

QI Project Application/Report for Part IV MOC Eligibility

Instructions

Complete the project application/report to apply for UMHS approval for participating physicians to be eligible to receive Part IV MOC credit through the Multi-Specialty Part IV MOC Pilot program. Questions are in bold font and answers should be in regular font (generally immediately below the questions). To check boxes electronically, either put an “X” in front of a box or copy and paste “☒” over the blank box.

Only a final application describing the completed project is required. However, submitting an earlier version helps assure that planned activities will meet Part IV requirements. Actions regarding the application depend on the stage of the project, as described below. As stages are accomplished, you may submit updates of the application with the description of planned activities replaced by descriptions of actual activities performed.

Preliminary approval. Plans are developed for the expected activities, but little actual work has been performed. (Complete at least items 1-11, 13a, 16-18a, 19a, 20a, 21, 22a, 23a, 27-33.)

Part IV credit approval. Baseline data have been collected and the intervention performed, with completion of both steps documented on an application (or application update). The project has demonstrated its operational feasibility and the likelihood that subsequent data collections and adjustment will be performed. (Complete at least items 1-18a, 19a, 20a, 21, 22a, 23a, 27-33.)

Participation (“attestation”) forms provided. The project has been completed with the expected sequence of activities performed and documented on a complete final application, which is the “final report” on the project.

For further information and to submit completed applications, contact either:

Grant Greenberg, MD, UMHS Part IV Program Lead, 763-936-1671, ggreenbe@med.umich.edu

R. Van Harrison, PhD, UMHS Part IV Program Co-Lead, 763-1425, rvh@umich.edu

Chrystie Pihalja, UMHS Part IV Program Administrator, 763-936-1671, cpihalja@umich.edu

Application/Report Outline

Section	Items
A. Introduction	1-6. Current date, title, time frame, project leader, specialties/subspecialties involved, funding
B. Plan	7-10. General goal, patient population, IOM quality dimensions addressed, experimental design 11-12. Baseline measures of performance, specific performance objectives 13. Data review and identifying underlying (root) causes
C. Do	14-16. Intervention(s), who is involved, initiated when
D. Check	17-18. Post-intervention performance measurement, data collection, performance level
E. Adjust – Replan	19. Review, continuing/new underlying causes,
F. Redo	20. Second intervention
G. Recheck	21-22. Post-adjustment performance measurement, data collection, performance level
H. Readjust plan	23. Review, continuing/new underlying causes to address
I. Future plans	24-26. Subsequent PDCA cycles, standardize processes, “spread” to other areas
J. Physician involvement	27-31. Physician’s role, requirements, reports, reflections, participation, number
K. Project Organization	32-34. Part of larger initiative, organizational structure, resources, oversight, Part IV opportunity

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A. Introduction

1. **Date** (*this version of the application*): November 24, 2014

2. **Title of QI project:** Written Chemotherapy Consent for Hematology/Oncology Patients

3. Time frame

a. At what stage is the project?

- Design is complete, but not yet initiated
 Initiated and now underway
 Completed (*UMHS Part IV program began 1/1/11*)

b. Time period

- (1) **Date physicians begin participating (may be in design phase):**
 (2) **End date:** actual _____ expected _____

4. QI project leader [*responsible for attesting to the participation of physicians in the project*]:

- a. **Name:** Rashmi Chugh, MD
 b. **Title:** Assistant Professor of Internal Medicine
 c. **Institutional/organizational unit/affiliation:** Division of Hematology/Oncology
 d. **Phone number:** 936-0453
 e. **Email address:** rashmim@umich.edu
 f. **Mailing address:** UMHS Int Med Hematology/Oncology, 1500 E Medical Ctr Dr
 C409 MIB Ann Arbor MI 48109-5912

5. What specialties and/or subspecialties are involved in this project?

Internal Medicine-Hematology/Oncology

6. Will the funding and resources for the project come only from internal UMHS sources?

- Yes, only internal UMHS sources
 No, funding and/or resources will come in part from sources outside UMHS,
 which are: _____

The Multi-Specialty Part IV MOC Program requires that projects engage in change efforts over time, including at least three cycles of data collection with feedback to physicians and review of project results. Some projects may have only three cycles while others, particularly those involving rapid cycle improvement, may have several more cycles. The items below are intended to provide some flexibility in describing project methods. If the items do not allow you to reasonably describe the methods of your specific project, please contact the UMHS Part IV MOC Program office.

B. Plan

7. General goal

a. Problem/need. What is the "gap" in quality that resulted in the development of this project? Why is this project being undertaken?

The treatment of cancer is a complex process using drugs and agents that can cause significant side effects and impact on quality of life. Education for patients receiving chemotherapy and biologic therapy for treatment of cancer is a key component in decision-making and documentation

of this through informed consent is an indicator of quality. Documentation of consent is a UMHS policy, a standard for accreditation through the American Society of Clinical Oncology (ASCO), and has been selected as a Joint Commission OPPE metric for the Division of Hematology/Oncology. Absence of a standard process to facilitate documentation of consent for chemotherapy has led to unacceptably low rates of documentation and can potentially jeopardize patient safety.

b. Project goal. What outcome regarding the problem should result from this project?

To ensure required Informed Consent documentation elements are performed and documented prior to the administration of all IV chemotherapy and biologics.

8. Patient population. What patient population does this project address.

Non-research, adult, competent patients receiving IV chemotherapy and biologics..

9. Which Institute of Medicine Quality Dimensions are addressed? [Check all that apply.]

- | | | |
|--|--|--|
| <input checked="" type="checkbox"/> Safety | <input checked="" type="checkbox"/> Equity | <input type="checkbox"/> Timeliness |
| <input type="checkbox"/> Effectiveness | <input type="checkbox"/> Efficiency | <input checked="" type="checkbox"/> Patient-Centeredness |

10. What is the experimental design for the project?

- Pre-post comparisons (baseline period plus two or more follow-up measurement periods)
- Pre-post comparisons with control group
- Other: _____

11. Baseline measures of performance:

a. What measures of quality are used? If rate or %, what are the denominator and numerator?

Measures: Percentage of patients with written chemotherapy consent documented prior the administration of chemotherapy or biologic therapy.

denominator: patients starting infusion therapy

numerator: number of patients with consent documented.

b. Are the measures nationally endorsed? If not, why were they chosen?

Yes – Informed consent documentation is an American Society of Clinical Oncology, Quality Oncology Practice Initiative Priority. It is also a University of Michigan institutional priority and has been identified as a Joint Commission Ongoing Professional Performance Metric by the Division of Oncology.

c. What is the source of data for the measure (e.g., medical records, billings, patient surveys)?

Medical records

d. What methods were used to collect the data (e.g., abstraction, data analyst)?

Data report generated automatically from the Electronic Health Record based on specific criteria to define the patient population: New patients with an appointment for infusion of a chemotherapeutic or biologic agent who had a preceding appointment with Hematology/Oncology, with a specific imaged document type for “chemotherapy consent”

e. How reliable are the data being collected for the purpose of this project?

Fairly reliable. However, data are dependent on consent documents being imaged and filed under a specific document type. Data will not capture consent documented in any other, non-standard manner.

f. How are data to be analyzed over time, e.g., simple comparison of means, statistical test(s)?

Comparison of percentages

g. To whom are data reported?

Division and Cancer Center leadership, Office of Clinical Affairs of the University of Michigan.

h. For what time period is the sample collected for baseline data?

12/1/12-11/30/13

12. Specific performance objectives

a. What is the overall performance level(s) at baseline? (E.g., for each measure: number of observations or denominator, numerator, percent. Can display in a data table, bar graph, run chart, or other method. Can show here or refer to attachment with data.)

Time Period	# Patients Starting Infusion Therapy	# with Informed Consent Documented	Percent with Consent Documented
Baseline Period 12/1/12–11/30/13)	Not tallied	0 (no adequate process)	0%

Since this is a new process, the baseline level is 0%. Previous consent has not been written, and documented with a specific document imaging type.

b. Specific aim: What is the target for performance on the measure(s) and the timeframe for achieving the target?

From the baseline observation period (12/01/2012- 11/30/2013) to the project's final observation period (7/1/2014 - 10/21/2014), the aim is to go from 0% informed consent documentation using a new process developed for this project to 100% informed consent documentation.

c. How were the performance targets determined, e.g., regional or national benchmarks?
UMHS standards of patient consent (62-10-000/62-10-001)

13. Data review and identifying underlying (root) causes.

a. Who will be/was involved in reviewing the baseline data, identifying underlying (root) causes of the problem(s), and considering possible interventions (“countermeasures”) to address the causes? Briefly describe who is involved, how (e.g., in a meeting of clinic staff), and when.

This topic and issue regarding need for consent and current low rates due to lack of existing process has been reviewed with hematology/oncology faculty at faculty meetings starting in July 2013. Hematology/Oncology physicians were involved in identifying the problem, developing the consent form and coming to consensus on a standardized process for implementation. In addition, the Office of Clinical Safety, Office of Clinical Affairs, and Health Information Management were involved in planning. These meetings were held in July 2013-January 2014 approximately every 6 weeks.

b. What are the primary underlying/root causes for the problem(s) that the project can address? (Causes may be aspects of people, processes, information infrastructure, equipment, environment, etc. List each primary cause separately. How the intervention(s) address each primary underlying cause will be explained in #14.c.)

1. Lack of provider understanding concerning the requirement for obtaining consent
2. Lack of a uniform process for documenting informed consent including all elements of consent
 - a. Lack of standard form
 - b. Variation in clinic processes
3. Lack of standard process for providing patients with information about drugs and agents
 - a. Multiple sources

- b. Confusion concerning responsibility for providing additional information
- 4. Difficulty in documenting process in MiChart
 - a. Lack of standard document type
 - b. Unclear location in EMR

C. Do

14. Intervention(s).

a. Describe the interventions implemented as part of the project.

- Physician Education: Education of physicians occurred prior to roll out regarding the requirement for obtaining consent and required steps for informed consent documentation.
- Patient Education: Information sources have been reviewed and the Lexicomp source has been selected as the preferred option.
- Performance feedback of Individual level data was provided to guide improvement.
- Standard tool: A written chemotherapy consent form has been created by consensus by hematology/oncology physicians, health information management, and Office of Clinical Safety. This consent encompasses the major elements of informed consent including major and significant risks to the patients as well as key reproductive health issues.
- Standard process: Attending physicians as well as providers they are supervising (fellows, Physician Assistants, Nurse Practitioners) are involved.
 - 1) When the provider identifies that a new chemotherapy intervention is planned, the provider will print the informed consent from the Health Information Management (HIM) website, which housed approved UMHS consent forms.
 - 2) The provider will present patients with the informed consent form to the patient. The provider will ensure the patient understands the risks/benefits/goals of treatment. Patients will signify understanding by signing the consent and providers will assure they reviewed the consent by likewise signing.
 - 3) Clinic staff will photocopy the consent, give the patient a copy, and send the signed form to HIM to scan into the patient's medical record. The consent will be uniquely identified as a "chemotherapy consent" to facilitate tracking of compliance.

b. How are underlying/root causes (see #13.b) addressed by the intervention(s)? (List each cause, whether it is addressed, and if so, how it is addressed.)

1. Lack of understanding concerning the requirement for obtaining consent
Education of Physicians at Division Meetings
2. Lack of a uniform process for documenting informed consent including all elements of consent
 - a. Lack of standard form: Development of a consensus, standardized form to be used for all consents
 - b. Variation in clinic processes: Development of a consensus workflow to both obtain and document appropriate consent.
3. Lack of standard process for providing patients with information about drugs and agents
 - a. Multiple sources: Identification of single information resource (Lexicomp)
 - b. Confusion concerning responsibility for providing additional information: Development of a standard process for providing the information
4. Difficulty in documenting process in MiChart
 - a. Lack of standard document type: Development of documentation type for specific consent form
 - b. Unclear location in EMR: Standardize location for imaging document to facilitate tracking and compliance, and finding document in subsequent encounters.

15. Who is involved in carrying out the intervention(s) and what are their roles?

The participating physicians will attend the educational sessions, identify relevant patients, print the form, explain the information, and co-sign the form (or oversee other providers performing these activities).

Others who will carry out the interventions are:

Fellows and extenders who act under the supervision of the above providers

Clinic staff who will photocopy the forms, give a copy to the patient, and send the form to HIM

HIM will scan into the patient record

- 16. The intervention will be/was initiated when?** (For multiple interventions, initiation date for each.)
Initiated on January 7, 2014

D. Check

- 17. Post-intervention performance measurement. Is this data collection to follow the same procedures as the initial collection of data described in #11: population, measure(s), and data source(s)?**

Yes No – If no, describe how this data collection

- 18. Performance following the intervention.**

- a. The collection of the sample of performance data following the intervention either:**

Has occurred for the period: 1/13/14-5/31/14

- b. If the data collection has occurred, what is post-intervention performance level?** (E.g., for each measure: number of observations or denominator, numerator, percent. Can display in a data table, bar graph, run chart, or other method. Can show here or refer to attachment with data.)

Time Period	# Patients Starting Infusion Therapy	# with Informed Consent Documented	Percent with Consent Documented
Baseline Period 12/1/12–11/30/13)	Not tallied	0 (no adequate process)	0%
Intervention Period 1/13/14–5/31/14	537	243	45% *

- Monthly rates ranged from 37% to 52%.

E. Adjust – Replan

- 19. Review of post-intervention data and identifying continuing/new underlying causes.**

- a. Who will be/was involved in reviewing the post-intervention data, identifying underlying (root) causes of the continuing/new problem(s), and considering possible adjustments to interventions (“countermeasures”) to address the causes? Briefly describe who is involved, how (e.g., in a meeting of clinic staff), and when.**

Participants identified above met in two sequential meetings (7/21 and 7/25/14) to review data and plan further interventions. Participants presented data at team-specific meetings. Data was also presented at a Heme/Onc Division Faculty meeting on 7/24/14

- b. What are the primary underlying/root causes for the continuing/new problem(s) that the project can address?** (Causes may be aspects of people, processes, information infrastructure,

equipment, environment, etc. List each primary cause separately. How the intervention(s) address each primary underlying cause will be explained in #20.c.)

Identified causes include:

1. Lack of understanding of clear definition of which agents require consent (e.g. hormonal therapies, bone resorption agents)
2. Failure to include midlevel practitioners in process.
3. Difficulty in counting consent when not documented separately from standard clinical documentation
4. Lack of clear understanding of consent document

F. Redo

20. Second intervention.

a. **The second intervention will be/was initiated when?** (For multiple interventions, initiation date for each.) July 2014.

b. **If the second intervention has occurred, what interventions were implemented?**

- Educational sessions were held for Cancer Center Teams including midlevel providers in July and August 2014.
- Review of process at team meetings, which include mid-level practitioners, as well as a separate educational session for mid-level practitioners
- Review of process and reinforcement of workflow, which now requires a separate document for consent.
- Review of content of document at team meetings conducted by project lead

c. **How are continuing/new underlying/root causes (see #19.b) addressed by the intervention(s)?** (List each cause, whether it is addressed, and if so, how it is addressed.)

Lack of understanding of clear definition of which agents require consent (e.g. hormonal therapies, bone resorption agents): Educational sessions held in August and September 2014

Failure to include midlevel practitioners in process: Review of process at team meetings, which include mid-level practitioners, as well as a separate educational session for mid-level practitioners.

Difficulty in counting consent when not documented separately from standard clinical documentation: Review of process and reinforcement of workflow, which now requires a separate document for consent.

Lack of clear understanding of consent document: Review of content of document at team meetings conducted by project lead

G. Recheck

21. Post-second intervention performance measurement. Is this data collection to follow the same procedures as the initial collection of data described in #11: population, measure(s), and data source(s)?

Yes No – If no, describe how this data collection

22. Performance following the second intervention.

a. **The collection of the sample of performance data following the intervention(s) either:**

Has occurred for the period: 07/01/2014 to 9/30/2014

- b. If the data collection has occurred, what is the performance level?** (E.g., for each measure: number of observations or denominator, numerator, percent. Can display in a data table, bar graph, run chart, or other method. Can show here or refer to attachment with data.)

Time Period	# Patients Starting Infusion Therapy	# with Informed Consent Documented	Percent with Consent Documented
Baseline Period 12/1/12–11/30/13)	Not tallied	0 (no adequate process)	0%
Intervention Period 1/13/14–5/31/14	537	243	45% *
2nd Intervention Period 7/1/14-10/21/14	343	128	37%**

- Monthly rates ranged from 37% to 52%.
- ** Monthly rates ranged from 32% to 42%

H. Readjust

23. Review of post-second intervention data and identifying continuing/new underlying causes.

- a. Who will be/was involved in reviewing the data, identifying underlying (root) causes of the continuing/new problem(s), and considering additional possible adjustments to interventions (“countermeasures”) to address the causes? Briefly describe who is involved, how (e.g., in a meeting of clinic staff), and when.**

Project team and Cancer Center Administration meetings to reviewed on Nov 4 for one physician and scheduled in December 2014 for all others.

- b. What are the primary underlying/root causes for the continuing/new problem(s) that the project can address?** (Causes may be aspects of people, processes, information infrastructure, equipment, environment, etc. List each primary cause separately.)

Major cause of lower results is the implementation of new chemotherapy ordering system in June 2014, which altered our ability to measure compliance. Due to the changed context, the results for this period are effectively a new baseline level from which to improve. New document types and imaging procedures are under development to address changes in measurements. Our next intervention will be to test the new documents and processes.

If no additional cycles of adjustment are to be documented for the project for Part IV credit, go to item #24.

If a few additional cycles of adjustments, data collection, and review are to be documented as part of the project to be documented, document items #20 – #23 for each subsequent cycle. Copy the set of items #20 – #23 and paste them following the last item #23 and provide the information. When the project to be documented for Part IV credit has no additional adjustment cycles, go to item #24.

If several more cycles are included in the project for Part IV credit, contact the UM Part IV MOC Program to determine how the project can be documented most practically.

I. Future Plans

24. How many subsequent PDCA cycles are to occur, but will not be documented as part of the “project” for which Part IV credit is designated?

2-4

25. How will the project sustain processes to maintain improvements?

This process will be refined and incorporated into the QOPI Certification for the Cancer Center . New document types and imaging procedures are under development to address changes in measurements.

26. Do other parts of the organization(s) face a similar problem? If so, how will the project be conducted so that improvement processes can be communicated to others for “spread” across applicable areas?

As part of the QOPI process, this will be expanded to all Cancer Center Providers. We will meet with the ACU leadership and discuss the data and processes that are available.

J. Physician Involvement

Note: To receive Part IV MOC a physician must both:

- a. *Be actively involved in the QI effort, including at a minimum:*
 - *Work with care team members to plan and implement interventions*
 - *Interpret performance data to assess the impact of the interventions*
 - *Make appropriate course corrections in the improvement project*
- b. *Be active in the project for the minimum duration required by the project*

27. Physician’s role. What are the minimum requirements for physicians to be actively involved in this QI effort?

- a. Interpreting baseline data and planning intervention: Review of baseline data and revised consent document at a series of meetings held July-December 2013.
- b. Implementing intervention: Obtaining consent and championing process in individual practices and team meetings starting January 7, 2014
- c. Interpreting post-intervention data and planning changes: Reviewing data and developing communication plan for further implementation in meetings held in July 2014.
- d. Implementing further intervention/adjustments: Attend presentations at faculty and team meetings occurring in July and August 2014. Carry out the additional expectations for improving the process of obtaining and documenting consent.
- e. Interpreting post-adjustment data and planning changes: Participate in one of the follow up meetings for data review and ongoing process changes held [Nov 4 and Dec 2014].

28. How are reflections of individual physicians about the project utilized to improve the overall project?

Physician input was solicited at each data review meeting and incorporated into process improvements

29. How does the project ensure meaningful participation by physicians who subsequently request credit for Part IV MOC participation?

Documentation of meeting attendance and review of data.

30. What are the specialties and subspecialties of the physician anticipated to participate in the project and the approximate number of physicians in each specialty/subspecialty?

Internal Medicine/Hematology and Medical Oncology: Approximately 20 physicians.

K. Project Organizational Role and Structure

31. UMHS QI/Part IV MOC oversight – this project occurs within:

University of Michigan Health System

• Overseen by what UMHS Unit/Group?

• Is the activity part of a larger UMHS institutional or departmental initiative?

No Yes – the initiative is:

Veterans Administration Ann Arbor Healthcare System

• Overseen by what AAVA Unit/Group?

• Is the activity part of a larger AAVA institutional or departmental initiative?

No Yes – the initiative is:

An organization affiliated with UMHS to improve clinical care

• The organization is:

• The type of affiliation with UMHS is:

Accountable Care Organization type (*specify which*):

BCBSM funded, UMHS lead Collaborative Quality Initiative (*specify which*):

Other (*specify*):

• **Who is the individual at UMHS responsible for oversight of the QI project regarding Part IV requirements?**

Name:

Title:

Institutional/organizational unit/affiliation:

Phone number:

Email address:

32. What is the organizational structure of the project? [Include who is involved, their general roles, and reporting/oversight relationships.]

Chugh, Rashmi, MD-Project leader

Smith, David, MD-Associate Chief for Clinical Services, MOC lead

Cooney, Kathleen, MD-Chief, Division of Hematology/Oncology

Henry, Lynn, MD, PhD-Participant

Krauss, John, MD- Participant

Merajver, Sofia, MD, PhD- Participant

Schott, Anne, MD- Participant

Schuetze, Scott, MD, PhD- Participant
Veenstra, Christine, MD- Participant
Wilcox, Ryan, MD, PhD- Participant
Bixby, Dale, MD, PhD- Participant
Buckanovich, Ronald, MD, PhD- Participant
Cease, Kemp, MD, M.B.A.- Participant
Kalemkerian, Gregory, MD- Participant
Malek, Sami, MD- Participant
Sahai, Vaibhav, MBBS, MS- Participant
Sood, Suman, MD- Participant
Worden, Frank, MD- Participant

Others who will carry out the interventions are:

Fellows and extenders who act under the supervision of the above providers

Clinic staff who will photocopy the forms, give a copy to the patient, and send the form to HIM

HIM will scan into the patient record

33. To what oversight person or group will project-level reports be submitted for review?

Cooney, Kathleen, MD-Chief, Division of Hematology/Oncology