Report on a QI Project Eligible for Part IV MOC

Instructions

Determine eligibility. Before starting to complete this report, go to the UMHS MOC website [ocpd.med.umich.edu], click on "Part IV Credit Designation," and review sections 1 and 2. Complete and submit a "QI Project Preliminary Worksheet for Part IV Eligibility." Staff from the UMHS Part IV MOC Program will review the worksheet with you to explain any adjustments needed to be eligible. (The approved Worksheet provides an outline to complete this report.)

Completing the report. The report documents completion of each phase of the QI project. Final confirmation of Part IV MOC for a project occurs when the full report is submitted and approved.

An option for preliminary review (recommended) is to complete a description of activities through the intervention phase and submit the partially completed report. (Complete at least items 1-16 and 27a-b.) Staff from the UMHS Part IV MOC Program will provide a preliminary review, checking that the information is sufficiently clear, but not overly detailed. This simplifies completion and review of descriptions of remaining activities.

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.

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

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

QI Project Report for Part IV MOC Eligibility

A. Introduction

1. Date *(this version of the report):*
11/19/2014

2. Title of QI project:
Compliance with Informed Consent Documentation Requirements in Cooperative Group Clinical Trials

3. Time frame

a. At what stage is the project?

☐ Design is complete, but not yet initiated
☒ Initiated and now underway
☐ Completed

b. Time period

(1) Date physicians begin participating (may be in design phase): March 2013
(**2) End date**: ☐ actual ☒ expected 10/31/2014

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

a. Name: Rajen Mody
b. Title: Associate Professor, Department of Pediatrics
c. Institutional/organizational unit/affiliation: University of Michigan
d. Phone number: 734-764-7126
e. Email address: rmody@umich.edu
f**. Mailing address**: 1500 E. Medical Center Dr., MPB Rm D4207, Ann Arbor, MI 48109

5. What specialties and/or subspecialties are involved in this project?
Pediatric Hematology/Oncology /Pediatric Bone Marrow Transplant

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?

Obtaining informed consent (IC) and documenting IC are important aspects of good clinical care. This is extremely important when performing clinical trials involving minor children. Clinical trials are essential for the treatment of childhood cancers and for improving outcomes of pediatric cancer. A Children's Oncology Group (COG) audit of the Pediatric Cancer Program at University of Michigan in March 2013 found:

1. Inconsistent documentation of the IC process within the patient medical records.
2. Some deficiencies of provider signatures and appropriate dates on the ICs.

3. No documentation in the patient's medical record of how it was determined that the patient met eligibility for the trial.

b. Project goal. What outcome regarding the problem should result from this project?
Improve the compliance with documentation of informed consent (including appropriate signatures and dates) and of eligibility criteria within the patient's medical record by providers for patients being treated on Cooperative Group clinical trials in oncology.

8. Patient population. What patient population does this project address.
Children ages and young adults <30 years followed within the Pediatric Hematology and Oncology/Bone Marrow Transplantation Program who are participating in cooperative group clinical trials.

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

☒ Safety	☐ Equity	☒ Timeliness
☒ Effectiveness	☒ Efficiency	☒ 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?
For baseline measures, we have data from the external audit indicating that upon review of randomly selected patient records that there were deficiencies in Eligibility Checklists, provider signature and/or appropriate date absent from the IC, appropriate names of patient and provider on the IC. For the subsequent intervention periods the following core measures of quality were used based on documentation within the patient medical record for every clinical trial participant:

Denominator for all four measures: number of patients beginning treatment in a clinical trial.

For the four measures the numerators are, respectively, number of these patients who had:
1. Eligibility Checklist Documentation adequate
2. Provider Signature present
3. Provider Signature with appropriate date
4. Appropriate names (patient and provider) on the consent

b. Are the measures nationally endorsed? If not, why were they chosen?
No. However, these measures are in keeping with best practices with regards to execution of clinical trials and are measures that are evaluated in multi-institutional ("Cooperative Group") clinical trial audits.

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)?
Manual abstraction from randomly select patients at time of external audit and from sequential charts for subsequent intervention time periods.

e. How reliable are the data being collected for the purpose of this project?
Data are retrieved directly from the patient's medical record by experienced data managers working within the Pediatric Oncology clinical trial program.

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

g. To whom are data reported?
Physicians, Nurse Practitioners, fellows, research coordinators

h. For what time period is the sample collected for baseline data?
Apr 2010 to Mar 2013

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	Number of Patients	% with			
		Adequate Eligibility Checklist Documentation	Provider Signature Present	Provider Signature with Appropriate Date	Appropriate Patient and Provider Names on Consent
Baseline 4/2010-3/2013	13 *	0%	85%	85%	85%

* Random sample from 130 patients.

b. Specific aim: What is the target for performance on the measure(s) and the timeframe for achieving the target? Target performance is 100% compliance for IC documentation and >90% for Eligibility Checklist Documentation at end of two cycles of interventions. Time frame for achieving targets is end of October 2014.

c. How were the performance targets determined, e.g., regional or national benchmarks?
100% compliance with study eligibility and IC documentation is a national best practice for clinical trial participation. >90% compliance with Eligibility Checklist Documentation was an agreed target based on the participants in this quality improvement project.

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.**
Physicians, Nurse Practitioners, fellows, research coordinators were all present at a Staff Meeting held on Mar 27 2013. They had an opportunity to review the baseline data from the audit findings and to discuss what our performance targets should be related to this project. They discussed the contributing major causes for the deficiencies and suggested appropriate countermeasures to address the major causes. We then put in place operational plans to implement the interventions.

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.)*

The group identified that the following were major causes of the inconsistencies in documentation:
1. Information to document for each study can vary.
1. Providers were too busy to prepare checklists on their own (*people, processes, environment*)
2. Lack of awareness of the need for this level of compliance (*people, processes*)
3. Providers were distracted by other aspects of clinical care workflow (*people, processes, environment*)

C. Do

14. Intervention(s).

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

1. We provided feedback to the staff regarding the results and expectations around this aspect of study compliance – this was to address the lack of awareness (Cause #3)
2. We prepared study-specific eligibility checklists for every clinical trial ((Cause #1 and 2)
3. We created templates with consistent language and incorporated them into the electronic medical record through SmartTexts within MiChart (Cause #1, 2 and 4)
4. We provided education and training to staff regarding the use of the templates and their respective roles in creating checklists (study coordinators), entering information (providers), and monitoring that it had been entered (all).

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. Needed information can vary by study – addressed by interventions 2, 3,and 4
2. Providers were too busy to prepare checklists on their own (*people, processes, environment*) – addressed by interventions 2 and 3
3. Lack of awareness of the need for this level of compliance (*people, processes*) – addressed by intervention 1
4. Providers were distracted by other aspects of clinical care workflow (*people, processes, environment*) - addressed by interventions 2, 3,and 4

By pre-preparing the checklists and the SmartText templates within MiChart, we improved the processes and infrastructure for the IC documentation process and made it easier for providers to incorporate this into their clinical care work flow. The educational meeting increased the level of awareness of the need for compliance, our deficiencies prior to intervention and the tools that would be implemented to improved the resources and processes for documentation.

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

Physicians, Nurse Practitioners, fellows - these are the providers that are responsible for acquiring IC and documenting in the medical record. They are also responsible to ensuring that the study participant meets eligibility criteria and that this is documented in the patient's record.

Research coordinators – responsible for preparing Eligibility Criteria checklists for each active study, preparing SmartTexts to be used within MiChart and ensuring compliance with the expected documentation. The Research Coordinators were responsible for acquiring the core measure data during the subsequent intervention periods.

Data compilation – Dr. Mody was responsible for evaluating and compiling the data for presentation to the group.

16. The intervention will be/was initiated when? (For multiple interventions, initiation date for each.)

Jul 1 2013

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:

Will occur for the period:
Has occurred for the period: Jul 1 2013 to Jun 30 2014

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	Number of Patients	% with			
		Adequate Eligibility Checklist Documentation	Provider Signature Present	Provider Signature with Appropriate Date	Appropriate Patient and Provider Names on Consent
Baseline 4/2010-3/2013	13 *	0%	85%	85%	85%
Post-intervention 7/1/13-6/30/14	70	82%	97%	97%	97%

* Random sample from 130 patients.

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.**

Physicians, Nurse Practitioners, fellows, research coordinators were all present at a Staff Meeting held on Aug 6, 2014. They had an opportunity to review the results from the first set of interventions.

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.)*

It was determined that overall we had made great strides in improving the compliance with our initial interventions. In particular, pre-prepared Eligibility Checklists and MiChart templates were viewed as effective interventions. In addition, the prior education as to the performance targets for compliance was deemed to have been highly effective. However, we have not achieved 100% compliance. The group determined that this was likely due to:

1. Continued distractions by the other clinical work flow
2. The addition of new providers joining the clinical research enterprise who still need ongoing education around this issue.

F. Redo

20. Second intervention.

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

Aug 7 2014

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

1. Providers will receive an email reminder from the Research Coordinators regarding any deficiencies in the core measures on a weekly basis (ongoing individual feedback)
2. New providers will receive education as part of their orientation
3. Continued review of data at subsequent staff meetings to maintain awareness and ensure providers remain appropriately educated (periodic group feedback)

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.)*

Continued distractions by the other clinical work flow – addressed by 1 and 3 to initiate real-time correction of deficiencies which should lead to incorporating this documentation into the routine clinical work flow and helping us reach our target compliance rates.

The addition of new providers – addressed by 2.

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:

Will occur for the period: Aug 7 to Oct 31 2014
Has occurred for the period:

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	Number of Patients	% with			
		Adequate Eligibility Checklist Documentation	Provider Signature Present	Provider Signature with Appropriate Date	Appropriate Patient and Provider Names on Consent
Baseline 4/2010-3/2013	13 *	0%	85%	85%	85%
Post-intervention 7/1/13-6/30/14	70	82%	97%	97%	97%
Post-adjustment 8/7/13-10/31/14	22	100%	100%	100%	100%

* Random sample from 130 patients.

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.**

Physicians, Nurse Practitioners, fellows, research coordinators
Staff Meeting on Nov 12 2014

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.)*

1. Continued distractions by the other clinical work flow. However, we now have a mechanism in place so that every week and this has improved our compliance to 100%.
2. New staff will join periodically, especially every July so we will continue to educate and re-educate the staff re; the need for full compliance with ICD process.

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?

We will continue audits every three months indefinitely to monitor performance with the ongoing addition of new staff.

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

1. Weekly reminders by study coordinators to assure compliance.
2. Audits every three months to assess the performance.
3. Any concerns will be discussed in staff meetings going forward.

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?
Compliance with informed consent process and its documentation is universal problems across various divisions and departments. We will present our project and its implementation in department clinical research meeting for spreading the word across department and feedback from other areas.

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: Attend staff meeting on March 27, 2013 to, review the data, participate in the education and in selecting the core measures
b. Implementing intervention: Participate in the intervention that was fully implemented by July 1, 2013, including education process, utilization of the new prepared checklists, incorporating into standard work flow for patient care
c. Interpreting post-intervention data and planning changes: Attend staff meeting held August 6, 2014 to, review the results and proposing next steps
d. Implementing further intervention/adjustments: Participate in the intervention that was implemented August 7, 2014, including education process, continued high compliance with utilization of the checklists and consolidating this into standard clinical work flow
e. Interpreting post-adjustment data and planning changes: Attend staff meeting on Nov 12th 2014 to, review the data, participate in ongoing education

28. How are reflections of individual physicians about the project utilized to improve the overall project?
All participants could share their reflections and suggestions with the project leader at the key planning and review meetings for the project and at any other time during the project.

29. How does the project ensure meaningful participation by physicians who subsequently request credit for Part IV MOC participation?
The project lead monitored participation of each individual. This included monitoring the performance of each individual on the measures to verify that individuals were implementing the interventions.

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?

PHO Faculty
Drew Campbell
Valerie Castle
Aghiad Chamdin
Ray Hutchinson
Brenda Kitchen
Beth Lawlor
Rajen Mody
Steve Pipe
Rama Jasty
Pat Robertson
Jordan Shavit
Kelly Walkovich

BMT Faculty
Sung Choi
James Connelly
Andy Harris
Greg Yanik
Carrie Kitko
John Levine

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? Pediatric Hematology/Oncology**
- **Is the activity part of a larger UMHS institutional or departmental initiative?**

X☐ No ☐

☐ **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.]***
Steven Pipe, MD – clinical oversight of approving the initiation of the project
Rajen Moody, MD – project lead, direct leadership of project and overseeing participants
Research coordinators – prepare templates/checklists and monitor completion by providers
Providers (physicians, nurse clinicians, fellows) – meet with patients to determine and record information regarding eligibility and informed consent.

33. To what oversight person or group will project-level reports be submitted for review?
Dr. Steven Pipe, Division Chief, Pediatric Hematology/Oncology