FAQ's

General Site Questions

1. What is MARCQI's relationship to the device or pharmaceutical industry?

None

2. Who are the sponsors of MARCQI?

Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network (BCN) are the sponsors for the MARCQI collaborative.

3. Will BCBS have access to the data?
No

4. Who owns the data?

MARCQI owns the data. MARCQI is made up of the collaborating orthopaedic surgeons and hospitals.

5. Can I (as a MARCQI participating surgeon) access the data?

Yes, anyone see their own data in their surgeon specific report.

6. What data can I (as a MARCQI participating surgeon) access?

Only your hospital's de-identified patient data and your own patient data.

7. How will data be submitted to the registry?

Data are submitted by abstraction from OR records and charts, electronic data capture of UB04 administrative data, and direct data entry into a web based system (pre-op, OR and web based patient outcomes data).

8. What do hospitals get out of participating in MARCQI?

a. Hospitals have access to up-to-date, best practices for THA and TKA patients to improve quality and safety.
b. MARCQI participating hospitals will receive financial benefits through the BCBSM P4P program
c. Participating hospitals will also receive FTE support for data abstraction at their institution. (There are a few hospitals in Michigan that have different agreements with BCBSM. Questions regarding financial payments may emailed to: P4Phospital@BCBSM.com)

9. What do surgeons get out of participating in MARCQI?

a. Their own registry data.
b. Quality improvement through collaboration across the state:
    i. Eventual reduction in revision rates
    ii. Reduction in infection rates
    iii. Improved practices for DVT/PE prophylaxis
    iv. Lower complication rates

10. What do patients get out of participating in MARCQI?

Patients benefit by improved safety and quality of care when undergoing hip and knee replacement.

11. How is the Registry organized?

The registry is governed by the MARCQI Executive Committee (EC) with authority for all policy and reporting decisions. The EC is chaired by the co-directors and is composed of six (6) orthopedic surgeons, the Director of the Data Center, the chairs of the Clinical Data Abstractor and Device Committees and the project manager. The Medical Advisory Committee (MAC) will serve to address medical issues related to data quality projects and include the clinical champions from each hospital.

12. What commitment is required for a hospital to participate in MARCQI?

a. **BCBSM** will provide funding for a Data Abstractor FTE. The hospital must have a participating hospital agreement (PHA) with BCBSM. Or without a PHA, you are welcome to participate but you will not get P4P from BCBSM or support for data abstractions efforts. (See MARCQI Eligibility and Expectations document)

b. **MARCQI** requirements of the participating hospital:

i. Hire an FTE for data abstraction.
ii. Cooperate with data audits/site visits
iii. Participate actively with the consortium
iv. Designate a Clinical Champion (Orthopaedic Surgeon)
v. Provide oversight and leadership to the staff involved in the MARCQI data capture process at your hospital.
vi. Attend Quarterly Meetings
vii. Participate in MAC and/or other MARCQI committees.
viii. Identify QI objectives for your hospital.
ix. Collaborate with other MARCQI clinical champions.

13. Should an Information Technology (IT) person from each site attend quarterly meetings?

In your first year of participation, your IT staff person should attend, at a minimum, the kick-off and the Database webinar. This attendance is part of the Performance Index. We encourage the IT staff to attend the Quarterly meetings to ask questions and learn what we expect from them for the MARCQI project to be successful at your hospital. Once the IT staff have set up monthly reports for your hospital, and are working smoothly, they are not REQUIRED to attend. There are annual webinars for the IT staff to educate them on the database enhancements.

14. What is the project specs/description for my IT person?

IT Lead - Role Responsibilities:

a. Provide an IT/ manager contact for the hospital to facilitate electronic data exchange (OR log, IT manager, and or an IT business systems analyst who can create a program to pull the electronic data from the EMRs at the hospital). This program will run on a monthly basis for several reports that will be uploaded to the database.

b. Extract Data from hospital electronic medical record (EMR) systems.

c. Attend Quarterly Meetings to ask questions and understand what MARCQI needs from each hospital's EMR.

d. Provide to the CDA or IT designate the proper FBA Upload files for transfer of the Data Elements to a secure, web-based data system (the MARCQI registry provided by Ortech).

e. Ensure that electronic data exchange can occur. Automate administrative data transfer process once a month in the required format.

15. Will there be any type of training that the IT staff will need to attend prior to the start of data collection/entry?

The IT staff will attend a webinar with the database administrator, Ortech, to review the requirements.

16. Where can I obtain the specifications manual in order to get working on things? Will there be any type of training I will need to attend prior to the start of data collection/entry?

This data will be in the MARCQI User's Guide, Specifications Manual and Specific Data Element File Based Data Acquisition (FBA) forms (Pt./Case Registration file, OR log, Hospitalization file, Device log) with each file format. All CDA's attend an in- person training session before data collection begins.

An electronic copy of the MARCQI User's Guide, Specifications Manual, Master Data Elements List, and Specific Data Element File Based Data Acquisition (FBA) forms (Pt./Case Registration file, OR log, Hospitalization file, Device log) is on the webpage.

17. Is there any anti-virus software protecting the data on the Ortech servers?

Yes, it is Symantec Endpoint Protection.

18. Do we need IRB approval?

No, MARCQI data collection is for quality improvement activities only and is not human subjects' research. As a result, under federal rules 45 CFR part 46, known as the "Common Rule", MARCQI activities are in the category **Not Regulated**. Consequently, IRB submission and review is **not** required

19. Can I find copies of the forms, i.e. data use agreement, BAA, etc. online?

Yes, you can find them on the MARCQI website (www.marcqi.org) under the Site Checklist Section.

20. Once the forms are completed where do I send them?

Please return completed new site check list forms to Anne Kagay-Lidster by email alidster@umich.edu or fax 734-998-9905.

21. Do the Ortho physicians need to complete the Registration forms?

Yes, everyone (data abstractors, physicians, and anyone with access to the registry) on the MARCQI project needs to complete the appropriate registration forms.

- The information on the Hospital registration form is necessary for MARCQI to add your hospital as participating site in the database.
- The information on the User form is needed to create a user name, password and to assign appropriate privileges for the database.
- The Surgeon form is needed from all participating surgeons. The Surgeon Name will appear in a drop down menu for each procedure that they are performing.
- If the surgeon's would like access to the database they will need to complete a User Registration form and sign the Physician Conflict of Interest disclosure for us to create a user name and password for them to login.

22. Do the Ortho physicians need to complete the Disclosure - Conflict of Interest form?

Yes, everyone (data abstractors, physicians, and anyone with access to the registry) needs to complete the Conflict of Interest /Disclosure form annually. There are two versions: Physician and Non-Physician.

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23. Can we participate in the national data registry American Joint Replacement Registry (AJRR)? What is the cost of participation?

MARCQI can submit the data directly to AJRR after the site has negotiated a BAA/DUA /Participation agreement with AJRR.

If your hospital chooses to have the MARCQI data submitted to the AJRR by the MARCQI Coordinating Center, the **only** information that would be shared with the AJRR are the 14 data elements listed on the MARCQI Addendum. These are **not** de-identified before going to the AJRR. However, they will be securely encrypted before being transmitted to the AJRR. We submit the SSN to the AJRR in a hashed and encrypted format.

Your MARCQI Data Use Agreement addendum must indicate that you want your data to be provided to the AJRR.

The cost to participate in AJRR varies.

24. Our HIPAA Security Officer is concerned about us obtaining emails from patients and then sending notices to complete the PROs with a link to the survey. Is there a permission form that we could use or would we have to create this?

Emails that are sent to patients are secure. No patient information is displayed on the email letter. The email sent to the patient doesn't even contain their name. The letter that goes to the patient has a salutation greeting of "Dear Dr. A patient". There is **no** additional PHI contained in the letter. You will see a sample of this at training. There is a security question that is answered at the time of registration.

The patient will NOT have any access to any other MARCQI registry system data from this email. They will only be able to answer the Patient Reported Outcome Survey (PROS) when they provide the answer the security question that they have provided to the data abstractor prior to being registered into the MARCQI system.

There are several pages of security information in the Ortech section of the binder you received at the Kick-Off meeting. No written permission form is required.