



MONTEFIORE MEDICAL CENTER
The University Hospital for the
Albert Einstein College of Medicine

ADMINISTRATIVE POLICY AND PROCEDURE

SUBJECT:	PRACTICAL GUIDANCE IN THE USE OF CLINICAL LOOKING GLASS	NUMBER: JC07.1a
OWNER:	MANAGEMENT INFORMATION SERVICES	
EFFECTIVE:	REVIEW/REVISED:	SUPERSEDES:
10/07	05/11	08/10, 10/07
CROSS-REFERENCE: Administrative Policy and Procedure JC07.1 – Appropriate Use of Clinical Looking Glass		

Purpose:

To ensure that the patient privacy principles espoused in JC07.1 are effectively put into practice while using Clinical Looking Glass in the evaluation of care, IRB approved Research and Education.

Scope:

To provide practical guidance to users of Clinical Looking Glass who have read JC07.1 Appropriate Use of Clinical Looking Glass.

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Background:

Montefiore Medical Center has committed to a strategy of providing distributed analytic capability of all of its work processes to its staff to

- encourage continuous quality improvement efforts,
- support Institutional Review Board Approved Research, and
- imbue the next generation of clinicians with a commitment to longitudinal outcome responsibility.

This groundbreaking commitment requires sensitivity to patient privacy. This Guidance Policy has been developed to address the practical issues to be considered by users of CLG, their authorizing supervisors, and supervising bodies at the Medical Center.

Clinical Looking Glass Operates in two distinct modes – privileged and restricted.

The privileged mode provides the user with full access to all patient identifiers with the exception of social security number. Identifiers accessible to users of Clinical Looking Glass (CLG) in the privileged mode include:

- Name
- Address
- Telephone number
- Geocode to Longitude and Latitude

The restricted mode produces a data set without names or addresses, but does include:

1. Dates of service, dates of birth,
2. Location mapped to census block group (average 500-1500 people) but not longitude and latitude.
3. Pathology identifiers numbers that can only be mapped to identifiers for those with access permission to the hospital computerized pathology system which does contain patient identifiers.
4. Text of lab tests and pathology tests scrubbed of patient's name and medical record number

Even with the limited elements available in the restricted mode, an individual with access to detailed clinical and laboratory data in an Electronic Medical Record system, and adequate time could “reverse engineer” the identity of the individuals under study. This “reverse engineering” is explicitly prohibited by policy and signed commitment by users. We rely on the professionalism of the user community to honor this commitment.

No system committed to flexible analytic access to unforeseen questions can afford to degrade the quality of the data beyond the restricted mode. It is this realization that has made the restricted mode the de facto standard for analytic questions.

The privileged mode is used only as a last step for cause documented at the time of query. This justification is reviewed at regular intervals by appropriate parties.

Uses of Clinical Looking Glass

Clinical Looking Glass is used for five domains at the Medical Center:

1. Quality Improvement Projects
2. Operational Supervision of Care by individuals with a direct care giving or care supervision role for patients under review.
3. Institutional Review Board approved Research
4. Work in Preparation for research to establish the presence of adequate numbers of relevant patients
5. Education

Quality Improvement Projects

Montefiore Medical Center considers Quality Improvement efforts to be an ongoing professional responsibility of its entire staff. Access to detailed Clinical Information is permitted to individuals authorized to perform QI projects who have registered those projects in advance of Clinical Looking Glass use in the hospital's intranet Performance Improvement Website.

For administrative QI projects a hospital Vice President or operations service chief is entitled to authorize administrative staff for CLG identifier access.

For Clinical QI projects, Chairs of Clinical Departments and their designees as well as identified Medical Directors or chiefs of service (such as division chiefs or residency directors) are empowered to authorize the use of Clinical Looking Glass in the identified mode for defined QI activities.

Registered users are linked to their QI supervisors in the CLG audit function. The Performance Improvement Office is advised of those individuals who have run identified analyses invoking a registered QI privilege. The Performance Improvement office can at any time require a progress report from those who have run a Clinical Looking Glass analysis invoking the QI privilege.

Operational Supervision

An immediate patient-physician or patient-administrator relationship exists when a patient is actively receiving care at the Medical Center. For patients in such a relationship, who is expected to personally benefit from the use of Clinical Looking Glass with identifiers, such use is covered by the notion of **Operational Supervision**. Clinical Looking Glass permits identified use of such patients without IRB or QI permission but does require that the relationship and justification be explicitly identified contemporaneously. The category invoked when HIPAA challenged in Clinical Looking Glass is “**patient worklist**”.

By recording in the text box the type of operational use of this data, Clinical Looking Glass provides the user with a way to maintain a defensible contemporary record of justification for identifier use if audited.

Institutional Review Board Approved Research

Montefiore Medical Center is the University Hospital of the Albert Einstein College of Medicine with a mission to increase generalizable medical knowledge (research) as approved by the Institutional Review Board. The Institutional Review Board is required to authorize access to patient records for a project for a defined time. This permission is understood to include the use of Clinical Looking Glass as a vehicle to obtain access to detailed clinical experience.

Clinical Looking Glass cannot isolate access to the specific data relevant to the study in question and relies on the professionalism of the investigator to restrict his own access to the approved content area. Since all queries with identifiers are recorded with date, time, user name, and actual question asked, there is the opportunity to review the actual use of Clinical Looking Glass should there be a suspicion of inappropriate use. Such an audit can be requested by the Montefiore Medical Center HIPAA security officer.

Work in Preparation for research

All research at Montefiore Medical Center whether in the Restricted or Privileged Mode requires IRB approval from the Einstein-Montefiore IRB.

Preparatory work before research to establish that the number of relevant patients exist in the information system to justify a research effort is permitted in the Restricted Mode without specific IRB approval so long as the user has committed to the following:

- 1. The researcher has taken the University of Miami CITI course in protection of human subjects and has evidence of course completion.*
- 2. The cohorts of patients have not been identified but remain in their deidentified state. Should the researcher wish to obtain the identifiers, then IRB permission must be sought. The researchers make no attempt to access any alternative source of information that could allow them to establish the identity of the individual cohort members such as the pathology information system.*
- 3. No sharing, transmission, or publication of hipaa privileged data has been made or will be made from any extraction performed. This explicitly means that neither date of birth nor any geographic information to the level of aggregation smaller than zip code will be shared. No text with any pathology identifier may be shared.*
- 4. Beyond establishing a sufficient Number of patients to support an IRB application for research, no actual research will be performed without IRB permission.*

Education

One of the key missions of the Montefiore Medical Center is the education of the next generation of caregivers and administrators and to imbue them with a sense of longitudinal health care outcome responsibility. To that end, Clinical Looking Glass in the restricted mode is made available to trainees under the supervision of their residency directors and chief residents. One good example of such use has been the Department of Medicine that in its ambulatory care month requires its residents to be trained in Clinical Looking Glass, to identify a clinical topic that they have seen in practice, and evaluate the Medical Center experience. Residents become aware of the magnitude of the issues and the challenges of deriving meaningful inference from administrative and clinical data sets. They are challenged to consider what system level quality improvement interventions might be useful and how their behavior in recording clinical information in the Clinical Information System impacts on their ability to evaluate the quality of care they provide. This “systems thinking” is a core competency required by the Accreditation Council for Graduate Medical Education (ACGME). ACGME requires that residency programs demonstrate:

1. Practice Based Learning and Improvement (PBLI) and
2. System Based Practice.

Clinical Looking Glass enables both.

Residency Directors at Montefiore or their chiefs can authorize residents to have de-identified access (restricted mode) to Clinical Looking Glass for educational purposes.

Einstein Medical Students can be authorized in the restricted mode by a sponsoring faculty member who assumes responsibility for their behavior.

Non Montefiore Residents or Researchers from outside of Einstein must seek permission of the Assistant Dean for Clinical Research at Montefiore (Brian Currie).

Supervisor Responsibility

1. Initial authorization of individual for access to Clinical Looking Glass either in the Restricted or Privileged Mode. The supervisor must identify whether the privilege derives from QI activity that he supervises or IRB approved research. The supervisor can also authorize internet access if necessary.
2. Inform CLG administrator if an individual he formerly authorized is no longer eligible for CLG identifier access due to change in work status (terminated, job change...) or that their access be downgraded from privileged to restricted access.
3. Review the content of QI projects undertaken with his permission and actively use the data collected in departmental improvement projects.
4. Yearly review those he has authorized at the request of the CLG administrator to ensure that their approved privilege level is still correct.

User Responsibility

1. Perform the analyses in the restricted mode if possible, only using identifiers when necessary.
2. Never share passwords or ID with others
3. Protect the output by using a secure computer or by encrypting the intermediate output
4. If using CLG offsite, the user must
 - a. Encrypt all output saved to home computer (even if de-identified)
 - b. Employ the following software with at least weekly updates:
 - i. Antivirus
 - ii. Antispyware
 - iii. Firewall
 - c. Destroy all output (even encrypted) when not needed using DOD standard secure delete with six overwrites.
 - d. Never leave the computer unattended with CLG open

CLG Validation Authorization for identifier access

As part of ongoing Quality Improvement of the CLG tool itself, CLG analytics are run in comparison with other analyses in the institution. This activity is undertaken in explicit collaboration with the development team. Analyses run with identifiers as part of this QI effort need to be authorized after HIPAA challenge as **CLG Validation** with an explicit text explanation of the validation project underway. The average user should not be invoking the CLG Validation authorization.

Case studies for the Justification of the Use of Clinical Looking Glass

Using Clinical Looking Glass to ensure vaccination of Clinic Population

Problem: A clinic administrator wants to bring his clinic into compliance with institutional goals of Pneumovax vaccination for all patients. He wants to use Clinical Looking Glass to find patients who have been vaccinated as well as those who have not to identify targets of needed vaccination.

Solution: Use of Clinical Looking Glass with Identifiers is permitted. The option to be invoked is the **Work List Option** with the rational **-pneumococcal vaccination initiative-** recorded in the text box.

Reasoning: While this could easily be also viewed as QI and potentially require a QI project registration, this is distinguishable from QI as its purpose is the direct delivery of service as an **operational activity of the clinic and medical center for a publicly acknowledged and accepted clinical goal**. Patients identified as not being vaccinated will be placed on a list for targeted vaccination. The use of Clinical Looking Glass in this operational way is no different from using a stethoscope to examine lung or heart sounds. Its use requires invoking “**Patient Worklist**” after the HIPAA challenge screen and documentation in the text box the **operational use** justifying this access.

Ultimately (ten years if not sooner), we expect that such activity will become so routine that even this documentation may not be required. However, as the clinical and societal culture has not yet acclimated to this capability, we are taking the conservative approach of preserving contemporaneous documentation of the justification for the use of identifiers.

Hospitalist wants to find a patient he cared for two years ago to write a clinical Case Report

Problem: A Hospitalist wants to find the name of a patient he cared for two years ago to write a case report on for publication.

Solution:

General Notions:

There are three sorts of relationships that permit identifier access:

1. **Care Giver – Patient relationship** - an active caregiver (administrators of a clinic can fulfill a caregiver role) needs to find information to identify or manage a patient for whom the caregiver or administrator has an ethical obligation to serve. Clinical Looking Glass can be used in this operational way without an IRB or specific QI project. In fact we have provided a place for such searches when you ask for identifiers, you can choose the option **patient worklist** and explicitly write down the justification - the nature of your relationship and follow up work required.
2. **Global relationship with patient – the CLG user is a responsible agent in the evaluation of the System of Care provided to the Class of Patients whose record he wants to review**. This is the classic QI project registered with performance improvement and approved of by the director of service or VP of operations.
3. **No relationship at all** - an IRB approved project grants access to the medical record for an IRB approved research purpose where the notion of informed consent is explicitly reviewed.

In this situation why is the hospitalist trying to find the old patient? Is there some follow up required? If so, then reason #1 obtains.

If this is not to support specific follow up with this patient is there some global qi issue that the hospitalist group is evaluating where you believe this patient constitutes a specific example of a qi issue? If so, then #2 obtains and the project must be registered with the Performance improvement office before using CLG.

In the old days, where patients had a longitudinal relationship with their M.D.s there would be no question that the MD has the right to look through his patient records to service them. In the modern fractured age of care where one's relationship as a caregiver is time-limited the nature of the permission to access the record must be specified so there will be no concern later that one has inappropriately accessed the record.

In this case:

“There was a patient I took care of 2 years ago that I accidentally dropped off of my HOTLIST, and I cannot remember her name. I wanted to use CLG to do a search for all the patients I took of during July 2005 as an inpatient at MMC.”

There is no ongoing relationship with the patient, nor is there a legitimate care or QI need to access his record. The record access is driven by the need to publish. Such access is research and the clg user should obtain expedited Institutional Review Board Review.