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, 27-36.)

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, 27-36.)

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:
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Application/Report Outline

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. Act/Adjust
19-20. Review, continuing/new underlying causes, adjustments (second intervention)

F. Recheck
21-22. Post-adjustment performance measurement, data collection, performance level

G. Readjust
23. Review, continuing/new underlying causes to address

H. Future plans
24-26, Subsequent PDCA cycles, standardize processes, "spread" to other areas

I. Physician involvement
27-31. Physician's role, requirements, reports, reflections, participation, number

J. Project Organizational Role and Structure
32-36. Part of larger initiative, organizational structure, resources, oversight, Part IV opportunity

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A. Introduction

1. Date *(this version of the application):* 1/8/13

2. Title of QI project: Improved Efficiency of Delivering Outpatient Cytoxan chemotherapy with lower dose MESNA does not increase incidence of hemorrhagic cystitis.

3. Time frame

a. At what stage is the project?

☐ Design is complete, but not yet initiated
☐ Initiated and now underway
X 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 _12/20/12_____ ☐ expected _____

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

a. Name: Steven C. Goldstein, MD
b. Title: Clinical Associate Professor
c. Institutional/organizational unit/affiliation: Department of Internal Medicine
d. Phone number: 734-764-8824
e. Email address: stevengo@med.umich.edu
f**. Mailing address**: 7310 Cancer Center, 1500 E. Medical Center Dr., Ann Arbor, MI 48109-5948

5. What specialties and/or subspecialties are involved in this project? Hematology/Oncology; subspecialist: Blood and Marrow Transplant Program

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?

It was determined that the Mesna being utilized in the BMT clinic possibly exceeded the necessary dose for pharmacologic benefit based on a review of the literature

It was also determined that the length of time that patients were required to spend in clinic to receive multiple bolus infusions of Mesna was often exceeded 10-12 hours which was problematic for patients and staff.

b. Background/Rationale

1. Intensive-dose Cytoxan with G-CSF is considered a standard approach to mobilizing autologous peripheral blood stem cells (PBSC) in anticipation of high dose therapy with autologous PBSC transplant
2. Cytoxan doses in the ranges used for mobilization are associated with a known risk for hemorrhagic cystitis (10-40%)
3. The infusion of Mesna at a ratio of 1:1 mg for mg with Cytoxan had been the UM standard for prevention of hemorrhagic cystitis (via binding of toxic metabolites and thereby decreasing the risk to the bladder where they otherwise may accumulate).
4. The performance of the laboratory and medical assessment on the morning of therapy (prior practice standard) required an additional 4 hours prior to the initiation of therapy which then took ~ 6-8 hours to complete the infusions. This required the patient (and nursing team) to remain in the infusion suite until early evening (often until 8pm).

c. Project aim. What aspects of the problem does this project aim to improve?
This project will confirm that the enhanced efficiency of outpatient chemotherapy delivery can be done without compromising the safety of patients in any way.

8. Patient population. What patient population does this project address.
Adult patients with hematologic malignancies receiving outpatient chemotherapy with intensive Cytoxan as chemo-mobilization of autologous peripheral blood stem cells in preparation for High Dose Chemotherapy with autologous stem cell transplant.

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?
Primary: incidence of hemorrhagic cystitis in patients receiving Cytoxan/Mesna in the calendar year prior to December, 2011. N=36

Secondary: time of discharge from clinic on day of chemo

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

c. What is the source of data for the measure (e.g., medical records, billings, patient surveys)?
Chart review of medical records in Careweb and/or MiChart

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

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

The data are very reliable

f. How are data to be analyzed over time, e.g., simple comparison of means, statistical test(s)?
The data is analyzed via determination of incidence of cystitis for primary goal and comparison of mean discharge time from clinic are for secondary goal.

g. To whom are data reported?
The data is reported to the members of the Adult BMT program, including nursing and pharmacy.

h. For what time period were baseline data collected?
January, 2011 – December, 2011

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 receiving Cytoxan	Incidence of hemorrhagic cystitis	Median Time of Discharge from clinic on day of cytoxan
January, 2011 – December, 2011	36	0	2030

b. What are the targets for future performance on the measures?
The target for the incidence of hemorrhagic cystitis is less than 10% of patients receiving Cytoxan as chemomobilization.

c. How were the performance targets determined, e.g., regional or national benchmarks?
The medical literature describes the incidence of hemorrhagic cystitis ranging from 10-40%.

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

a. Regarding the process reviewing the baseline data, identifying underlying (root) causes of the problem(s), and considering possible interventions ("countermeasures") to address the causes: who will be/was involved, how *(e.g., in a meeting of clinic staff)***, and when?**

In December, 2011, the QI project leader exchanged a series of communications with nursing and pharmacy.

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. **Root Cause #1:** **Previous clinical standard using high dose of mesna***
a. Historical practice of the BMT program
b. Staff unaware of the available literature defining a lower dose as effective in preventing hemorrhagic cystitis

c. *Concern that change in dose might compromise clinical outcome as assessed by the incidence of cystitis*

2. ***Root Cause #2**: **Use of Bolus therapy for Mesna required extended clinic time***
   a. *Presumed lack of availability of home care services*
   b. *Evaluation and infusion were scheduled for the same day, thereby delaying initiation of chemotherapy and prolonging time in clinic for patients*

This project addresses the safety of improved efficiency of cytotoxic drug delivery in the outpatient setting. It takes into account the infrastructure of the outpatient infusion area in terms of hours of operation and staffing.

Did the reduction in Mesna dose and conversion from bolus Mesna to continuous infusion Mesna dose associated with an increase in the incidence of hemorrhagic cystitis?

Did the schedule modification for pre-treatment labs and evaluation enable patients to be discharged earlier from clinic on the day of treatment?

C. Do

14. Intervention(s).

a. Describe the interventions implemented as part of the project. (see background/rationale section above)

a. Education of team re: safety of lower mesna doses given as continuous infusion based on literature review
b. Established feasibility of home infusion for this agent after detailed pharmacologic review
c. Developed a chemotherapy order set with a 40% reduction in Mesna dose,
d. In this new order set, the mode of infusion was converted from bolus to continuous infusion of mesna/NS,
e. Laboratory and clinical evaluation was scheduled for the day prior to the anticipated infusion, thereby allowing the chemotherapy to begin earlier.
f. Monitor incidence of hemorrhagic cystitis after dose modification was implemented
g. Monitor discharge times from clinic on day of chemotherapy

b. How are underlying/root causes *(see #12.b)* addressed by the intervention(s)? *(List each cause, whether it is addressed, and if so, how it is addressed.)*

Root Cause #1:

- The use of higher doses of Mesna was addressed by the education of the clinical team and the reduction in Mesna dose by 40%

- Determination of a low incidence of cystitis after the changes in Mesna administration would confirm the safety of the intervention.

Root Cause #2:

- Regarding presumed lack of availability of home care services, the feasibility of home infusion was established in consultation with pharmacy and the development of a new order set was completed.

- The same day scheduling of the evaluation and chemotherapy was addressed by separating these components over 2 days.

- Determination of an earlier discharge time from clinic on the day of chemotherapy would confirm the improvement in efficiency of the intervention.

15. Who is involved in carrying out the intervention(s) and what are their roles?
The intervention was implemented in a multidisciplinary fashion involving

- physician who reviewed the literature and made final revisions of the chemotherapy order set, including supportive care orders
- chemotherapy nursing who reviewed order set for feasibility and implementation aspects
- pharmacists in reviewing order sets with modification based on pharmacologic aspects of the drugs (solubility, stability, etc)

16. The intervention will be/was initiated when? (For multiple interventions, initiation date for each.)
December, 2011

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 time period for collection of performance data following the intervention either:
Will occur for the period:
Has occurred for the period: December, 2011 – June, 2012

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 receiving Cytoxan	Incidence of hemorrhagic cystitis	Median Time of Discharge from clinic on day of cytoxan
December, 2011 – June, 2012	26	0	1700

E. Act/Adjust

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

a. Regarding the process of 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: who will be/was involved, how *(e.g., in a meeting of clinic staff)***, and when?**

At 6 months following intervention, outcome data was reviewed with clinicians, outpatient nursing team in infusion suite, extenders, and pharmacists.

N= 26 patients were treated during the post-intervention time period. Review found a low incidence of hemorrhagic cystitis and a 3.5 hour decrease in discharge time. The review confirmed the promise of the intervention.

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.)*

The major problem was the small sample size, so confidence was uncertain regarding the reliability of the findings (wide confidence interval) in a larger cohort of patients.

20. The adjustment (second intervention).

a. The adjustment (second intervention) will be/was initiated when? (For multiple interventions, initiation date for each.)
December, 2011

b.If the adjustment has occurred, what adjustments/interventions were implemented?

As per section 14, but monitored for a longer period of time.

It was decided to review charts for the incidence of hemorrhagic cystitis for an additional 6 month interval after the initial intervention to confirm the reliability of the initial findings of a low incidence of this complication in a larger cohort of patients.

It was also decided to continue to review discharge times from clinic for an additional 6 month interval to confirm that initial findings of a 3.5 h decrease in discharge time was reliable and sustained.

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

The only cause to be addressed was for the ongoing surveillance of hemorrhagic cystitis

F. Recheck

21. Post-adjustment 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 adjustment.

a. The time period for collection of performance data following the adjustment(s) either:
Will occur for the period:
Has occurred for the period: June, 2012 – December, 2012

c. **If the data collection has occurred, what is post-adjustment 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 receiving Cytoxan	Incidence of hemorrhagic cystitis	Median Time of Discharge from clinic on day of cytoxan
January, 2011 – December, 2011	36	0	2030
December, 2011 – June, 2012	26	0	1700
June, 2012 – December, 2012	**14**	**0**	**1700**

An additional 14 patients were treated during the second post-intervention time period. Review again found a low incidence of hemorrhagic cystitis and a 3.5 hour decrease in discharge time. The review confirmed the promise of the intervention in a larger cohort.

G. Readjust

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

a. Regarding the process of reviewing the post-adjustment data, identifying underlying (root) causes of the continuing/new problem(s), and considering additional possible adjustments to interventions ("countermeasures") to address the causes: who will be/was involved, how *(e.g., in a meeting of clinic staff)***, and when?**

In December 2012, the QI project leader reviewed and discussed the outcome data with clinicians, outpatient nursing team in infusion suite, extenders, and pharmacists.

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.)*

The outcome review after the intervention employed in this analysis led to the identification of other aspects of outpatient chemotherapy that can modified that might lead to further improvements in clinic efficiency and patient satisfaction without compromising safety or outcome. Specifically, this review brought up the possibility that patients may be discharged from clinic on day 2 of therapy several hours earlier than current practice suggests. This option will be reviewed as a future QI project with nursing and pharmacy.

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

<u>If a few additional cycles</u> 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.

<u>If several more cycles</u> 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.

H. 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?

No further PDCA cycles will occur for this project.

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

Based on the the confirmation of the safety and improved efficiency of the interventions employed in December, 2011, the chemotherapy modifications implemented at that time will be continued. This is with the consensus of the physicians, nursing, and pharmacists of the BMT program.

26. Do other parts of UMHS 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?

The patient-oriented modification of the evaluation, lab schedule, and chemotherapy delivery outlined in this project may be applicable to other services in the cancer center, though the specific drugs employed are unique to the BMT patient population. This information will be shared with pharmacy, clinicians, and nursing leadership.

I. 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. Reviewing literature re drug dosing and known toxicities
b. Drafting/finalization of new chemotherapy orders in collaboration with pharmacy, nursing
c. Implementation of new schedule for pre-chemo, post-chemo assessment
d. Chart review, monitoring of toxicity trends in outpatient setting.

28. If not addressed in #25, in conjunction with each cycle of data collection, what local (physician-level or practice/unit-level) feedback report and what overall project level report will be provided to physicians?

29. If not addressed in # 25, how are reflections of individual physicians about the project utilized to improve the overall project?

The project leader was involved in discussions at all stages of this project.

30. How will the project ensure meaningful participation by physicians who subsequently request credit for Part IV MOC participation?
Only the Project Leader is participating for MOC credit.

31. What is the approximate number of physicians anticipated to participate in this project? ***[Provide number or range – by specialties and/or subspecialties if more than one.]***

one

J. Project Organizational Role and Structure

32. Is this project part of a larger UMHS institutional or departmental initiative?
☐ Yes ☒ No *If No, go to #33.*

a. What UMHS unit/group is overseeing or coordinating the larger initiative?

b. What is the larger initiative?

c. How does this project advance it?

d. Is this project coordinated with related quality improvement activities?

e. Has someone at a higher institutional level authorized/approved this project? If so, who?

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

34. Are resources needed beyond those under the control of the project lead(s)?
☐ Yes ☒ No *If No, go to #33.*

a. What types of resources are needed and who has agreed to provide them?

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

36. Have UMHS physicians who will participate in this project had the opportunity to participate in a UMHS Part IV project within the past two years?
☐ Yes ☒ No

a. If "Yes," why do these physicians need more frequent opportunities for Part IV credit *(e.g., board gives additional credit for more Part IV activities in a time period; qualify for CMS incentive payment)*?