th>2 – High Risk</th>
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<td>Living Arrangements</td>
<td>With loved ones</td>
<td>Alone, in assisted living</td>
<td>Alone, in community</td>
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If we can distinguish the curable from the dying, then we can avoid futile care.
You're Cured Till You're Not: Should Disease-Free Survival Be Used as a Regulatory or Clinical End Point for Adjuvant Therapy of Cancer?

Alberto F Sobrero, Alessandro Pastorino, John R Zalcberg
• Artificial (artificialis, Latin): made of produced by human beings, lacking naturalness, forced, contrived, feigned, artful, cunning

• Intelligence: to understand, comprehend

• Artificial intelligence: the science and engineering of making intelligent machines (1956)

• In this construct, providers have natural intelligence
U Penn Model: Solving the futility equation with medical data

1. A machine learning analysis of the medical record
2. Identify a population with a 10% 180-day mortality
3. Communicate that to the provider
4. Have the provider intervene
Jvion Model: Solving the futility problem with big data

• Jvion is an established AI company in the medical space, now purchased by *Lightspeed*

• Use big data to identify risk and change outcomes

• Identify impactable patient, provider to intervene

• ALL data welcome
Jvion Model

• Predicted 30-day mortality
• Notified physicians to intervene
• Not to prevent death but to limit end-of-life intervention
4. What if Our Words Don’t Fit?
December 23, 1971:
Nixon Declares War on Cancer:

- Etymology: *werre* (German), and *guerre* (French) “To bring into confusion”
- Intense armed conflict between states, societies, groups

- Are providers engaged in a war on cancer?
- Is a patient engaged in a war with his cancer?
- Is the patient “the battlefield” or “the warrior”?
We use the language of war to describe our patient’s course

• Chemotherapy kills the cancer
• Radiation “nukes” cancer
• Immunotherapy lets your immune system attack cancer
• Surgery removes the cancer
• Treatment stops the invasion and progress of cancer
• Patient is a “fighter”
What our words tell us to do

• In the Rhetoric of War, don’t stop shooting?

• In the Rhetoric of Cure, don’t stop treating?

• In the Rhetoric of Palliation, cover it over?

• In the Rhetoric of Value, spend less?
In Conclusion

• The words we use to describe cancer care, and the way we use them, has changed over the last 38 years

• The practice of oncology has led to evolving and overlapping meanings of “palliation” and “cure” (confusion)

• Our description of cancer and its treatment using the terms of “war” may not be as helpful in framing our patient’s experiences if in fact, “you’re cured till you’re not”
Thank You.
Hope

• To cherish a desire with anticipation (secular)

• A confident expectation and desire for something good in the future (religious)
Closing Items

Keli DeVries, LMSW
Continuing Education Credits

This meeting has been approved for 4.75 CEU

1. MOQC will send out the evaluation to everyone’s email address as part of the follow-up email
2. Attendees should complete the evaluation
3. Attendees will receive a certificate from the CE accreditation organization with their credits
   • The certificate will be sent from ipceapps@umn.edu

Questions? Please reach out to moqc@moqc.org
## Next Meetings

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<th>MOQC 2023 Spring Regional Meetings</th>
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Register at: [https://moqc.org/events/](https://moqc.org/events/)
Testimonials

There are aspects of MOQC that bring in other voices that we don’t, as clinicians, sometimes hear in that way because we see them in the patient exam room. But to have patient representation at MOQC also helps because it allows us to get some feedback, as clinicians, from the group that we need to address.

PHYSICIAN

Each meeting, we share, we collaborate, and we celebrate the success that’s being done around the state. I feel that MOQC really supports the practice, which then allows us to go back and support the patient.

SOCIAL WORKER

MOQC has given us the opportunity to benchmark our quality data against other cancer programs throughout the state. This helps us to identify opportunities for improvement.

PRACTICE MANAGER

https://umich.qualtrics.com/jfe/form/SV_06VDGWqXExJExnM
THANK YOU!
Cancer care. Patients first.
The best care. Everywhere.