

**REPORT OF THE  
QUALITY AND PATIENT SAFETY COMMITTEE OF THE  
BOARD OF DIRECTORS OF THE  
COOK COUNTY HEALTH AND HOSPITALS SYSTEM**

**JULY 28, 2009**

**ATTENDANCE**

Present: Chairman David Ansell, MD, MPH and Directors Hon. Jerry Butler and Luis Muñoz, MD, MPH (3)

Mary Driscoll, Lois Elia and Pat Merryweather (Non-Director Members)

Absent: None (0)

Also Present: Homer Abiad, MD – President of the Medical Staff, Oak Forest Hospital of Cook County; David Barker, MD – Chief Medical Officer, Ruth M. Rothstein CORE Center of Cook County; Robert Cohen, MD - Chairman of Pulmonary and Critical Care at John H. Stroger, Jr. Hospital of Cook County; Patrick T. Driscoll, Jr. – Deputy State’s Attorney, Chief, Civil Actions Bureau, Office of the State’s Attorney; William T. Foley – Chief Executive Officer, Cook County Health and Hospitals System; David Goldberg, MD – President of the Medical Staff, John H. Stroger, Jr. Hospital of Cook County; Aaron Hamb, MD - Chief Medical Officer, Provident Hospital of Cook County; Avery Hart, MD – Interim Chief Medical Officer, Cermak Health Services; Randall Johnston – Office of the State’s Attorney; Sue Klein – Director of Quality, John H. Stroger, Jr. Hospital of Cook County; Mark Krause, MD – President of the Medical Staff, Provident Hospital of Cook County; Roz Lennon – Chief Clinical Officer, Cook County Health and Hospitals System; Charlene Luchsinger – Credentials Verification Officer, Cook County Health and Hospitals System; Elizabeth Marcus, MD – Chair, Breast Oncology, John H. Stroger, Jr. Hospital of Cook County; Michael Puisis, MD – Chief Operating Officer, Cermak Health Services; John M. Raba, MD – Interim Chief Medical Officer, Cook County Health and Hospitals System; Deborah Santana –Secretary to the Board, Cook County Health and Hospitals System; Jeffrey Schaider, MD – Chairman of Emergency Medicine, John H. Stroger, Jr. Hospital of Cook County; David Small – Chief Administrative Officer, Cook County Health and Hospitals System; Anthony J. Tedeschi, MD, MPH, MBA – Interim Chief Operating Officer, Cook County Health and Hospitals System

Ladies and Gentlemen:

Your Quality and Patient Safety Committee of the Board of Directors of the Cook County Health and Hospitals System met pursuant to notice on Tuesday, July 28, 2009 at the hour of 12:00 P.M. at Stroger Hospital, 1901 West Harrison Street, in the fifth floor conference room, in Chicago, Illinois.

Your Quality and Patient Safety Committee has considered the following items and, upon adoption of this report, the recommendations follow.

**Roll Call**

Deborah Santana, Secretary to the Board, called the roll of members, and it was determined that a quorum was present.

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**Public Comments**

Chairman Ansell asked the Secretary to call upon the registered speakers.

The Secretary responded that there were none.

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**Review and accept minutes of the meeting of June 17, 2009**

**Director Muñoz, seconded by Director Butler, moved to accept the minutes of the meeting of the Quality and Patient Safety Committee of June 17, 2009. THE MOTION CARRIED UNANIMOUSLY.**

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**Receive quarterly quality report from the Ruth M. Rothstein CORE Center**

Dr. David Barker, Chief Medical Officer of the Ruth M. Rothstein CORE Center of Cook County, presented the quarterly quality report (Attachment #1).

The Committee reviewed and discussed the information provided.

Chairman Ansell inquired regarding the integration of HIV services System-wide. Dr. Barker stated that most of the other clinics that provide HIV services are relatively small. For example, the clinic at Provident Hospital serves only 400 patients. He added that the CORE Center offers these clinics technical assistance with quality assurance.

During the presentation, the subject of annual performance improvement plans for all System entities arose. Chairman Ansell stated that The Joint Commission requires that performance improvement plans be approved by the Board annually. He suggested that these be rolled-up into one and presented for approval, for example, each year in the month of August. In response to the suggestion, Dr. John M. Raba, Interim Chief Medical Officer of the Cook County Health and Hospitals System, stated that at the August meeting, a timeline on the subject will be provided.

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**Receive status report on draft recommendations for new System quality structure**

Dr. Raba presented a status report on the draft recommendations for the new System quality structure (Attachment #2).

The Committee reviewed and discussed the information provided.

In response to Chairman Ansell's inquiry regarding when this will be finalized, Dr. Raba responded that he expected this part to be finalized by mid-September. This will allow the Chief Medical Officers to review it at least once or twice if they have any concerns. The next step will be to go to the local quality programs to review their internal quality structures. Chairman Ansell indicated that he would like to have a follow-up item on the subject at the next Committee meeting.

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**Review and approve the following Sub-Agreements (no fiscal impact)**

- a. Sub-Agreement with West Suburban Hospital – JSH EM residents to rotate to WSH in the ED.
- b. Sub-Agreement with UIC– Bilateral agreement allowing UIC residents to rotate in toxicology at JSH, and JSH residents to rotate at UIC
- c. ~~Sub-Agreement with Jackson Park Hospital – JPH residents rotate at JSH on the endocrine service.~~ (Withdrawn)
- d. Sub-Agreement with Children’s Memorial Hospital – JSH pediatric residents receive training in Child Protective Services at CMH.
- e. Sub-Agreement with Children’s Memorial Hospital - JSH urology residents get experience in pediatric urology
- f. Sub-Agreement with Children’s Memorial Hospital - JSH EM residents get experience with pediatric patients in CMH’s Emergency Room.
- g. Sub-Agreement with Provident –JSH urology residents get greater exposure to urologic surgery by rotating to Provident.
- h. Sub-Agreement with Northwestern – Bilateral agreement allowing JSH Oral surgery residents to rotate at Northwestern, and Northwestern residents to rotate at JSH.
- i. Sub-Agreement with ~~Rush~~ Resurrection – Their residents rotate in trauma at JSH.
- j. Sub-Agreement with Rush – Rush psychiatry residents rotate in the JSH clinic and ER, seeing psychiatric patients.
- k. Sub-Agreement with University of Chicago - JSH EM residents get experience with pediatric patients at U of C’s Children’s hospital.
- l. Sub-Agreement with Our Lady of the Resurrection - Their residents rotate on JSH’s toxicology service.

It was noted that Sub-Agreement 6(c.) with Jackson Park Hospital was being withdrawn at this time. Additionally, a correction was made to 6(i.). This should be a Sub-Agreement with Resurrection, not Rush.

Dr. Jeffrey Schaidler, Chairman of Emergency Medicine at John H. Stroger, Jr. Hospital of Cook County, presented information on the proposed sub-agreements.

**Director Butler, seconded by Chairman Ansell, moved to approve the Sub-Agreements, as amended. THE MOTION CARRIED UNANIMOUSLY.**

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**Approve request to enter into and execute an agreement with the Metropolitan Chicago Breast Cancer Task Force, to participate in the Chicago Breast Cancer Quality Consortium**

Dr. Elizabeth Marcus, Chair of Breast Oncology at John H. Stroger, Jr. Hospital of Cook County, presented information on the proposed agreement (Attachment #3).

**Director Muñoz, seconded by Director Butler, moved to approve the request to enter into and execute an agreement with the Metropolitan Chicago Breast Cancer Task Force. THE MOTION CARRIED UNANIMOUSLY.**

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**Receive update on the issue of Smoke-free campuses**

Dr. Robert Cohen, Chairman of Pulmonary and Critical Care at John H. Stroger, Jr. Hospital of Cook County, provided an update on the issue of Smoke-free campuses. He stated that the target date for the campuses to become smoke-free is November 19, 2009, which coincides with the date of the Great American Smoke-Out. He added that this ban also extends to all System-owned cars. The press announcement is expected to occur next week. He noted that there was an interest to try to get the County to extend the same type of smoking ban for all properties owned by the County.

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**Receive update on Laboratory surveys at Stroger Hospital**

Sue Klein, Director of Quality at John H. Stroger, Jr. Hospital of Cook County, presented an update on the Laboratory surveys at Stroger Hospital.

The Committee reviewed and discussed the information provided.

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**Follow up item for August 19<sup>th</sup> meeting:**  
**Approval of affiliates' annual performance improvement plans**

This subject was discussed during the presentation of the CORE Center's quality report.

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**Receive report on status of preparations for Cermak re-accreditation**

**Receive report of the Joint Conference Committee of Provident Hospital for the meeting of April 8, 2009**

**Receive reports from the Medical Staff Executive Committees from Oak Forest, Provident and Stroger Hospitals**

**Receive and approve Medical Staff Appointments/Re-appointments/Changes**

**Receive reports on the following:**

- Any Sentinel Events or Near Misses
- Any Patient Grievance Reports
- Update on "never" events
- Report on Recent Regulatory Visits

Director Muñoz, seconded by Chairman Ansell, moved to recess the regular session and convene into closed session, pursuant to an exception to the Illinois Open Meetings Act, 5 ILCS 120/2(c)(17), et seq., which permits closed meetings for consideration of "the recruitment, credentialing, discipline or formal peer review of physicians or other health care professionals for a hospital, or other institution providing medical care, that is operated by the public body," and pursuant to an exception to the Open Meetings Act, 5 ILCS 120/2(c)(11), which states: "litigation, when an action against, affecting or on behalf of the particular body has been filed and is pending before a court or administrative tribunal, or when the public body finds that an action is probable or imminent, in which case the basis for the finding shall be recorded and entered into the minutes of the closed meeting." THE MOTION CARRIED UNANIMOUSLY.

**Chairman Ansell, seconded by Director Butler, moved to adjourn the closed session and convene into regular session. THE MOTION CARRIED UNANIMOUSLY.**

**Director Muñoz, seconded by Director Butler, moved to approve the Medical Staff Appointments/Re-appointments/Changes. THE MOTION CARRIED UNANIMOUSLY.**

Following are the Medical Staff Appointments/Re-appointments/Changes that were approved:

JOHN H. STROGER, JR. HOSPITAL OF COOK COUNTY

INITIAL APPOINTMENTS

Blunt, Trina, D.D.S. Appointment Effective:	Correctional Health Svcs/Dentistry July 28, 2009 through July 27, 2011	Voluntary Dentist
Choi, Humberto, M.D. Appointment Effective:	Medicine/Hospital Medicine July 28, 2009 through July 27, 2011	Voluntary Physician
Christians, Melody, M.D. Appointment Effective:	Medicine/General Medicine July 28, 2009 through July 27, 2011	Active Physician
Collison, Edgar, M.D. Appointment Effective:	Surgery/General Surgery July 28, 2009 through July 27, 2011	Voluntary Physician
Ezeokoli, Chukwudozie, M.D. Appointment Effective:	Medicine/General Medicine July 28, 2009 through July 27, 2011	Active Physician
Fakhran, Sherene, M.D. Appointment Effective:	Medicine/Pulmonary & Critical Care July 28, 2009 through July 27, 2011	Active Physician
Franco, Pablo Moreno, MD Appointment Effective:	Medicine/General Medicine July 28, 2009 through July 27, 2011	Voluntary Physician
Franco, Pablo Moreno, MD Appointment Effective:	Medicine/General Medicine July 28, 2009 through July 27, 2011	Voluntary Physician
Garcia, Patricia, M.D. Appointment Effective:	Obstetrics/Gynecology July 28, 2009 through July 27, 2011	Voluntary Physician
Guerra, Yannis, M.D. Appointment Effective:	Medicine/Endocrinology July 28, 2009 through July 27, 2011	Active Physician
Jolepalem, Jyothi, M.D. Appointment Effective:	Medicine/Pulmonary & Critical Care July 28, 2009 through June 21, 2011	Affiliate Physician
Littleton, Stephen, M.D. Appointment Effective:	Medicine/Pulmonary & Critical Care July 28, 2009 through July 27, 2011	Active Physician
Malapati, Radha, M.D. Appointment Effective:	Obstetrics/Gynecology July 28, 2009 through July 27, 2011	Active Physician

John H. Stroger, Jr. Hospital of Cook County  
Initial Appointments (cont'd)

Mankowski, Joan, M.D. Appointment Effective:	Emergency Medicine/Adult Emerg. Med. July 28, 2009 through July 27, 2011	Voluntary Physician
Milad, Magdy, M.D. Appointment Effective:	Obstetrics/Gynecology July 28, 2009 through July 27, 2011	Voluntary Physician
Mekhael, Fayez, M.D. Appointment Effective:	Correctional Health Srvs/Family Medicine July 28, 2009 through July 27, 2011	Active Physician
Ochoa-Lubinoff, Cesar, MD Appointment Effective:	Pediatrics July 28, 2009 through July 27, 2011	Active Physician
Orbana, Myrna, MD Appointment Effective:	Medicine/Pulmonary & Critical Care July 28, 2009 through July 27, 2011	Affiliate Physician
Rubinstein, Paul G., MD Appointment Effective:	Medicine/Hematology Oncology July 28, 2009 through July 27, 2011	Active Physician
Senseng, Carmencita, M.D. Appointment Effective:	Pathology July 28, 2009 through July 27, 2011	Active Physician
Theodorakis, Spyros, MD Appointment Effective:	Surgery/General Surgery July 28, 2009 through April 27, 2011	Affiliate Physician
Totonchi, Kameel F., M.D. Appointment Effective:	Pathology/Anatomic Pathology July 28, 2009 through September 18, 2010	Affiliate Physician
Uy, Juanito, M.D. Appointment Effective:	Medicine/Hospital Medicine July 28, 2009 through July 27, 2011	Voluntary Physician

REAPPOINTMENT APPLICATIONS

Department of Medicine

Boddicker, Marc E., MD Reappointment Effective:	General Medicine September 17, 2009 through September 16, 2011	Voluntary Physician
Lubelchek, Ronald J., MD Reappointment Effective:	Infectious Disease September 7, 2009 through September 6, 2011	Active Physician
Patch, Olivia E., MD Reappointment Effective:	ACHN/General Medicine July 28, 2009 through July 27, 2011	Active Physician
Zahner, Scott, MD Reappointment Effective:	Medicine/Dermatology July 28, 2009 through July 27, 2011	Service Physician

John H. Stroger, Jr. Hospital of Cook County  
Reappointment Applications (cont'd)

Department of Pediatrics

Mayefsky, Jay, MD	Peds Ambulatory	Affiliate Physician
Reappointment Effective:	September 15, 2009 through September 14, 2011	

Rudinsky, Brian F., MD	Peds Critical Care	Voluntary Physician
Reappointment Effective:	September 15, 2009 through September 14, 2011	

Department of Radiology

Holloway, Nathaniel O., MD	Radiation Oncology	Voluntary Physician
Reappointment Effective:	July 28, 2009 through July 27, 2011	

Department of Surgery

Mejia, Alfonso, MD	Orthopedic	Voluntary Physician
Reappointment Effective:	September 6, 2009 through September 5, 2011	

Szczerba, Stefan, MD	Plastics	Voluntary Physician
Reappointment Effective:	September 17, 2009 through September 16, 2011	

Medical Staff Appointment to be Amended From Provisional to Full Status Effective

Shah, Rai, MD	Family Med/ACHN	Active Physician
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Medical Staff Change with no Change in Clinical Privileges

Abcarian, Herand , MD	Surgery/Colon Rectal	From Voluntary to Active
Beck, Traci P., MD	Surgery/Urology	From Voluntary to Active
Blumetti, Jennifer, MD	Surgery/Colon Rectal	From Voluntary to Active
Turbay, Rafael F., MD	Medicine/General Medicine	From Voluntary to Active

PROVIDENT HOSPITAL OF COOK COUNTY

INITIAL APPOINTMENTS

Ezeokoli, Chukwudozie, M.D.	Internal Medicine	Affiliate Physician
Appointment Effective:	July 28, 2009 through July 27, 2011	

Hasan, Jafar, M.D.	Surgery/Plastic	Affiliate Physician
Appointment Effective:	July 28, 2009 through July 21, 2010	

Okochi, Chimezi, M.D.	Family Medicine	Active Physician
Appointment Effective:	July 28, 2009 through July 27, 2011	

Provident Hospital of Cook County (cont'd)

REAPPOINTMENT APPLICATIONS

Department of Emergency Medicine

Adusumilli, Chowdary, MD Ancillary Physician  
 Reappointment Effective: July 28, 2009 through July 27, 2011

Department of Internal Medicine

Mallik, Naveed, MD Active Physician  
 Reappointment Effective: July 31, 2009 through July 30, 2011

Department of Family Medicine

Ovalle, Alfredo, MD Active Physician  
 Reappointment Effective: July 28, 2009 through July 27, 2011

Department of Obstetrics/Gynecology

Gandia, Justin, MD Active Physician  
 Reappointment Effective: September 15, 2009 through September 14, 2011

Department of Pediatrics

Kates, Gayle MD Active Physician  
 Reappointment Effective: August 2, 2009 through August 1, 2011

Department of Surgery

Alsaden, Mahdi, MD Active Physician  
 Reappointment Effective: September 15, 2009 through September 14, 2011

Canning, John, MD Active Physician  
 Reappointment Effective: September 16, 2009 through July 11, 2010

Harrison, Jacqueline, MD Affiliate Physician  
 Reappointment Effective: September 16, 2009 through August 14, 2011

STATUS CHANGE

Akbar Khan, M.D. From Active Physician to Ancillary Physician  
 Medicine/Critical Care

OAK FOREST HOSPITAL OF COOK COUNTY

MEDICAL STAFF INITIAL APPOINTMENTS

<u>Name</u>	<u>Department</u>	<u>Status</u>
Friedman, Yaakov, M.D. Appointment effective:	Medicine/ICU July 28, 2009	Affiliate Physician through June 16, 2011
Hanna, Aseel Appointment effective:	ACHN July 28, 2009	Active Physician through July 27, 2011



Cook County Health and Hospitals System  
Report of the Meeting of the Quality and Patient Safety Committee  
July 28, 2009

ATTACHMENT #1

# Ruth M. Rothstein CORE

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July 2009

## Patient Satisfaction Survey Report

Dave Barker, MD, MPH – CMO, Jennifer Catrambone, MA – Director, QI & Eval

# Patient Satisfaction Survey

## Thanks to...

- Jennifer Catrambone – Director, QI & Evaluation
- Dr. Jack Kowalski – CORE Associate Medical Director and Chair QI Committee
- Peter McLoyd – Director Peer Educators
- Our Patients who participate

# Caveats

- The most dissatisfied patients are those you cannot survey because they have voted with their feet – *and gone elsewhere.*
- Therefore this Survey is an estimate of the maximum patient satisfaction. Between 5-8% of patients exit care each year.

# History

- HIV Primary Care Clinics initiated ~annual patient satisfaction surveys in 1995.
- “Home-grown” instruments used from 1995-2003 generally similar to current survey.
- Changed in 2004 to National model survey from HIVQUAL.

# HIVQUAL

- A program of HRSA linked to Ryan White HIV CARE Act funded agencies.
- HIV Quality activities based on HHS HIV/AIDS Bureau, and New York State Department of Health AIDS Institute.
- Provides basic model survey instrument  
Main Survey with validated questions

# Modular design

- Each clinic adopts modules that suit the programs it provides.
- CORE is among the most comprehensive programs in the U.S. and adopted available modules for:
  - Overall satisfaction
  - Demographics
  - Primary Care
  - Mental Health
  - Social Work
  - Chemical Dependency

# Created Additional Modules

- CORE Center had to create modules for:
  - Dental Services
  - Health Educators
  - Lab
  - Nursing
  - Nutrition
  - Peer Educators
  - Pharmacy
  - Registration
  - Research
- New modules created based on assessments by managers, CORE administration, peer reviewers and patients. Developed by Director of QI with managers and approved by QI committee. There are 6-16 questions per module.

# Quality of Questions

- CORE's QI Committee reviews annual data for internal consistency (positive and negative responses to other questions) and makes changes to improve patient understanding.
- Simplify questions with low response choices (e.g. in "circle all that apply" all responses chosen by less than 1% might be lumped into "other" in future).

# Executive & Clinic Operations Committees

- Reviews overall data, makes recommendations about adding or deleting modules.
- In 2007 we added a module on Dental Care as part of new Dental Peer Review
- In 2008 we deleted section on Chaplains, and added modules on both Peer and Health Educators.

# All Staff Meeting

- Results including year-over-year results presented annually at all staff meetings.
- Underperforming departments identified and challenged to improve. Explanations and intentions for improvements provided to all staff.
- Summarized in clinic wide “COREspondence” newsletter including distribution to medical staff.

# Survey Instrument

- Four years data available from current survey.
- Some changes from year to year, most questions intentionally unchanged to allow for comparisons.
- Questions explore patient demographics, overall satisfaction, and 12 clinical and supporting departments.
- Current main survey has 57 questions, plus each patient receives 1 or 2 modules, depending on module length

# Conduct of Survey

- Survey is conducted annually in September / October.
- Typically conducted over a 2 week period.
- All HIV primary care clinic sessions are surveyed at least once.
- Survey is distributed by Peer Educators, available in English and Spanish. Peers will help read questions for persons with vision or literacy limitations.

# Conduct of the Survey II

- Respondents are a *convenience* sample of patients waiting to be seen.
- Incentives for completing survey include candy and a raffle ticket with a \$50 gift card as the prize
- Sample size goal is 350-450 patients or 6-8% of census, with 439 surveyed in 2008
- Goal is 50 completed modules for each service.

# Sample

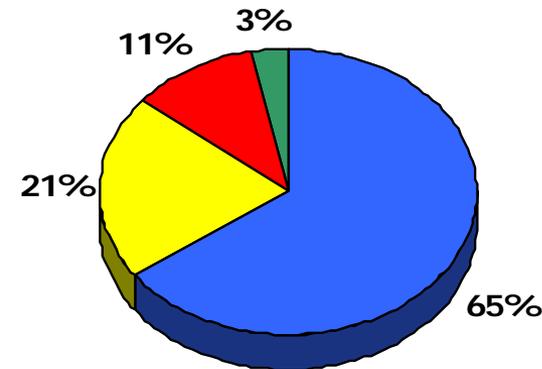
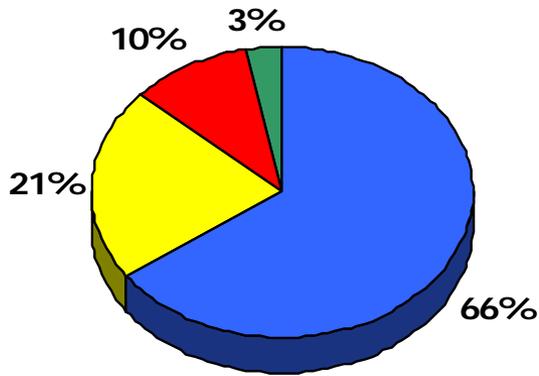
- Walk-in (unscheduled) patients likely to be oversampled (longer waits to be seen).
- Possible bias to lower satisfaction among unscheduled patients; more Chemical Dependency and Mental Health issues than those with scheduled appointments.
- Includes new patients and those not fully engaged in care (unlike QA sample).

# Demographics

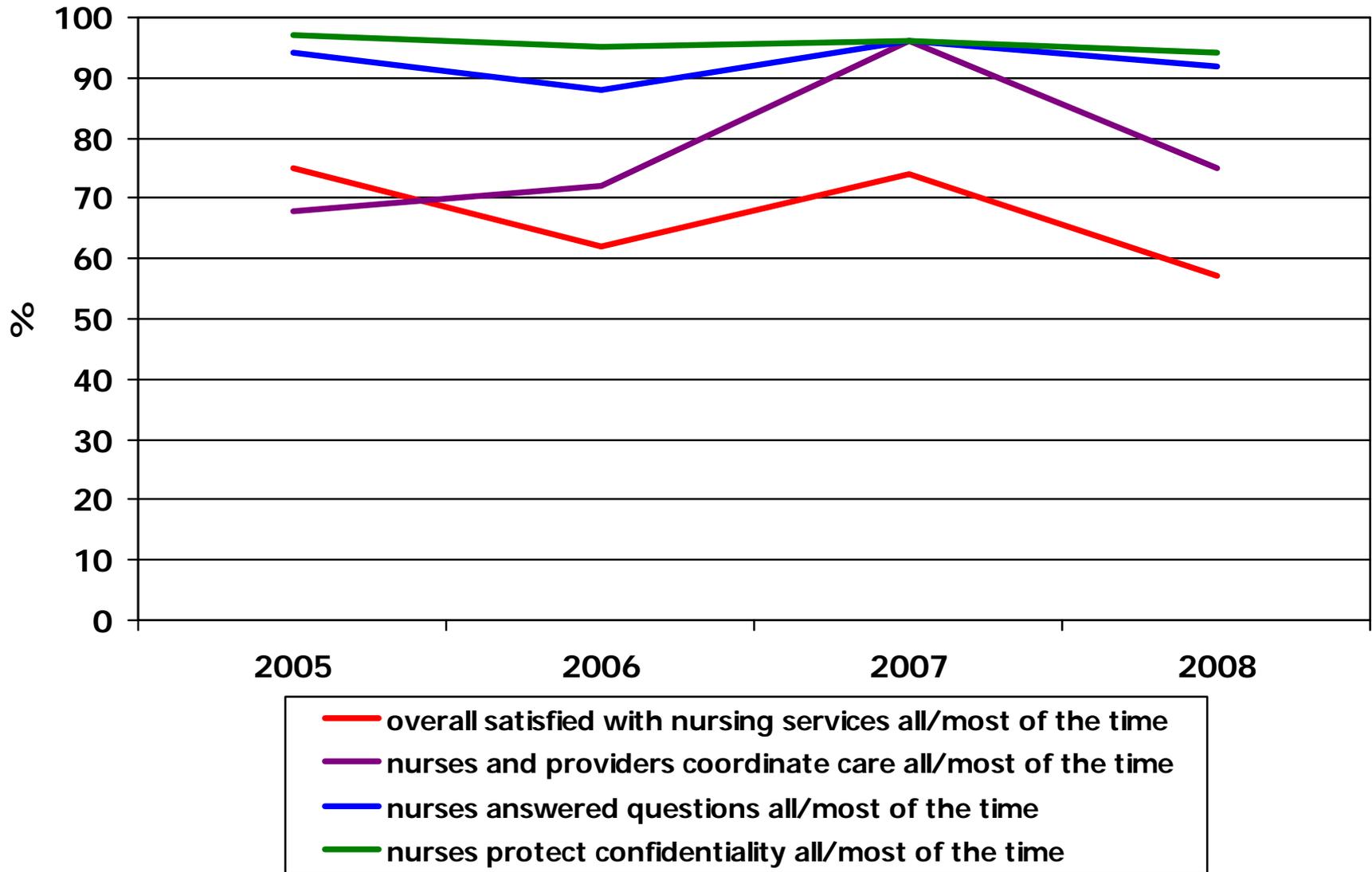
Summary of patients responding vs. known/estimated demographics of entire clinic.

2008 Survey Demography

2008 Clinic-Wide Demography

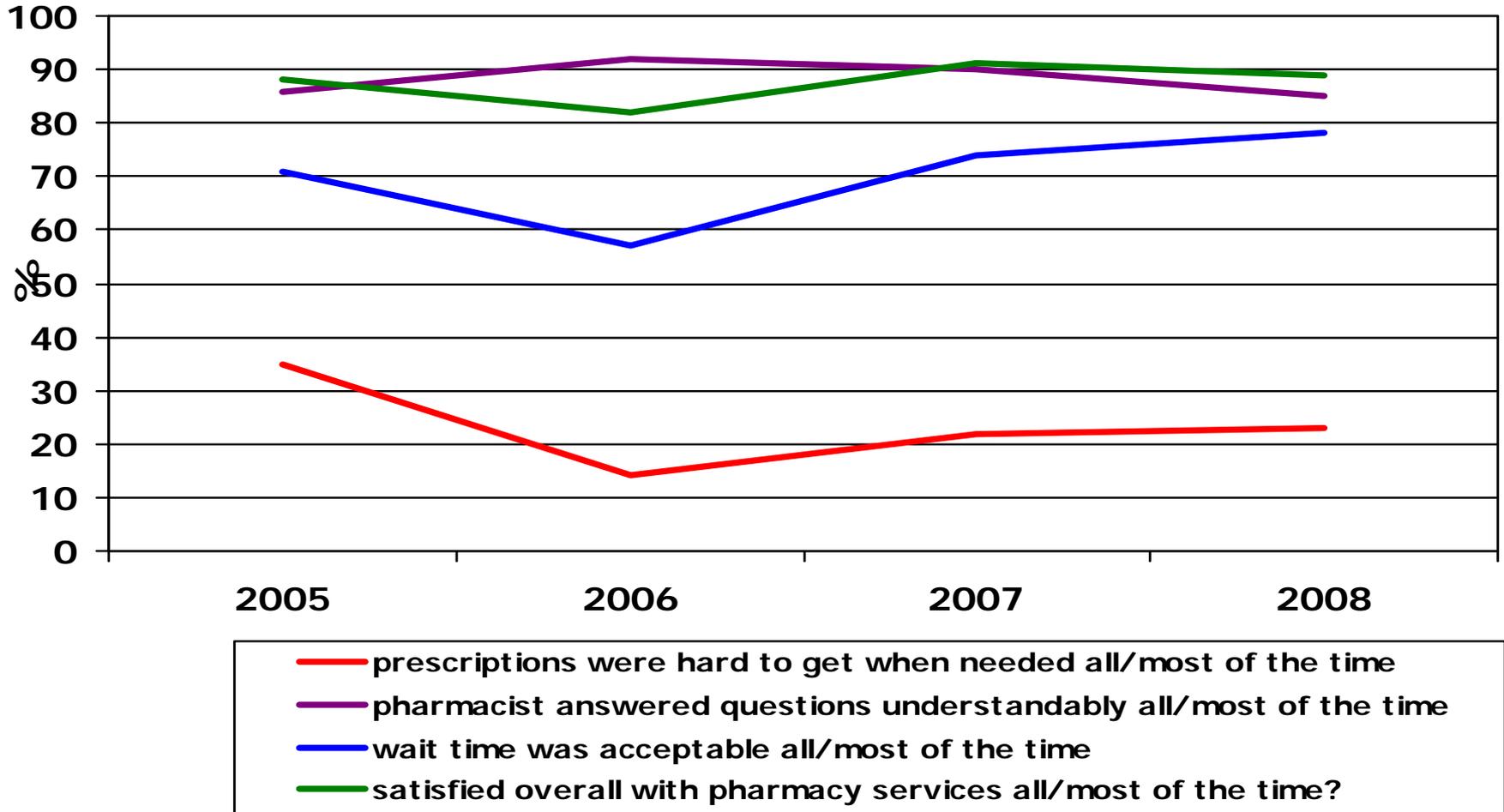


# Departmental Summaries: Nursing<sup>26</sup>

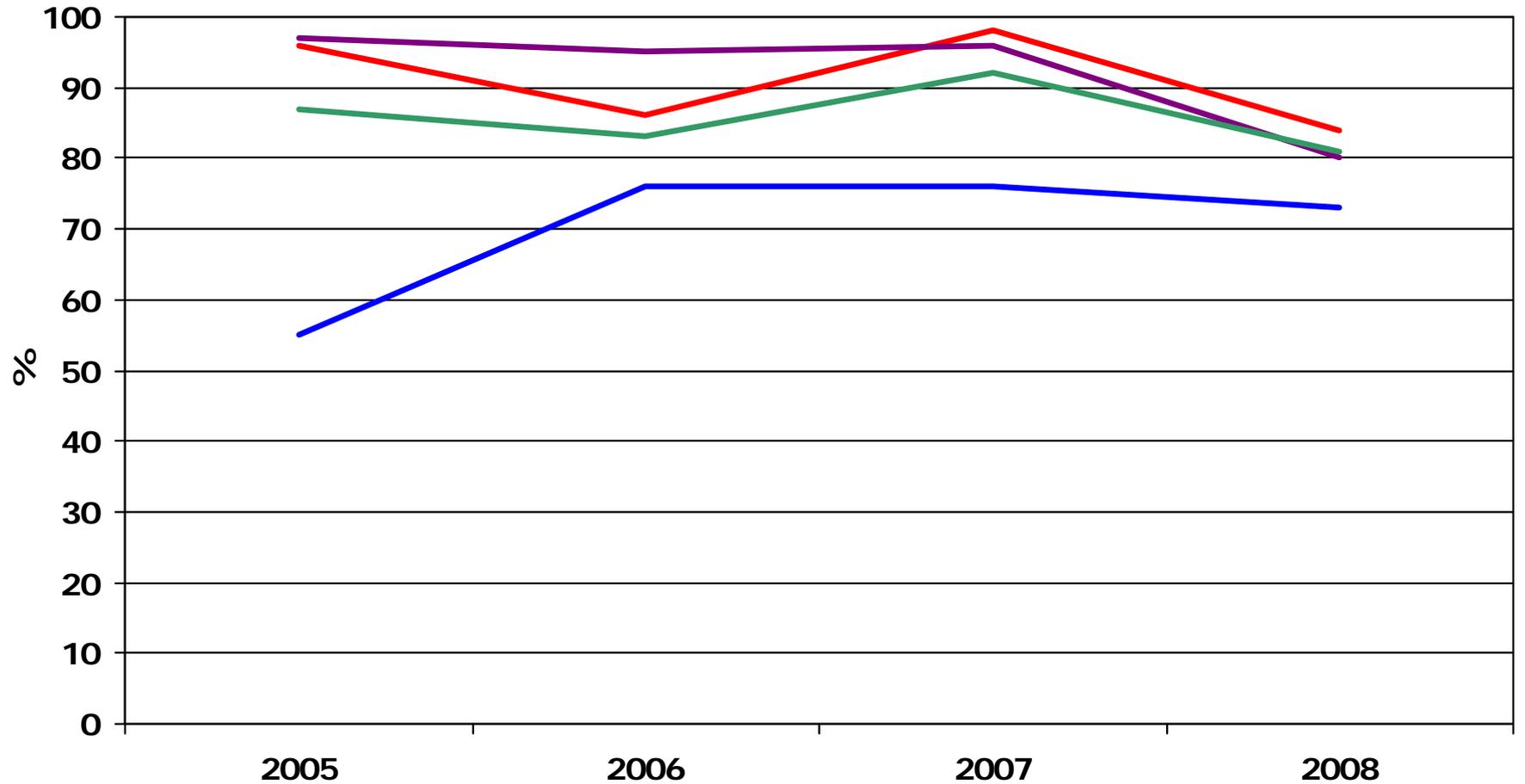


# Departmental Summaries: Pharmacy

CORE refuses to provide meds to Medicaid and most Medicare patients, insists patients sign up for MAP programs and collects co-pays.

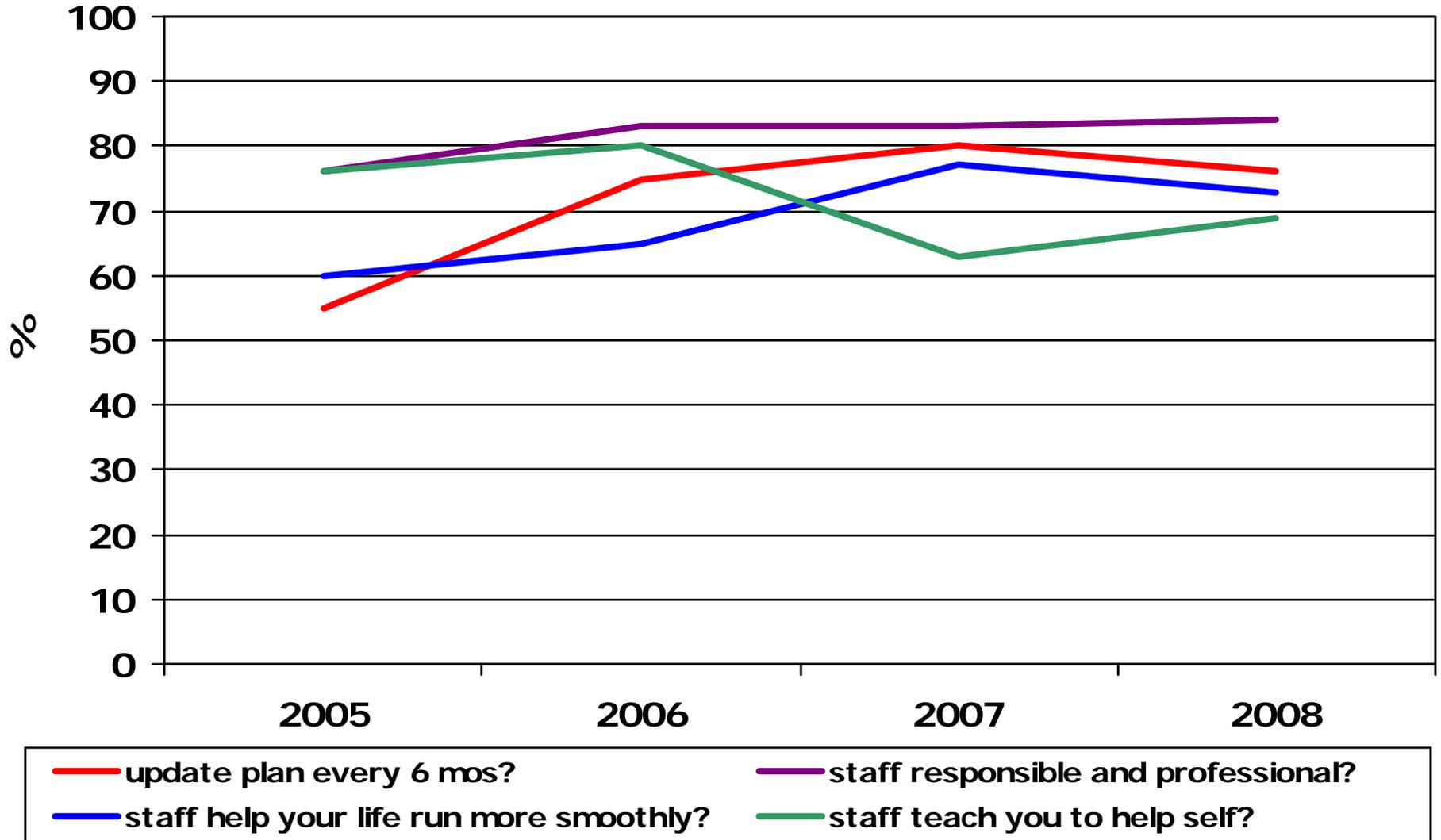


# Departmental Summaries: Labs

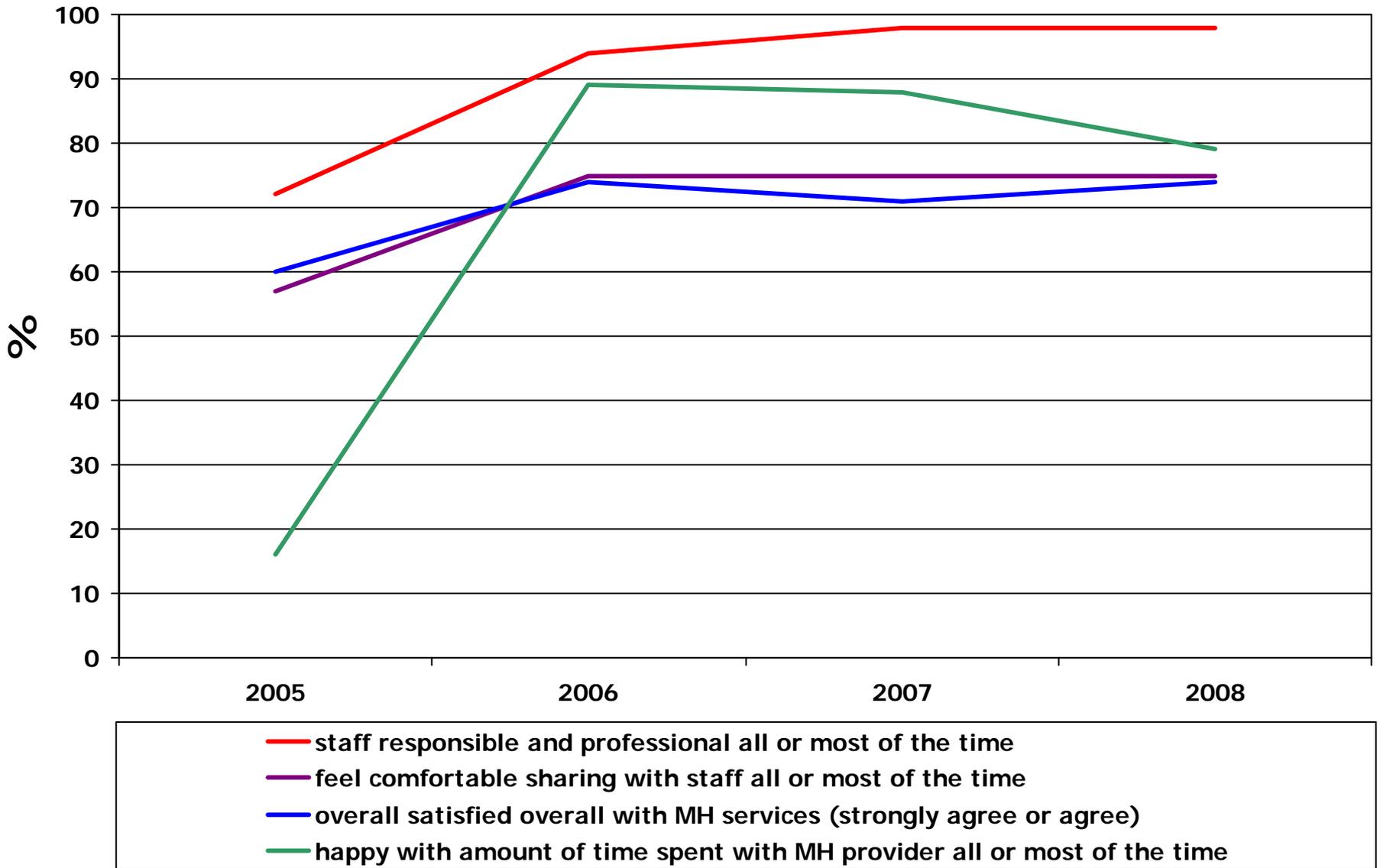


- lab staff protect confidentiality all or most of the time?
- lab staff responsible and professional all or most of the time?
- wait time was acceptable all or most of the time
- quality of service excellent or very good

# Departmental Summaries: Social Work



# Departmental Summaries: Mental Health



# Departmental Summaries: Registration<sup>31</sup>

2008 was the first year Registration had a module.

CORE's registration/ reception staff was responsible and professional. 82%

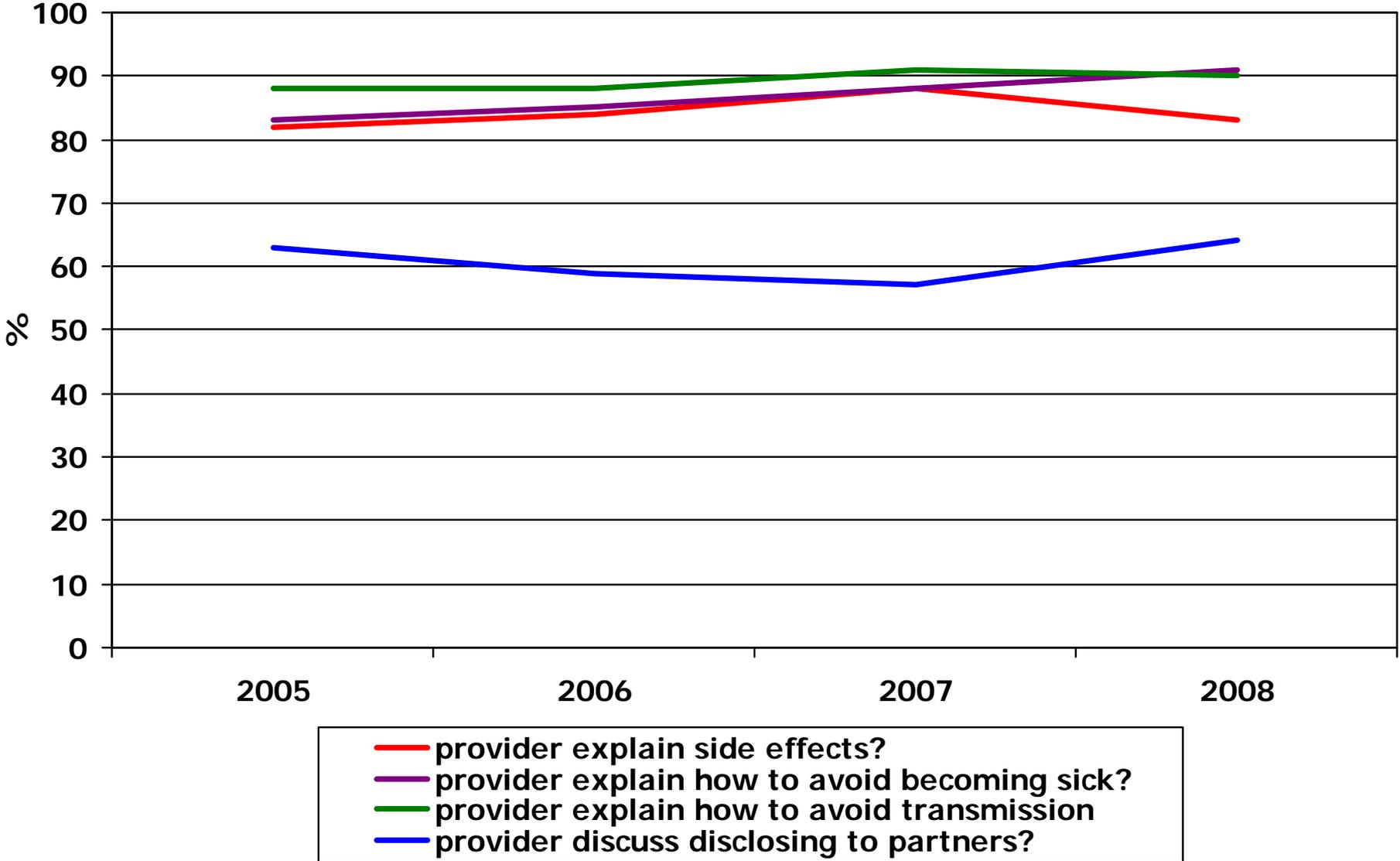
CORE's registration/ reception staff has a good attitude towards customers. 78%

I was asked both to give my name or birthday *and* to show my orange card by CORE's registration staff. 79%

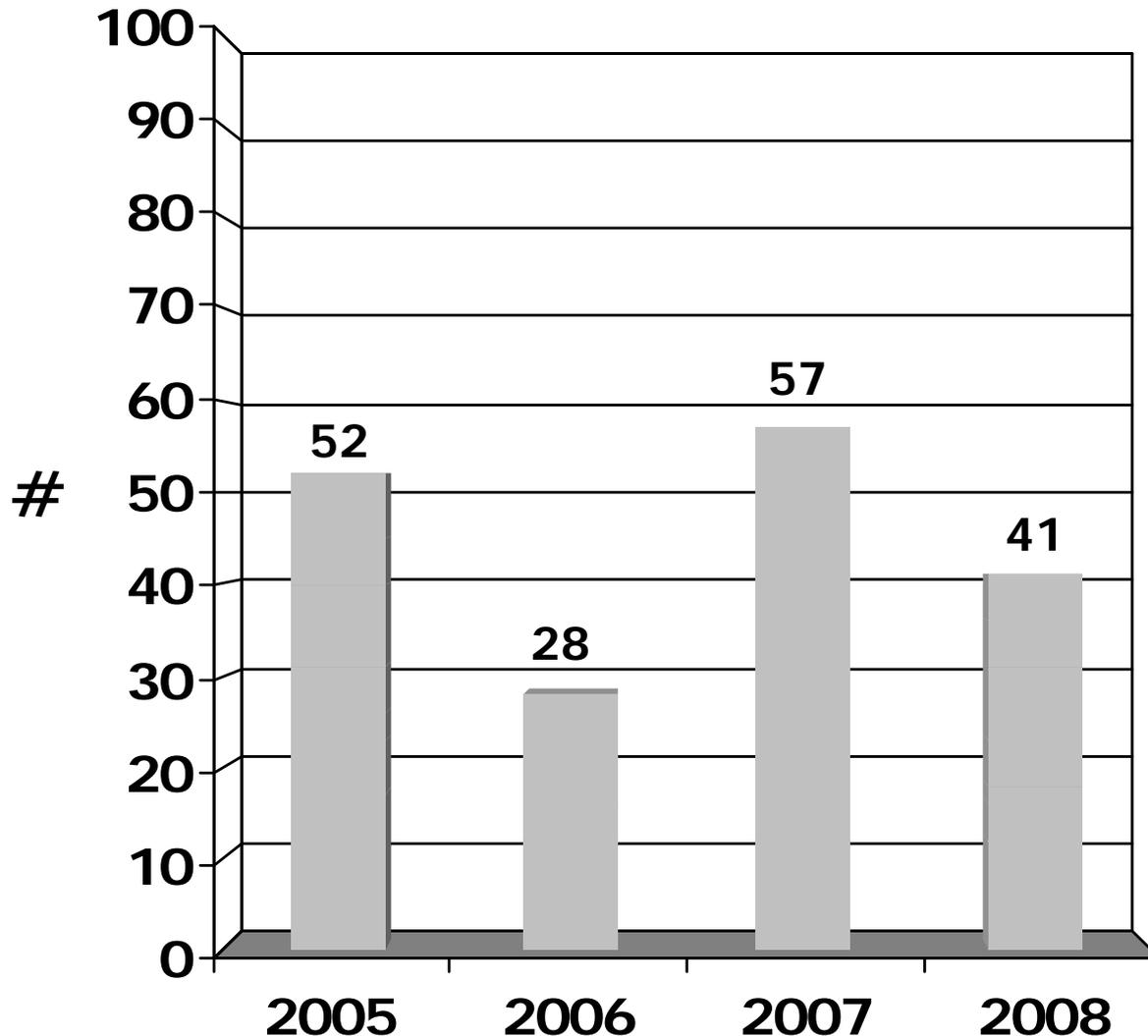
CORE's registration staff checked with me to make sure my address and phone were current in the computer. 80%

CORE's registration worked to help me if I had trouble with paperwork. 72%

# Departmental Summaries - Providers



# Treated Poorly at CORE?



**Lists total number of responses, not percentages nor number of surveys.**

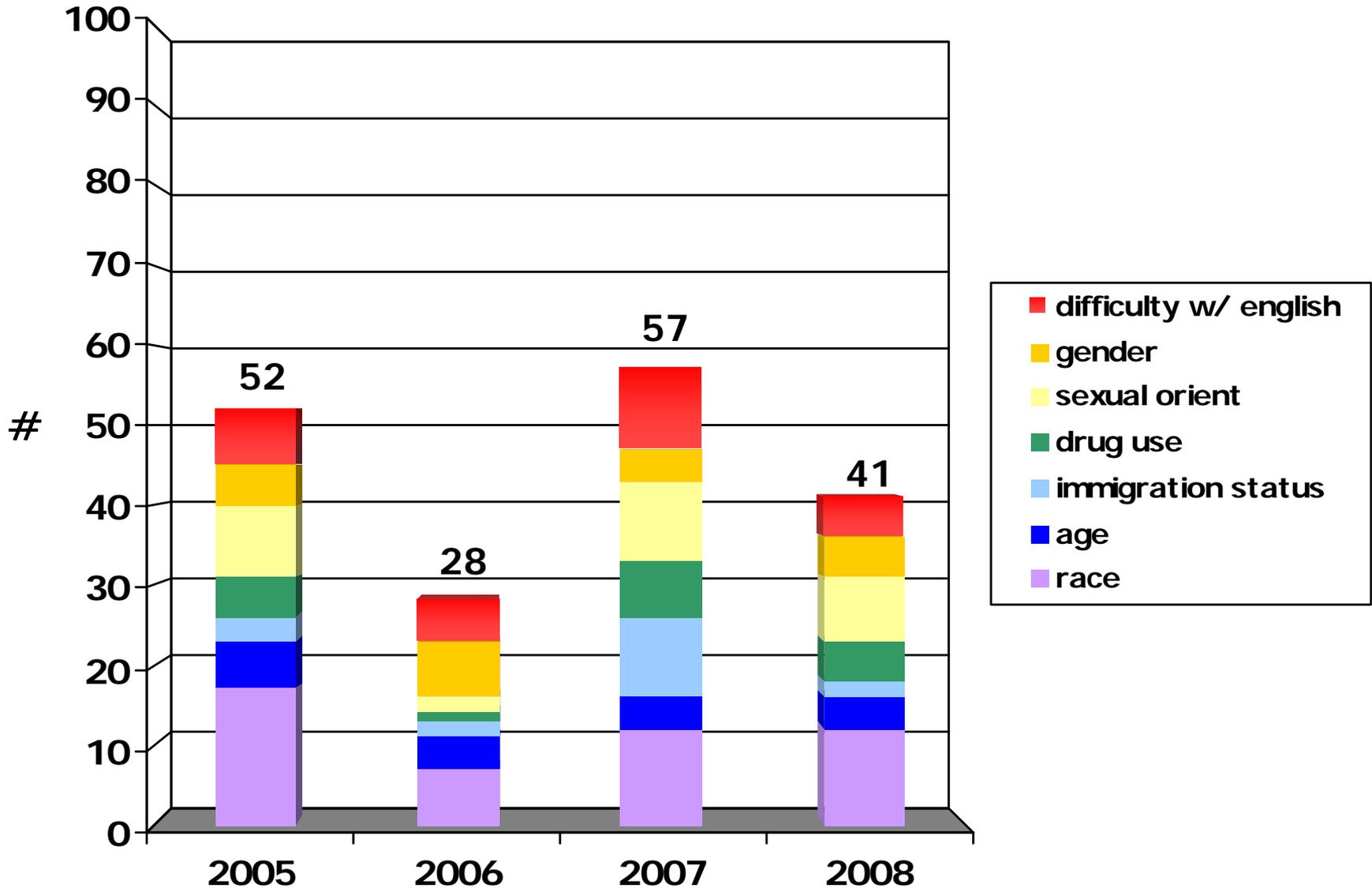
**In each of the past four years 11% of patients picked one or more answers.**

***Remember the question asked whether they were ever treated poorly.***

# Question #42

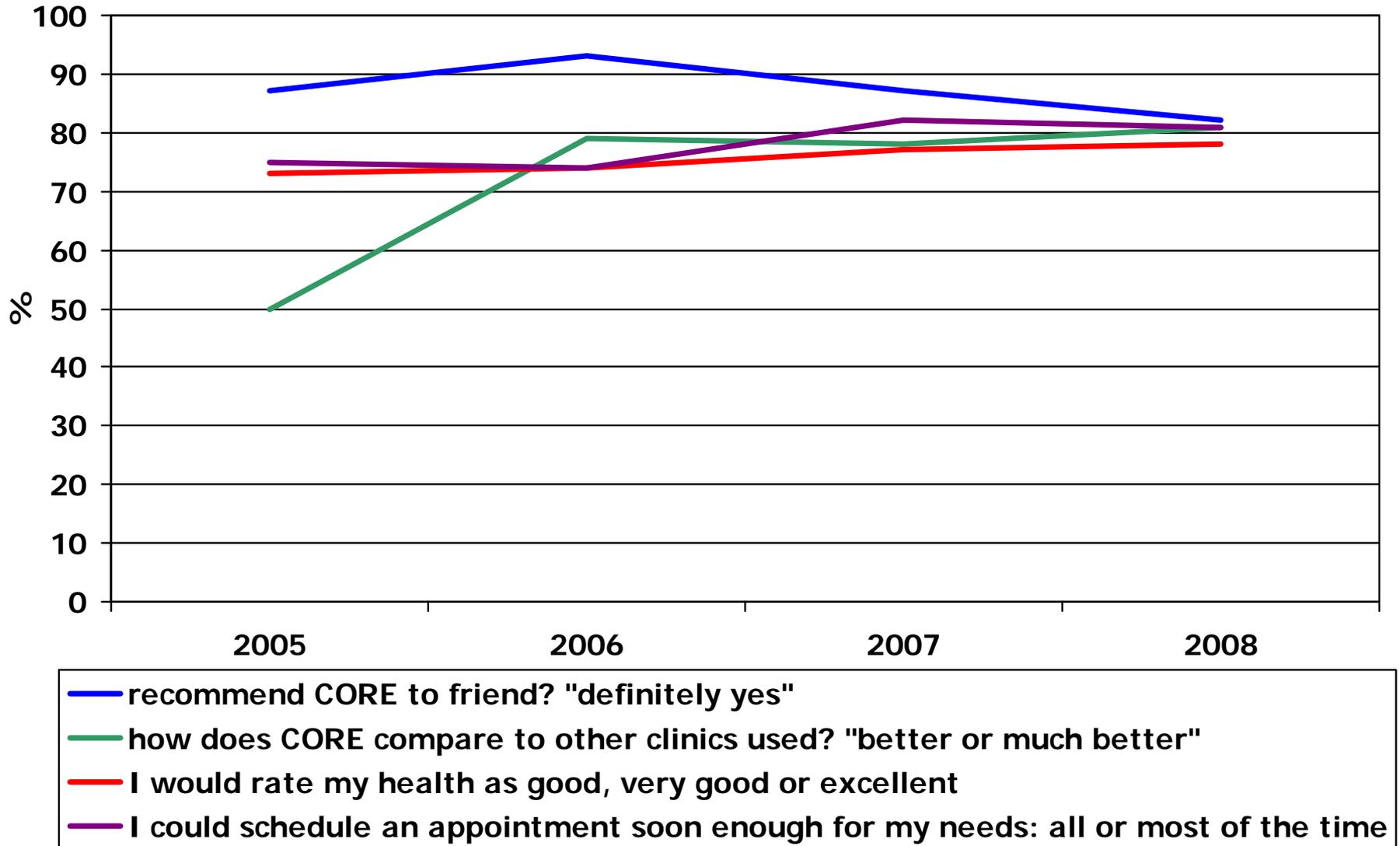
- **42. At any point, did you feel treated poorly at your clinic?**
- yes                      no (If “No,” Skip to Question 45)
  
- **43. If “Yes,” please help us understand why by checking any of the reasons you feel may have caused you to be treated poorly.**
- \_\_\_my race
- \_\_\_my sexual orientation
- \_\_\_my age
- \_\_\_my gender/sex
- \_\_\_my immigration status
- \_\_\_my difficulty speaking English
- \_\_\_my drug use (\_\_\_i am not using drugs )
- \_\_\_other (please specify) \_\_\_\_\_

# Treated Poorly at CORE?



	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>
<b>When I think about my care at CORE, these words come to mind...</b>				
most common response	excellent 64%	excellent 56%	excellent 57%	excellent 61%
2 <sup>nd</sup> most common response	caring 50%	safe 50%	safe 52%	safe 51%
3 <sup>rd</sup> most common response	respectful 47%	friendly 46%	friendly 51%	understanding 50%

# Main Survey



**Ruth M. Rothstein CORE Center  
Patient Satisfaction Main Survey 2005 – 2008**

<b>QUESTION</b>		<b>2005 N=371</b>	<b>2006 N=321</b>	<b>2007 N=422</b>	<b>2008 N=439</b>
<b>I have received medical care here for...</b>					
	less than 1 year	19%	25%	18%	24%
	1 to 2 years	25%	18%	19%	19%
	3 to 5 years	26%	24%	24%	20%
	more than 5 years	29%	32%	40%	37%
<b>I would rate my health today as</b>					
	good/ very good/ excellent	73%	74%	77%	80%
<b>If you ever called the clinic to make an appointment or speak with someone about your care, what happened?</b>					
	I got the help I needed	45%	53%	39%	43%
<b>When I needed an appointment, I could schedule one soon enough for my needs</b>					
	all/ most of the time	75%	74%	82%	81%
	sometimes	15%	16%	12%	13%
	rarely/ never	9%	10%	7%	6%
<b>HIV- specific educational materials were available for me to read</b>					
	all/ most of the time	86%	88%	90%	94%
	sometimes	10%	7%	6%	3%
	rarely/ never	3%	4%	4%	3%
<b>When I saw my providers, my visit was interrupted (by phone calls, patients, etc...)</b>					
	all/ most of the time	8%	9%	10%	10%
	sometimes	17%	18%	13%	15%
	rarely/ never	75%	72%	77%	75%

QUESTION		2005 N=371	2006 N=321	2007 N=422	2008 N=439
<b>I had questions that I wanted to ask my providers about my HIV care but did not ask</b>					
	all/ most of the time	17%	19%	18%	20%
	sometimes	25%	25%	19%	17%
	rarely/ never	58%	56%	64%	63%
<b>I felt uncomfortable talking about personal or intimate issues with my provider</b>					
	all/ most of the time	11%	17%	16%	15%
	sometimes	19%	15%	12%	11%
	rarely/ never	70%	68%	72%	74%
<b>If I had a complaint about my health care, my providers ignored it</b>					
	all/ most of the time	7%	9%	10%	10%
	sometimes	7%	7%	3%	6%
	rarely/ never	85%	85%	87%	84%
<b>I was able to get the services that my provider referred me to</b>					
	all/ most of the time	82%	75%	76%	76%
	sometimes	12%	14%	16%	18%
	rarely/ never	6%	11%	8%	6%
<b>When I think about my care at CORE, these words come to mind...</b>					
	most common response	excellent 64%	excellent 56%	excellent 57%	excellent 61%
	2 <sup>nd</sup> most common response	caring 50%	safe 50%	safe 52%	safe 51%
	3 <sup>rd</sup> most common response	respectful 47%	friendly 46%	friendly 51%	understanding 50%
<b>I would rate the quality of care at this clinic in comparison to other clinics I know about as...</b>					
	much better/ better	75%	79%	78%	80%
	the same	10%	12%	10%	8%
	worse/ much worse	3%	3%	2%	2%
	not sure	13%	5%	10%	10%

QUESTION	2005 N=371	2006 N=321	2007 N=422	2008 N=439
<b>I would recommend this clinic to my HIV-positive friends with similar needs</b>				
definitely yes	87%	93%	72%	85%
maybe	11%	3%	22%	10%
definitely not	2%	3%	3%	2%
not sure	--	--	--	3%
<b>I did not get medical care I needed because I could not pay for it</b>				
all/ most of the time	15%	16%	15%	16%
sometimes	4%	5%	5%	4%
rarely/ never	81%	79%	80%	80%
<b>My sex/gender is ...</b>				
female	26%	32%	36%	28%
male	73%	65%	63%	71%
transgender	1%	3%	2%	1%
<b>My sexual orientation is...</b>				
straight/ heterosexual	61%	63%	63%	63%
gay/ lesbian/ homosexual	29%	25%	28%	27%
bisexual	10%	10%	6%	8%
not sure	--	2%	3%	3%

**Patient Satisfaction Survey for HIV Ambulatory Care (PSS-HIV)**

Following each statement or question, please circle the answer that best matches your opinion. Circle only one answer, unless other directions are given.

If a statement does not apply to you because you did not encounter the situation described, or did not receive a service, please check "does not apply."

Please answer the questions based on your experiences AT CORE over the last year (12 months). If you have been coming here for less than 12 months, answer the questions based on your experiences since you started coming here.

Your answers to questions about providers should express your general feeling about all of the people who have provided you with medical care over the past year.

Your responses will remain private and completely anonymous so please, speak your mind.

**Definition of Terms**

**Staff:** non-medical people (like the receptionist) whom you see when you come for a visit

**Providers:** doctors, physician's assistants, nurse practitioners or nurses who give you medical care.

**1. I have received medical care here for . . .**

less than 1 year      1 to 2 years      3 to 5 years      more than 5 years

**2. My last visit here was . . .**

less than 1 month ago      1 to 2 months ago      3 to 6 months ago      more than 6 months ago

**3. I would rate my health today as . . .**

poor      fair      good      very good      excellent

**Access To HIV Care (in the last 12 months...)**

**4. Did you ever call the clinic to make an appointment or speak with someone about your care?**

yes      no (if no, go to question 6)

**5. If Yes, what was it like when you called the clinic? (please check all that apply)**

- I got a busy signal       I was put on hold too long
- I was disconnected       I left a message and no one called me back
- I don't like to call because a machine always answers
- The phone rang many times before it was answered
- The person who answered the phone was unfriendly
- I talked to several different people before talking to the right person
- I got the help I needed
- Other \_\_\_\_\_

**6. When I needed an appointment, I could schedule one soon enough for my needs.**

all of the time      most times      sometimes      rarely      never      does not apply

**7. My providers told me how important it was to keep my appointments.**

all of the time      most times      sometimes      rarely      never      does not apply

**8. If I needed care during off hours (evenings and weekends), I could reach a CORE provider.**

all of the time      most times      sometimes      rarely      never      does not apply

**9. If I had a medical question, I could get someone on the phone to discuss it with me.**

all of the time      most times      sometimes      rarely      never      does not apply

**Waiting For Your Appointment (in the last 12 months...)**

**10. While I checked in and waited for my visit, the staff was unfriendly to me.**

all of the time      most times      sometimes      rarely      never      does not apply

**11. HIV-specific educational materials were available for me to read.**  
 all of the time      most times      sometimes      rarely      never      does not apply

**12. At my scheduled appointment, I waited to see my provider...**  
 less than a half –hour      a half –hour      within an hour      1-2 hours      over two hours

**Your HIV Medical Visit (In the last 12 months...)**

**13. When I saw my providers, my visits got interrupted (by phone calls, other patients, etc.).**  
 all of the time      most times      sometimes      rarely      never      does not apply

**14. My providers made sure I understood what my lab test results (such as CD4 and viral load) meant for my health.**  
 all of the time      most times      sometimes      rarely      never      does not apply

**15. I was happy with the amount of time my provider spent with me.**  
 all of the time      most times      sometimes      rarely      never      does not apply

**16. I had questions that I wanted to ask my providers about my HIV care but did not ask.**  
 all of the time      most times      sometimes      rarely      never      does not apply

**17. I felt uncomfortable talking about personal or intimate issues with my providers.**  
 all of the time      most times      sometimes      rarely      never      does not apply

**18. I felt I was involved in making decisions about my health care.**  
 all of the time      most times      sometimes      rarely      never      does not apply

**19. If I had a complaint about my medical care, my providers would ignore it.**  
 all of the time      most times      sometimes      rarely      never      does not apply

**20. When I asked my providers questions about my HIV care, it was hard to understand their answers.**  
 all of the time      most times      sometimes      rarely      never      does not apply

**21. I found my providers to be accepting and non-judgmental of my life and health care choices.**  
 all of the time      most times      sometimes      rarely      never      does not apply

**22. It was hard for me to get my HIV medication prescriptions filled when I needed them.**  
 all of the time      most times      sometimes      rarely      never      does not apply

**23. My providers explained the side effects of my HIV medications in a way I could understand.**  
 yes      no      not sure

**24. My providers suggested ways to help me remember to take my HIV medications.**  
 yes      no      not sure

**25. My providers talked to me about telling my sexual partners about my HIV status.**  
 yes      no      not sure

**26. My providers explained to me how to avoid getting sick.**  
 yes      no      not sure

**27. My providers talked to me about how to avoid passing HIV to other people and how to protect myself from getting infected again with HIV.**  
 yes      no      not sure

**28. My providers talked to me about how to protect myself from getting Hep C or how to avoid passing it on to others if I already had it.**  
 yes      no      not sure

**Referrals (In the last 12 months...)**

**29. My providers or case managers asked me about my life situation (housing, my finances, etc.), and made a referral if I needed help.**

yes                      no                      not sure

**30. My providers or case managers asked me how I was feeling emotionally and made a referral to a mental health provider, counselor or support group if I needed help.**

yes                      no                      not sure

**31. My providers asked about my teeth and made a referral if I needed to see a dentist.**

yes                      no                      not sure

**32. My providers asked me about how I am eating and made a referral to a nutritionist if I needed help.**

yes                      no                      not sure

**33. My providers asked me whether I needed help to tell my sexual partners about my HIV status and made a referral if I needed help.**

yes                      no                      not sure

**34. My providers asked me about my drug and alcohol use and made a referral if I needed help (answer only if you are not receiving care at a drug treatment center).**

yes                      no                      not sure

**35. I was able to get the services that my provider referred me to.**

all of the time    most times                      sometimes                      rarely                      never                      does not apply

**Overall Quality of HIV Care (In the last 12 months...)**

**36. I would rate my providers' knowledge of the newest developments in HIV medical standards as . . .**

excellent            very good            average            fair                      poor                      not sure

**37. When I think about my care at CORE, these words come to mind (circle all that apply):**

excellent            adequate            ok                      busy                      personal            caring                      friendly  
safe                      rushed                      warm                      impersonal            dignified            respectful                      understanding

**38. I would rate the quality of care at this clinic in comparison to other clinics I know about as...**

much better                      better                      the same                      worse                      much worse                      not sure

**39. I would recommend this clinic to my HIV-positive friends with similar needs.**

definitely yes                      maybe                      definitely not                      not sure

**40. I got services in the language I wanted.**

all of the time                      most times                      sometimes                      rarely                      never                      does not apply

**41. I did not get the medical care I needed because I could not pay for it.**

all of the time                      most times                      sometimes                      rarely                      never                      does not apply

**42. At any point, did you feel treated poorly at your clinic?**

yes                      no (If "No," Skip to Question 45)

**43. If "Yes," please help us understand why by checking any of the reasons you feel may have caused you to be treated poorly.**

my race     my sexual orientation  
 my age     my gender/sex  
 my immigration status                       my difficulty speaking English  
 my drug use (  i am not using drugs )                       other (please specify) \_\_\_\_\_

**45. I thought about leaving this clinic to find better care somewhere else.**

all of the time                      most times                      sometimes                      rarely                      never                      does not apply

**46. The staff and my providers kept my HIV status confidential.**

all of the time                      most times                      sometimes                      rarely                      never                      does not apply

**A Little Information About You**

These questions are being asked to make sure we are hearing from all kinds of patients.

**47. I have family members, friends, or professionals who give me a lot of support.**

strongly agree      agree      disagree      strongly disagree

**48. My sex/gender is...**

female      male      transgender (m to f)      transgender (f to m)

**49. My sexual orientation is...**

straight/ heterosexual      gay/ lesbian/ homosexual      bisexual      not sure

**50. My racial/ethnic background is . . . (circle all that apply)**

African American/Black      Hispanic/Latino      Asian/Pacific Islander  
 Native American/Alaska Native      White      Other (specify) \_\_\_\_\_

**51. My age is...**

Below 20      20 to 29      30 to 39      40 to 49      50 to 59      60 to 69      70 or above

**52. I have completed this survey ...**

By myself, with no help      With some help from the clinic staff  
 With someone reading the survey to me and filling it out based on my answers

**Registration/ Reception**

**53. CORE's registration/ reception staff was responsible and professional.**

all the time      most of the time      sometimes      rarely      never

**54. CORE's registration/ reception staff has a good attitude towards customers.**

all the time      most of the time      sometimes      rarely      never

**55. I was asked both to give my name or birthday *and* to show my orange card by CORE's registration staff.**

all the time      most of the time      sometimes      rarely      never

**56. CORE's registration staff checked with me to make sure my address and phone were current in the computer.**

all the time      most of the time      sometimes      rarely      never

**57. CORE's registration worked to help me if I had trouble with paperwork.**

all the time      most of the time      sometimes      rarely      never

Cook County Health and Hospitals System  
Report of the Meeting of the Quality and Patient Safety Committee  
July 28, 2009

ATTACHMENT #2

DRAFT

## CCHHS System-wide Quality Structure

### Quality Initiatives Sub-Councils

**Purpose:** This is a quality brainstorming taskforce. Its charge is to identify a number of new quality initiatives for possible system-wide implementation. The initiatives should be important, electronically measurable, and applicable across the CCHHS. The councils will forward their recommendations to the Quality Initiatives Council.

#### **Membership:**

**Ambulatory Sub-Council:** Chair: ACHN Quality Director. Members: Clinical providers and nursing staff from ACHN, CORE, CCDPH, Cermak Health Services, Quality/Patient Safety staff, physician/nurse quality champions. ACHN should have 4-5 members, CORE-2, Cermak-2, CCDPH-1-2.

**Inpatient Sub-Council:** Chair: SH Quality/Patient Safety Director or designee. Members: Physician and nurse leaders, Chairs of key departments/division, nursing representatives, physician/nurse quality champions, clinical oversight committee staff, quality/patient safety staff. SH should have 7-8 members, OFH 4-5, PH 4-5, Cermak 1-2.

**Timing and Frequency of Meetings:** The two quality sub-councils will meet 1-3 times in June of each year.

### Quality Initiatives/Planning Council

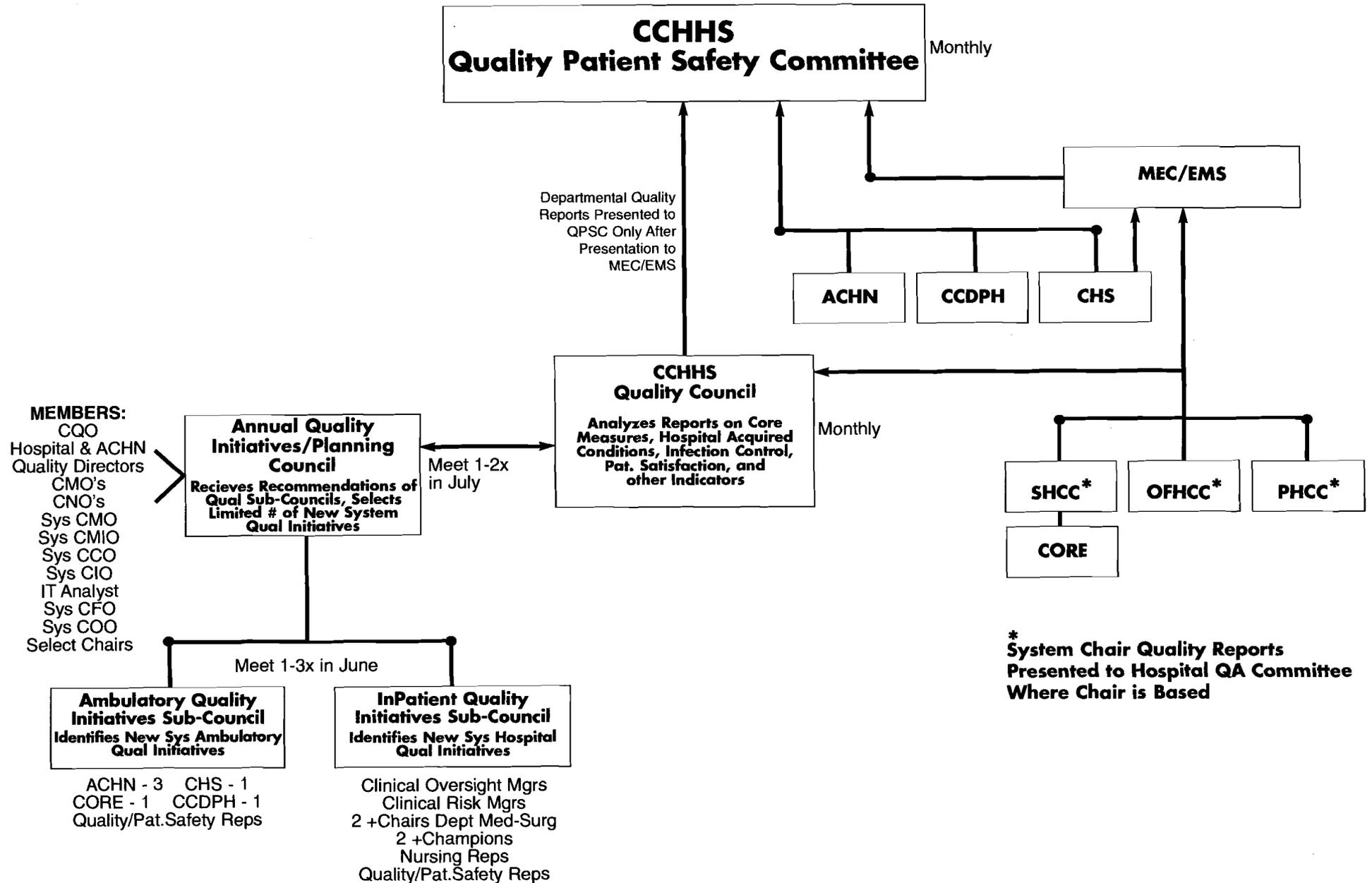
**Purpose:** This Council will annually receive recommendations from the quality initiatives sub-councils and will select a limited number of new system-wide quality initiatives that are important, electronically measurable, and applicable across the CCHHS. These new initiatives will be implemented in the upcoming year.

**Membership:** Hospital and ACHN Quality/Patient Safety Directors, System CMO, System CQO, System CMIO, System CIO, IT clinical analyst, System CFO, System COO, System CCO, CMOs, CNOs, and certain System Chairs.

**Timing and Frequency of Meetings:** The Quality Initiatives/Planning Council will meet 1-2 times in early July of each year.

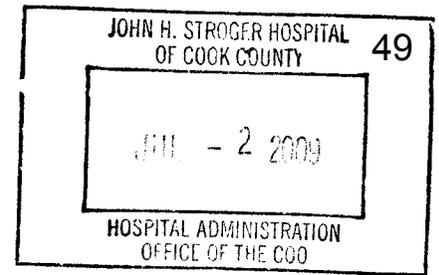
# COOK COUNTY HEALTH & HOSPITALS SYSTEM

## System Quality Structure



Cook County Health and Hospitals System  
Report of the Meeting of the Quality and Patient Safety Committee  
July 28, 2009

ATTACHMENT #3



Chicago Breast Cancer Quality Consortium

A project of the MCBCTF, in collaboration with the IHA

Elizabeth Marcus, MD  
John H. Stroger, Jr. Hosp of Cook Co.  
1900 W. Polk, Rm 601  
Chicago, IL 60612

Dear Partner:

Thank you for agreeing to participate in the Chicago Breast Cancer Quality Consortium. We are excited to be starting this very important project, through which we hope to reduce racial health disparities in breast cancer in the Metropolitan Chicago area. Over 60 healthcare institutions have agreed to collaborate in sharing data with the aim of identifying areas for quality improvement and ultimately to save lives.

As with any quality project involving data sharing, a data sharing agreement is necessary between the parties sharing data. Please find attached a data sharing agreement for signature between the Consortium's legal entity, the Metropolitan Chicago Breast Cancer Taskforce and your institution. This agreement lays out the rationale for this quality improvement project, its goals, its link to the Illinois Medical Studies Act, and the tasks that each party will perform (including the Consortium's obligation to refrain from publishing or disclosing any hospital specific data relating to this project as enunciated in Section 1.2.3).

This agreement should be signed by a person at your institution with contracting authority and returned to:

Anne Marie Murphy, Ph.D.  
Director  
Chicago Breast Cancer Quality Consortium  
1645 W. Jackson Blvd, Suite 450  
Chicago, IL 60612

If you have questions regarding this agreement or the Consortium, please contact the Consortium's Director, Anne Marie Murphy at (312)942-0309 or [Anne\\_M\\_Murphy@rush.edu](mailto:Anne_M_Murphy@rush.edu). If you have a specific legal question, please contact Anne Murphy at Holland and Knight, who is serving as legal counsel to the Consortium. She can be reached at (312)578-6544 or [anne.murphy@hkllaw.com](mailto:anne.murphy@hkllaw.com).

Again, thank you for agreeing to participate in this first in the nation project to reduce racial health disparities in breast cancer through quality improvement.

Sincerely,

Anne Marie Murphy, Ph.D.  
Director

## PARTICIPATING HEALTHCARE PROVIDER AGREEMENT

This Participating Healthcare Provider Agreement (the "Agreement") is made and entered into on the \_\_\_\_\_ day of \_\_\_\_\_, 2009 (the "Effective Date") by and among the Metropolitan Chicago Breast Cancer Task Force (the "Task Force"), an Illinois not-for-profit corporation with its principal place of business at 1645 West Jackson Blvd, Suite 450 Chicago, Illinois 60612, and \_\_\_\_\_ ("Participating Healthcare Provider"), a \_\_\_\_\_ [type of organization] with its principal place of business at \_\_\_\_\_ [address]. The Task Force and Participating Healthcare Provider are hereinafter each individually referred to as a "Party" and collectively as the "Parties."

### RECITALS

**WHEREAS**, the Chicago healthcare community mobilized over 70 organizations and over 100 physicians, clinicians, researchers, community members and breast cancer survivors to form the Task Force for the purpose of improving access to and quality of breast cancer screening and treatment for all women across the Metropolitan Chicago area and reducing morbidity and mortality rates for all women in the Metropolitan Chicago area;

**WHEREAS**, the Task Force, formed as an Illinois not-for-profit corporation, was established in 2007 in response to a report from the Sinai Urban Health Institute describing the growing African-American/Caucasian breast cancer mortality gap and from other published research regarding breast cancer in the Metropolitan Chicago area;

**WHEREAS**, data released in October 2008 showed a sharply increasing disparity in breast cancer mortality rates between African-American and Caucasian women in the Metropolitan Chicago area (African-American mortality rates in 2005 were 116% higher than Caucasian mortality rates and the corresponding national average disparity was 41% compared 2004 disparity rates of 68% for African-American women when the corresponding national average disparity was 37%);

**WHEREAS**, the Task Force has as its mission to serve as a catalyst to reduce the racial, ethnic, and class disparity in the breast cancer mortality rate in the Metropolitan Chicago area;

**WHEREAS**, in 2008, the Task Force established as one of its initiatives the Chicago Breast Cancer Quality Consortium (the "Consortium") to bring health care providers from all across the Metropolitan Chicago area together to collaborate on improving the quality of breast cancer screening and treatment by sharing data on quality measures for breast cancer screening and treatment and developing quality improvement projects based on analysis of this data and examination of other research and discussion;

**WHEREAS**, the Consortium, supported by grant funding from the Susan G. Komen for the Cure Foundation is the first comprehensive quality improvement project in the United States to address a community wide breast cancer health disparity based on race and ethnicity;

**WHEREAS**, there are over 60 Participating Healthcare Providers in the Metropolitan Chicago area, each of whom has agreed to assist the Task Force and the Consortium in achieving its quality improvement, patient care improvement, and morbidity and mortality reduction goals through production of certain breast cancer screening and treatment data;

**WHEREAS**, the Consortium, as a component of the Task Force, will collect from each Participating Healthcare Provider certain aggregated data from years 2006-2012, as available, on select breast cancer screening and treatment quality standards across the continuum of care, analyze the data and may report back to Participating Healthcare Provider in a confidential manner, and shall produce a general community report on quality standards for mammography screening and breast cancer treatment for the Metropolitan Chicago area;

**WHEREAS**, all data to be collected by the Consortium will be aggregated at the Participating Healthcare Provider level, and such data will not include protected health information within the meaning of the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"), or individually identifiable health information under state confidentiality laws;

**WHEREAS**, Participating Healthcare Provider also can assist the Task Force and the Consortium by serving on various Consortium sub-committees, and contributing feedback to a forum of physicians, clinicians, and researchers convened by the Consortium, who will share strategies for improving outcomes of breast cancer care in the Metropolitan Chicago area;

**WHEREAS**, the Task Force shall be permitted to subcontract with one or more third parties to assist in data collection and analysis efforts, provided that the contracting party agrees to abide by applicable provisions of HIPAA and other applicable state and federal laws, as well as applicable confidentiality and use terms of this Agreement;

**WHEREAS**, the purpose of the Illinois Medical Studies Act ("MSA") is to encourage voluntary studies used to improve patient care, or to reduce the rates of death and disease (735 ILCS 5/8-2101);

**WHEREAS**, the MSA states that: "All information, interviews, reports, statements, memoranda, recommendations, ... or other data of ... medical organizations under contract with ... health care delivery entities or facilities, ... and their agents, ..., or committees of licensed or accredited hospitals or their medical staffs, ... or their designees (but not the medical records pertaining to the patient), used in the course of internal quality control or of medical study for the purpose of reducing morbidity or mortality, or for improving patient care ... , shall be privileged, strictly confidential and shall be used only for medical research, ..., the evaluation and improvement of quality care ..." (735 ILCS 5/8-2101);

**WHEREAS**, the Illinois Hospital Licensing Act (IHLA) states that "no hospital and no individual who is a member ... of a hospital, hospital medical staff, hospital administrative staff, or hospital governing board shall be liable for civil damages as a result of the acts, ... except those involving willful or wanton misconduct, of a medical utilization committee, medical review committee, patient care audit committee, medical care evaluation committee, quality review committee ... peer review committee, or any other committee or individual whose purpose,

directly or indirectly, is internal quality control or medical study to reduce morbidity or mortality, or for improving patient care within a hospital, or the improving or benefiting of patient care and treatment, whether within a hospital or not ..." (210 ILCS 85/10.2 Sec. 10.2.);

**WHEREAS**, each Party intends that the Task Force and the Consortium, in providing the services described in this Agreement, will be a "medical organization" under contract with "health care delivery facilities" in order to undertake medical study of breast cancer screening and treatment for the purposes of quality and patient care improvement, and of reducing morbidity and mortality, all within the meaning of the MSA;

**WHEREAS**, each Party intends that Participating Healthcare Provider, in providing the services described in this Agreement, will act through committees of the provider and/or its medical staff in order to undertake the medical study for the purposes of quality and patient care improvement, and reducing morbidity and mortality, all within the meaning of the MSA and as applicable, the IHLA;

**WHEREAS**, each Party intends that all information, reports or other data of the Consortium or Participating Healthcare Provider used or created pursuant to this Agreement in order to undertake medical study of breast cancer screening and treatment for the purposes of quality and patient care improvement, and of reducing morbidity and mortality, shall be used only for medical research, the evaluation and improvement of quality care;

**WHEREAS**, each Party intends that the information, reports and other data described above and elsewhere in this Agreement are to be privileged and strictly confidential under the MSA, and each Party intends to take action reasonably necessary in order to enhance the likelihood that the research described in this Agreement is deemed protected under the MSA;

**WHEREAS**, if the Participating Healthcare Provider is a hospital, each Party intends to be protected under Section 10.2 of the IHLA;

**WHEREAS**, the Parties agree that Participating Healthcare Provider will go through any Institutional Review Board (IRB) procedures as may be required by law or by applicable Participating Healthcare Provider protocols governing research;

**WHEREAS**, the Parties agree that Participating Healthcare Provider will comply with research provisions of HIPAA in regards to data extraction from charts;

**WHEREAS**, this Agreement addresses the conditions under which the Consortium will obtain and use the data released under this Agreement;

**WHEREAS**, throughout this Agreement, the Consortium is a component of the Task Force and acts on behalf of the Task Force;

**NOW, THEREFORE**, in consideration of the foregoing recitals, which are incorporated herein as covenants, the mutual promises herein made and exchanged, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the

Task Force and Participating Healthcare Provider hereby agree as follows:

**1. General Obligations.**

**1.1 General Obligations of Participating Healthcare Provider.**

- 1.1.1 Within time frames reasonably set and announced by the Consortium, Participating Healthcare Provider shall report to the Consortium certain retrospective, aggregated data, as available, for patients initially screened, diagnosed or treated during calendar years 2006-2012 at Participating Healthcare Provider for breast cancer (the "Study Data"). The Consortium intends to make public on its website that Participating Healthcare Provider is one of the provider entities participating in the Consortium by providing Study Data, unless Participating Healthcare Provider requests in writing that it not be identified in this manner.
- 1.1.2 The Parties agree that the 2006 data set (the "2006 Study Data") is set forth as Exhibit 1.
- 1.1.3 The Parties agree that data sets for subsequent years (2007-2012) will be produced by the Consortium after consultation with its sub-committees.
- 1.1.4 The Parties agree that Participating Healthcare Provider will provide the Study Data to the Consortium for the sole and exclusive purposes of: (1) improving the quality of breast health services provided in the Metropolitan Chicago area; and (2) reducing morbidity and mortality associated with breast cancer in the Metropolitan Chicago area, particularly among African-American women.
- 1.1.5 The Parties agree that the Study Data provided to the Consortium by Participating Healthcare Provider will be treated as privileged and strictly confidential, and will not be disclosed or released by Participating Healthcare Provider to any third party unless done with the advance written consent of the Task Force, unless disclosed to an authorized subcontracting party, or unless required by law or court order. Each Party intends to take action reasonably necessary in order to enhance the likelihood that the research described in this Agreement is deemed protected under the MSA.
- 1.1.6 The Parties agree that any institution-specific reports generated by the Consortium will be treated as privileged and strictly confidential, and will not be disclosed or released by Participating Healthcare Provider to any third party unless done with the advance written consent of the Task Force, unless an authorized subcontracting party, or unless required by law or court order.
- 1.1.7 The Parties agree that Participating Healthcare Provider will go through any IRB procedures as may be required by law or by applicable Participating Healthcare Provider protocols governing research. The Task Force and the

Consortium have provided Exhibit 2 as an example of an IRB protocol. However, the Parties acknowledge and agree that this example is provided for illustration purposes only and that each Participating Healthcare Provider will need to independently evaluate the content of any IRB protocol it implements and any conclusions within such a protocol. Accordingly, Participating Healthcare Provider acknowledges and agrees that it does not and will not rely upon Exhibit 2 as providing advice or conclusions in the development or implementation of an IRB protocol.

- 1.1.8 The Parties agree that if Participating Healthcare Provider desires on site technical assistance from the Task Force in connection with collection of the Study Data, then a separate agreement will be entered into by the Parties.
- 1.1.9 The Parties agree that Participating Healthcare Provider will comply with research provisions of HIPAA in regards to data extraction from charts or other records containing protected health information.

## **1.2 General Obligations of the Task Force and the Consortium.**

- 1.2.1 The Parties agree that all referenced obligations of the Consortium are the legal responsibility of the Task Force. The Consortium is a component of the Task Force.
- 1.2.2 The Parties agree that the Study Data provided to the Consortium by Participating Healthcare Provider will be treated as privileged and strictly confidential, and will not be disclosed or released by the Consortium to any third party unless done with the advance written consent of Participating Healthcare Provider, unless disclosed to an authorized subcontracting party, or unless required by law or court order. Each Party intends to take action reasonably necessary in order to enhance the likelihood that the research described in this Agreement is deemed protected under the MSA.
- 1.2.3 The Parties agree that in producing any community reports based on the Study Data, the Consortium will not identify any Participating Healthcare Provider-specific data or information, and will not identify or tend to identify Participating Healthcare Provider.
- 1.2.4 The Parties agree that the Consortium will provide Participating Healthcare Provider with a Participating Healthcare Provider-specific written report regarding the Participating Healthcare Provider Study Data. The Parties agree that any Participating Healthcare Provider-specific reports generated by the Consortium will be treated as privileged and strictly confidential, and will not be disclosed or released by the Consortium to any third party unless done with the advance written consent of Participating Healthcare Provider, unless an authorized subcontracting party, or unless required by law or court order.

### **1.3 Data Content, Treatment and Use.**

- 1.3.1 The Parties agree that the Study Data does not include protected health information within the current meaning of HIPAA or individually identifiable health information under applicable state confidentiality laws.
- 1.3.2 The Parties agree that the 2006 Study Data, as reflected in Exhibit 1, includes the following categories of aggregated breast cancer screening and treatment information from Participating Healthcare Provider: number of women screened in 2006 by screening BIRADS category, number of women receiving follow up diagnostic imaging and or biopsies received or recommended within 30 days and/or 12 months, number of cancers detected among the screenings, size and stage of cancers detected, number of women diagnosed in 2006 and treated at the facility by stage of diagnosis, number of women who received breast conserving surgery (BCS), number of patients who received radiation therapy (RT) post BCS and known to have completed RT, number of women who were tested for estrogen receptor status, progesterone receptor status and HER-2 status, the proportion of positive results among those tested for various receptor status and the number of women who subsequently received or were recommended for hormonal therapy or herceptin respectively.
- 1.3.3 The Parties agree that the Study Data may include patient race/ethnicity information in order to advance the goals of the medical study to improve patient care and quality care, and to reduce racial and ethnic disparities in breast cancer morbidity and mortality.
- 1.3.4 The Parties agree that the Task Force is permitted to subcontract with one or more third parties to assist in the Study Data collection and analysis efforts, provided any such third party agrees to abide by the applicable terms of this Agreement, including without limitation provisions regarding confidentiality, use and treatment of the Study Data, and reasonably necessary efforts in connection with the MSA; and further provided such party agrees to abide by applicable HIPAA and state confidentiality law obligations.
- 1.3.5 In implementing this Agreement, the Parties agree that all patient information provided to the Consortium will first be de-identified in accordance with HIPAA such that it will not be considered protected health information subject to HIPAA's constraints on use or disclosure.
- 1.3.6 The Parties agree that the Consortium will use the Study Data provided by Participating Healthcare Provider for the sole purpose of reducing morbidity and mortality and for improving patient care in the Metropolitan Chicago area.
- 1.3.7 Each Party intends that the Task Force and the Consortium, in providing the services described in this Agreement, will be a "medical organization" under

contract with “health care delivery facilities” (i.e. Participating Healthcare Provider) pursuant to the provisions of the MSA. Each Party intends that Participating Healthcare Provider, in providing the services described in this Agreement, will act through committees of the hospital and/or medical staff in order to undertake the medical study for the purposes of quality and patient care improvement, and reducing morbidity and mortality, all within the meaning of the MSA and, as applicable, the IHLA.

- 1.3.8 The Parties agree that to the extent Participating Healthcare Provider chooses to act through a medical staff committee in an effort to enhance MSA protection (as discussed in Section 1.3.7), the Task Force and the Consortium have provided Exhibit 3 as a sample Medical Staff Committee Statement. The Parties acknowledge and agree that Participating Healthcare Provider's medical staff committee can adopt this or a similar statement to express its intentions that the services provided in this Agreement constitute quality assurance activity protected by the MSA.
- 1.3.9 If Participating Healthcare Provider is a hospital, each Party intends that under Section 10.2 of the IHLA, Participating Healthcare Provider, the Task Force and the Consortium shall not be liable for civil damages as a result of the acts of the committees referenced in Section 1.3.7 of this Agreement. Each Party intends to take action reasonably necessary in order to enhance the likelihood that each Party is deemed non-labile for civil damages under the IHLA.
- 1.3.10 The Parties agree that the Study Data is to be treated as privileged and strictly confidential and shall be used only for medical research, the evaluation and improvement of quality care.
- 1.3.11 The Parties agree that each Party will exert reasonably necessary efforts to maximize the likelihood that the Study Data will be protected by the MSA.

## **2. Term and Termination.**

**2.1 Term.** The term of this Agreement shall commence on the Effective Date of this Agreement and shall terminate two (2) years from the Effective Date, unless terminated earlier in accordance with the provisions herein. This Agreement will automatically renew for successive one (1) year terms through 2013 (after the initial 2 year term) unless terminated earlier by either Party.

**2.2 Termination.** Either Party may terminate this Agreement at any time for any reason upon thirty (30) days written notice. Upon such notice, Participating Healthcare Provider permits the Task Force and the Consortium to continue to analyze and use the Study Data for the purposes outlined in Section 1.1.1 of this Agreement. The Consortium agrees that no Participating Healthcare Provider-specific data will be disclosed in any future report or publication prepared by the Consortium pursuant to Section 1.2 of this Agreement.

**3. Miscellaneous.**

**3.1 Non-Assignability.** Except to the extent subcontracting is allowed in Section 1.3.4, no Party shall assign any of its rights or responsibilities under this Agreement to any other person or entity without the other Parties' written consent.

**3.2 Modification and Amendments.** This Agreement may not be modified, amended or renewed except in writing signed by all Parties.

**3.3 Notices.** Any notice, demand, or communication required, permitted, or desired to be given hereunder shall be deemed effectively given when personally delivered, when received by overnight courier, or five (5) days after being deposited in the United States mail, and sent first class with postage prepaid thereon, certified and return receipt requested, addressed as follows:

The Task Force:	Anne Marie Murphy, Ph.D. Consortium Director 1645 W. Jackson Blvd, Suite 450 Chicago, IL 60612-3244
With copies to:	Anne M. Murphy, Esq. Holland & Knight LLP 131 South Dearborn Street 30 <sup>th</sup> Floor Chicago, Illinois 60603
Participating Healthcare Provider:	<u>John H. Stroger, Jr. Hospital</u> <u>Johnny C. Brown, COO</u> <u>1901 West Harrison Street</u> <u>Chicago, IL 60612</u>
With copies to:	<u>Elizabeth Marcus, MD</u> <u>John H. Stroger, Jr. Hospital</u> <u>1900 West Polk Street - 601</u> <u>Chicago, IL 60612</u>

Any Party may change its above address by giving ten (10) days prior written notice to the other Parties.

**3.4 Integration.** Except as expressly set forth herein, this Agreement embodies, and expressly supersedes, all prior communications and agreements of the Parties relating to the subject matter hereof, and constitutes the entire agreement of the Parties.

**3.5 Governing Law.** This Agreement has been entered into in the State of Illinois and shall be construed and interpreted in accordance with, and shall be governed by, the laws of the State of Illinois. The parties of this Agreement recognize that the federal government, through an agency, department, or other bureau, may, in the future,

implement statutes, rules, regulations (including, but not limited to, safe harbor regulations) or guidance that relate to the legality of the arrangement contemplated by this Agreement. Should any such statute, rule, regulation, or guidance be issued during the term of this Agreement, both Parties shall meet and, in good faith, attempt to renegotiate any aspect of this Agreement which may be deemed unlawful and, if no compromise can be reached, this Agreement shall immediately terminate.

**3.6 Authority.** The individuals signing this Agreement on behalf of the Task Force and Participating Healthcare Provider are the duly authorized representatives of the respective Party with full power and authority to execute this Agreement.

**3.7 Severability.** Each paragraph, section, provision, sentence, and part thereof of this Agreement shall be deemed separate from each other paragraph, section, provision, sentence, or part thereof of this Agreement, and the invalidity or unenforceability of any such paragraph, section, provision, sentence, or part thereof of this Agreement shall not affect the validity or enforceability of the balance of this Agreement.

**3.8 Non-Waiver.** No failure by any Party to insist upon the strict performance of any term of this Agreement shall constitute a waiver of such term or a waiver of the right to assert a breach thereof. No waiver of any breach shall alter or affect this Agreement, which shall continue in full force and effect until terminated.

**3.9 Definitions; Construction.** All undefined terms shall be given their plain and ordinary meaning in the context of this Agreement. The paragraph headings in this Agreement are for convenience only and shall not be construed to define, modify, expand or limit the terms and provisions of this Agreement which shall be construed according to their plain meaning. There shall be no rule of construction for or against any Party by reason of the physical preparation of this Agreement.

**3.10 Independent Contractors.** The Parties agree that the relationship between the Task Force and Participating Healthcare Provider created by this Agreement is that of independent contractors. Nothing contained in this Agreement shall be deemed to create a partnership, joint venture, or other joint business relationship between the Task Force and Participating Healthcare Provider, and neither Party shall have the authority to enter into any contracts binding upon the other Party, or to incur or create any obligations binding on the other Party other than as expressly provided in this Agreement.

**3.11 Third Party Beneficiaries.** This Agreement is solely for the benefit of the Task Force and Participating Healthcare Provider and shall in no way be construed to entitle any other third party (including researchers and referenced employees) to any benefit, and it does not create any third-party beneficiaries and shall not confer any rights or remedies upon any person or entity other than the Parties, and their respective successors and permitted assigns.

**3.12 Interpretation.** Any ambiguity or inconsistency in this Agreement shall be resolved in favor of a meaning that permits Participating Healthcare Provider to comply with

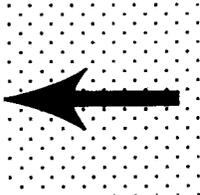
applicable law. However, no change, amendment, or modification of this Agreement shall be valid unless it is set forth in writing and agreed to by both parties.

**SIGNATURE PAGE IMMEDIATELY FOLLOWS**

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement on the date first above written.

**THE METROPOLITAN CHICAGO BREAST  
CANCER TASK FORCE**

By:   
Name of Individual: Marie Rule Gilliam  
Its: Executive Director  
Date: 5/22/09



**PARTICIPATING HEALTHCARE PROVIDER**

Name of Healthcare Provider: John H. Stroger, Jr. Hospital  
By: \_\_\_\_\_  
Name of Individual: Johnny C. Brown  
Its: Chief Operating Officer  
Date: \_\_\_\_\_

**EXHIBIT 1**  
**2006 STUDY DATA**

## DATA COLLECTION FORM INSTRUCTIONS

### Treatment Data Tool Instructions

**Information for breast cancers diagnosed between January 1, 2006 - December 31, 2006 and contained in your facility's tumor registry.** While the patient population for whom data are collected have been diagnosed in 2006, data for treatment may take place in 2006 or later.

Include women with primary breast cancers (non-recurrences) contained in your facility's tumor registry whose date of biopsy that lead to diagnosis was in 2006. If your facility is collecting treatment data by race/ethnicity, then please fill in one sheet for **all** patients regardless of race/ethnicity and an additional sheet for each race/ethnicity. The categories of race/ethnicity included in this form are non-Hispanic White, non-Hispanic Black, Hispanic and Other. 'Hispanic' includes any Hispanic ethnicity (e.g. Mexican, El Salvadorian, Puerto Rican, Cuban, Dominican, etc). 'Other' includes all other races/ethnicities not explicitly listed (e.g. Alaskan Native/American Indian, Asian/Pacific Islander, Multi-Racial, etc). Please note that you can choose to submit data on one, all or none of the race/ethnicity categories. It is expected that if your facility is collecting data on treatment that the minimum that will be submitted is one sheet that includes all patients diagnosed with primary breast cancer (non-recurrences) in 2006, regardless of race/ethnicity.

#### **TABLE 1. Number of patients by stage at diagnosis**

**A. Diagnosis and first treatment at your institution:** Please record the number of primary breast cancer cases diagnosed in 2006 who were diagnosed at your facility and received their first treatment at your facility, be it surgery, chemotherapy, radiation or hormone therapy. Include in this number any patients diagnosed at your facility for whom a decision was made not to treat.

**NOTE regarding definition of first treatment at your institution:** To be included in this definition, the patient does not have to have received their full first course of treatment at your institution, but does have to have received their very first treatment at your institution. For early stage cancers their very first treatment would tend to be a surgical treatment, while for later stage cancers their very first treatment could be radiation, chemotherapy or hormone therapy. A biopsy does not count as a treatment unless it is an excisional biopsy which removes the entire mass or abnormal area.

**B. Diagnosis elsewhere; first treatment at your institution:** Record the number of primary breast cancer cases diagnosed in 2006 who were not diagnosed at your facility but who received their first treatment (surgery, chemotherapy, radiation or hormone therapy) at your facility.

**(A+B) Number of patients with first treatment at your institution:** This is the sum of A and B above, equal to the number of patients who received their first treatment at your institution.

**First treatment within 30 days of diagnosis:** For patients who received their first treatment at your institution, record the number who began treatment within 1 month of the date of the biopsy that definitively diagnosed breast cancer.

#### **TABLE 2. Breast conserving surgery (BCS) +/- radiation therapy (RT)**

**First treatment at your institution:** The number of patients who received their first treatment at your institution, automatically filled in from Table 1 above.

**Number receiving breast conserving surgery at your institution:** For patients who received their first treatment at your institution, record the number who received breast conserving surgery, defined as lumpectomy or partial mastectomy.

**For Patients receiving breast conserving surgery:**

**Total number that received RT:** For patients receiving breast conserving surgery, record the number known to have received radiation therapy.

**RT on site:** *For patients receiving breast conserving surgery, record the number known to have received radiation therapy at your facility.*

**RT elsewhere:** *For patients receiving breast conserving surgery, record the number known to have received radiation therapy at another facility.*

**Total number that refused RT:** *For patients receiving breast conserving surgery, record the number known to have refused radiation therapy that was offered them (either at your facility or another facility).*

**Information for breast cancers diagnosed between January 1, 2006 - December 31, 2006 and contained in your facility's tumor registry.** While the patient population for whom data are collected have been diagnosed in 2006, data for treatment may take place in 2006 or later.

Include women with primary breast cancers (non-recurrences) contained in your facility's tumor registry whose date of biopsy that lead to diagnosis was in 2006. If your facility is collecting treatment data by race/ethnicity, then please fill in one sheet for **all** patients regardless of race/ethnicity and an additional sheet for each race/ethnicity. The categories of race/ethnicity included in this form are non-Hispanic White, non-Hispanic Black, Hispanic and Other. 'Hispanic' includes any Hispanic ethnicity (e.g. Mexican, El Salvadorian, Puerto Rican, Cuban, Dominican, etc). 'Other' includes all other races/ethnicities not explicitly listed (e.g. Alaskan Native/American Indian, Asian/Pacific Islander, Multi-Racial, etc). Please note that you can choose to submit data on one, all or none of the race/ethnicity categories. It is expected that if your facility is collecting data on treatment that the minimum that will be submitted is one sheet that includes all patients diagnosed with primary breast cancer (non-recurrences) in 2006, regardless of race/ethnicity.

### TABLE 3. Hormone receptor testing and hormone therapy

**First treatment at your institution:** The number of patients who received their first treatment at your institution, automatically filled in from Table 1 above.

**Number tested for ER and/or PR:** *For patients who received their first treatment at your institution, please record the number known to have been tested for ER and/or PR.*

**Number tested positive for ER and/or PR:** *For patients who received their first treatment at your institution, please record the number known to have tested positive for one or both receptors.*

**If ER/PR Positive: Prescribed or recommended HT:** *For patients who tested positive for one or both receptors, record the number known to have been recommended or prescribed hormone therapy. Types of Hormone Therapy include: nolvadex (Tamoxifen), Raloxifene (Evista), acetate (Zoladex) , letrozole (Femara), anastrozole (Arimidex) , megestrol (Megace), droloxifene, exemestane (Aromasin), formestane (Lentaron) , toremifene (Fareston), Fulvestrant (Faslodex), vorozole (Rivisor), and idoxifene.*

### TABLE 4. Her2/neu testing and herceptin

**First treatment at your institution:** The number of patients who received their first treatment at your institution, automatically filled in from Table 1 above.

**Number tested for Her2/neu:** *For patients who received their first treatment at your institution, record the number of patients known to have been tested for Her2/neu.*

**Number tested positive:** *For patients who received their first treatment at your institution, please record the number known to have tested positive for Her2/neu.*

**Indeterminate result:** *For patients who received their first treatment at your institution, please record the number with an indeterminate, equivocal or ambiguous Her2/neu test result. (Note: negative tests are not being tabulated here.)*

**If Her2 positive: Recommended Herceptin:** *For patients who tested positive for Her2/neu, record the number known to have received Herceptin treatment. Only include those patients who both tested positive for Her2/neu and who were recommended Herceptin.*

### Screening Data Tool Instructions

**ALL Screening Mammograms performed from January 1, 2006 - December 31, 2006** While the patient population for whom data are collected have been screened in 2006, data for follow up (further screenings, biopsy etc.) may take place in 2006 or later.

If your facility is collecting screening data by race/ethnicity, then please fill in one sheet for **all** patients regardless of race/ethnicity and an additional sheet for each race/ethnicity. The categories of race/ethnicity included in this form are non-Hispanic White, non-Hispanic Black, Hispanic and Other. 'Hispanic' includes any Hispanic ethnicity (e.g. Mexican, El Salvadorian, Puerto Rican, Cuban, Dominican, etc). 'Other' includes all other races/ethnicities not explicitly listed (e.g. Alaskan Native/American Indian, Asian/Pacific Islander, Multi-Racial, etc). Please note that you can choose to submit data on one, all or none of the race/ethnicity categories. It is expected that if your facility is collecting data on screening mammograms that the minimum that will be submitted is one sheet that includes all patients screened in 2006 regardless of race/ethnicity.

**TABLE 1. Number of screening mammograms by BIRADS classification:**

Please record the total number of screening mammograms performed at your facility in 2006, separately for each BIRADS category. If BIRADS classification is something other than 0,1,2,3,4,5 or is missing then record in the other category.

**TABLE 2. Number of screens resulting in follow-up imaging and/or biopsy recommendation.**

Please record data separately for each BIRADS category grouping.

**Number of screens:** Automatically filled in from Table 1 above.

**Number with follow-up imaging within 12 months of screen:** Record the number of screens that receive some sort of follow-up breast imaging within 12 months (365 days) of the date of the screen.

**Number with follow-up imaging within 30 days of screen:** Record the number of screens that receive some sort of follow-up breast imaging within 30 days of the date of the screen.

**Number with biopsy recommended within 12 months of screen:** Record the number of screens that eventually resulted in a recommendation for biopsy within 12 months of the date of the screen. Recommendation for biopsy is defined as any imaging (screening or diagnostic) resulting in BIRADS of 4 or 5. Note that any screening BIRADS of 4 or 5 is automatically assumed to be a recommendation for biopsy regardless of the results of any follow-up imaging that may have occurred and therefore is automatically tabulated.

**TABLE 3. Number of screens resulting in a biopsy**

**Number with biopsy recommended:** The number of screens that eventually resulted in a recommendation for biopsy. These numbers are automatically filled in from Table 2 above.

**Number with biopsy received within 12 months of screen:** *For screens that eventually resulted in a recommendation for biopsy,* record the number that received a biopsy within 12 months (365 days) of the date of the screen.

**Number with biopsy received within 60 days of screen:** *For screens that eventually resulted in a recommendation for biopsy, record the number that received a biopsy within 60 days of the date of the screen.*

**TABLE 4. Number of cancers following screening**

**Number with biopsy received within 12 months of screen:** These numbers are automatically filled in from Table 3 above.

**Cancers diagnosed within 12 months of screen:** *For biopsies within 12 months of a screen, record the number of resulting cancer diagnoses.*

**Minimal cancers:** *For biopsies within 12 months of a screen, record the number of minimal cancers, defined as cancers that are either  $\leq 1$  cm in diameter or non-invasive (in situ) diagnoses.*

**Stage 0,1 cancers:** *For biopsies within 12 months of a screen, record the number of cancers that were either stage 0 or 1.*

**EXHIBIT 1 Cont'd**  
**2006 STUDY DATA**  
**DATA COLLECTION FORM**

**Screening Tool**

ALL Screening Mammograms performed from January 1, 2006 - December 31, 2006

TABLE 1. Number of screening mammograms by BIRADS classification

Screening BIRADS category	Number of screens
0	
1 and 2	
3	
4 and 5	
6	
Other	0

TABLE 2. Number of screens resulting in follow-up imaging and/or biopsy recommendation

Screening BIRADS category	Number of screens	Among all screens		
		Number with Follow-up Imaging within 12 months of screen	Number with Follow-up Imaging within 30 days of screen	Number with Biopsy Recommended within 12 months of screen
0	0			
1 and 2	0			
3	0			
4 and 5	0			0
6	0			
Total	0	0	0	0

TABLE 3. Number of screens resulting in a biopsy

Screening BIRADS category	Biopsy Recommended	Among all screens	
		Number with Biopsy received within 12 months of screen	Number with Biopsy received within 60 days of screen
0	0		
1 and 2	0		
3	0		
4 and 5	0		

Other	0		
Total	0	0	0

TABLE 4. Number of cancers following screening

Screening BIRADS category	Number with Biopsy received within 12 months of screen	Cancers diagnosed within 12 months of screening	Minimal cancers (≤ 1 cm in diameter)	Stage 0,1 cancers
	0			
	0			
	0			
	0			
	0			
	0	0	0	0

**Treatment Tool**

Information for breast cancers diagnosed between January 1, 2006 - December 31, 2006 and contained in your facility's tumor registry

TABLE 1. Number of patients by stage at diagnosis

Stage	A. Diagnosis and first treatment at your institution	B. Diagnosis elsewhere; first treatment at your institution	(A+B) Number of patients with first treatment at your institution	First treatment within 30 days of diagnosis
			0	
			0	
			0	
			0	
			0	
			0	
	0	0	0	0

Tables 2-5 refer to the patients in Table 1 with known stage at diagnosis who received their first treatment at your institution.

TABLE 2. Breast conserving surgery (BCS) +/- radiation therapy (RT)

Stage	First treatment at your institution	Number receiving breast conserving surgery at your institution	For Patients receiving breast conserving surgery			
			Number known to have received RT			Total number that refused RT
			Total number that received RT	RT on site	RT elsewhere	

	0				
	0				
<b>Total</b>	0	0		0	0

TABLE 3. Hormone receptor testing and hormone therapy

Stage	First treatment at your institution	Number tested for ER and/or PR	Number tested positive for ER and/or PR	If ER/PR Positive:
				Prescribed or recommended hormone therapy
	0			
	0			
	0	0	0	0

TABLE 4. Her2/neu testing and herceptin

Stage	First treatment at your institution	Number tested for Her2	Her2 Result		If Her2 Positive
			Number tested positive	Indeterminate result	Recommended Herceptin
	0				
	0				
	0	0	0	0	0

# 6266705\_v9

**EXHIBIT 2**  
**EXAMPLE OF IRB PROTOCOL**

To: Participating Healthcare Provider

**THIS EXAMPLE PROTOCOL IS NOT INTENDED TO BE IMPLEMENTED IN ITS CURRENT FORM BY THE PARTICIPATING HEALTHCARE PROVIDER OR ANY PRIMARY INVESTIGATOR. INSTEAD, IT IS MADE AVAILABLE AS A POTENTIAL RESOURCE FOR THE PROVIDER, BUT THE CONTENT MUST BE INDEPENDENTLY EVALUATED AND ASSESSED BY THE PROVIDER, AND THE PROTOCOL THEN MUST BE CUSTOMIZED AND REVISED BY THE PROVIDER BASED ON THIS REVIEW. PROVIDER WILL NOT RELY UPON THE CONTENT OR CONCLUSIONS IN THIS EXAMPLE IN DEVELOPMENT OR IMPLEMENTATION OF ANY IRB PROTOCOL FOR THE PROVIDER.**

Listed here is additional information that may be helpful for IRB submission.

Additional Information

- This project may qualify for submission under exempt status because- “This research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are either publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.”
- A list of all participating institutions should be noted in your IRB submission.
- In some instances, this research involves viewing protected health information (PHI)
  - The PHI reviewed is existing PHI and not part of ongoing prospective collection.
  - Direct identifiers (name, date of birth, etc.) may be recorded for the purpose of ensuring there is no double counting.
  - Other PHI (e.g. dates) may be recorded for the purpose of tabulations. For example, dates of diagnosis and date of first treatment are recorded in order to define a patient as having or not having treatment within a specified time period.
- Sharing data
  - Data will be shared with the Chicago Breast Cancer Quality Consortium
    - The data submitted to the CBCQC will not have any PHI included. All data submitted is aggregate level and will have no individual level components.
    - Per the confidentiality agreements signed by [Name of Institution] and the Chicago Breast Cancer Quality Consortium, the data submitted will not be shared as belonging to any particular hospital or institution.

## **Title: Chicago Breast Cancer Quality Consortium**

### Abstract:

The Chicago Breast Cancer Quality Consortium is an initiative of the Metropolitan Chicago Breast Cancer Task Force: an organization dedicated to tackling the black-white disparity in breast cancer mortality across Metropolitan Chicago. In keeping with the Task Force aims, the Consortium is specifically geared towards the quality of breast cancer care received in the health care setting. In order to improve the quality of care received by all women in Chicago, the Consortium will collect and share quality data across Chicago institutions and review processes of care within those institutions.

Six screening measures and four treatment measures have been selected by a panel of experts as indicators of quality that are also reasonable for multiple institutions to assess. Data on these measures will be collected from more than 60 committed health care centers across Chicago. The data collected will be aggregate and retrospective including women who were screened for breast cancer or diagnosed with breast cancer from January 1, 2006 to December 31, 2006. (Name of institution) will participate by collecting data on these measures and submitting them to the Chicago Breast Cancer Quality Consortium.

Once the data has been collected, the data will be reviewed and reported to the respective hospitals and the community at large. Any data shared with the community will be done so in a de-identified format: no hospital will be linked with any data that is made public. The goal is that data will help drive quality improvement in breast cancer care for all women in Metropolitan Chicago.

### Objective/ Hypothesis

The aim of this project is to collect and analyze aggregate data on breast cancer screening and treatment. This data will help in assessing the quality of breast care received at (name of institution) and institutions across Metropolitan Chicago.

By collecting and sharing data among a consortium of Chicago breast centers, we will gain insight into improving the quality of breast care for all women in Metropolitan Chicago.

### Background

According to research published in 2007, there is a large and growing disparity in breast cancer mortality between Black and White women in Chicago. The article, authored by the Sinai Urban Health Institute, reviewed twenty three years of data and analyzed the trend in breast cancer mortality over this time span. In 1980, the rates were roughly similar. By 2003 however, the mortality rate from breast cancer among Black women in Chicago was 68% higher than the White rate; in 2005 it was 116% higher. In response to these staggering statistics, a 'Call to Action' Summit was held at [Name of Institution]. The summit brought together clinicians, researchers, breast cancer survivors and other interested community members. The attendees divided into three separate groups relevant to the three areas hypothesized to be at the root cause of the disparity: Access to Mammography, Quality of Mammography and Quality of Treatment. Individuals who were a part of these committees met over the course of five months to assemble a list of recommendations to the city. A report was subsequently released in October 2007 detailing 37 recommendations to Chicago in how to improve breast cancer outcomes for all women in Chicago.

The Metropolitan Chicago Breast Cancer Task Force is a non-profit established to plan and carry out the 37 recommendations released in the 2007 report. One of those recommendations was to develop a Chicago consortium of breast centers that would collect and share data on breast care quality measures, develop quality benchmarks and work together to improve the quality of breast cancer care for all women in Metropolitan Chicago. Susan G. Komen for the Cure Foundation funded this particular initiative of the Task Force for 3 years and in the summer of 2008 planning for the Consortium began.

As of April, 2009, more than 60 health care centers in the Metropolitan Chicago area have agreed to participate in the Chicago Breast Cancer Quality Consortium. (Name of institution) is one of those hospitals and anticipates collecting and sharing aggregate data on breast cancer screening and treatment measures as part of this quality improvement initiative.

## Methods

### *Subjects/Selection Criteria*

Sampling of subjects will include all women who were screened for breast cancer or diagnosed with breast cancer at (Name of Institution) between January 1, 2006 and December 31, 2006.

### *Data Collection*

The following data items will be collected and reported on a standard form (See Appendix A and B).

Data Items	
Screening Data <i>Optional reporting by race/ethnicity</i>	Treatment Data <i>Optional reporting by race/ethnicity</i>
Total number of women screened <ul style="list-style-type: none"> <li>By screening BIRADS code</li> </ul>	Total number of women diagnosed in 2006 and first treated at facility <ul style="list-style-type: none"> <li>By Stage of Cancer</li> <li>By place of diagnosis</li> </ul>
# of women receiving follow up diagnostic imaging <ul style="list-style-type: none"> <li>By screening BIRADS code</li> <li>Within 12 months</li> <li>Within 30 days</li> </ul>	# of women with evidence of testing for both estrogen and progesterone receptor status <ul style="list-style-type: none"> <li># with a positive test were recommended to receive hormone therapy</li> </ul>
# of women receiving biopsy <ul style="list-style-type: none"> <li>Within 12 months</li> <li>Within 60 days</li> </ul>	# of women with evidence of testing for Her2 receptor status <ul style="list-style-type: none"> <li># with a positive test who received or were recommended herceptin</li> </ul>
# of women with biopsy detected cancer <ul style="list-style-type: none"> <li>By tumor size</li> </ul>	# of women who received breast conserving surgery (BCS) # of women who received BCS who went on to

<ul style="list-style-type: none"> <li>• By cancer stage</li> </ul>	receive radiation (RT)
<ul style="list-style-type: none"> <li>•</li> </ul>	<ul style="list-style-type: none"> <li>• # who received RT elsewhere, at facility</li> <li>• # who complete RT</li> </ul>
	# of women receiving treatment within 30 days of their diagnosis date

### *Confidentiality*

Only key research personnel will have access to identifying personal health information.

*Treatment data (optional if using chart abstraction tool and access database)*

A chart abstraction tool has been provided to assist in the chart review process. A unique study ID will be entered onto the form which can be linked to a cross-linked file with names and dates of birth in order to ensure that patients are not counted or abstracted twice. Race and ethnicity data may also be abstracted as well as dates of service (e.g. diagnosis). Dates will be used in order to calculate the variables related to timeliness of care. Data entry will be performed using a Microsoft Access Database system which will automatically aggregate data into counts of patients (e.g. number of patients with breast conserving therapy who received radiation, number of patients diagnosed with stage 1 disease, etc.) The counts represent the final product that will be submitted to the Chicago Breast Cancer Quality Consortium.

### *Reporting/Analysis*

The standard data forms (Appendix A and B) will be submitted to the Chicago Breast Cancer Quality Consortium as part of participation in this initiative.

Data Analysis will involve simple percentage calculations. The aggregate numbers and simple percentage calculations based on these data may be included as part of a community report and other presentations given by the Metropolitan Chicago Breast Cancer Task Force. Multiple Chicago area hospitals will be submitting these same data from their respective institutions to be included in the public report.

No hospital will be linked to their data in any public report or presentation; rather, each hospital will be assigned a letter or code (example: hospital A, B, etc.). Below is an example of what information may be represented in a report.

	Hospital A	Hospital B	Hospital C	Hospital D
Cancer detection rate (per 1,000 screening mammograms)	6	3	8	4

### *Project Duration*

Data will be collected from April 15, 2009 through December 31, 2009. The data collected will be relevant to patients who were either screened or diagnosed with breast cancer between January 1, 2006 and December 31, 2006.

### Anticipated Risks

### Anticipated Benefits

*Racial and ethnic disparities in breast cancer outcomes and survival are widely acknowledged. This research will lead to an improved understanding of processes and patterns of breast care quality in Chicago, which in turn will have two beneficial effects. First, results will point to areas where individual facilities are excelling and may serve as a model for other institutions, and point to areas where individual facilities may benefit from quality improvement initiatives to improve tracking of patient care and/or quality of care itself. Second, results will inform the development of quality improvement initiatives for breast cancer in Metropolitan Chicago as a whole.*

### Description of Study Population

The population will include all adult women (ages 18 and older), regardless of race or ethnicity, who were screened for breast cancer or diagnosed with breast cancer between January 1, 2006 and December 31, 2006. There were \_\_\_\_\_ screened and \_\_\_\_\_ diagnosed during this time.

### Citation

<sup>1</sup> Hirschman J, Whitman S, Ansell D. The black: white disparity in breast cancer mortality: The example of Chicago. *Cancer Causes Control* 2007; 18:323-333.

**EXHIBIT 3**

**SAMPLE MEDICAL STAFF COMMITTEE STATEMENT**

**THIS STATEMENT CAN BE ADOPTED BY PARTICIPATING HEALTHCARE PROVIDER'S MEDICAL STAFF COMMITTEE TO EXPRESS ITS INTENTIONS THAT THE SERVICES PROVIDED IN THIS AGREEMENT CONSTITUTE QUALITY ASSURANCE ACTIVITY AND ARE PROTECTED BY THE MSA.**

By participating in the Chicago Breast Cancer Quality Consortium (the "Consortium"), [Participating Healthcare Provider] shall report to the Consortium certain retrospective, aggregated data, as available, for patients initially screened, diagnosed or treated during calendar years 2006-2012 at [Participating Healthcare Provider] for breast cancer (the "Study Data"). [Participating Healthcare Provider] has entered into a written agreement through which it provides the Study Data to the Consortium (the "Agreement"). [Participating Healthcare Provider] will provide the Study Data to the Consortium for the sole and exclusive purposes of: (1) improving the quality of breast health services provided in Metropolitan Chicago; and (2) reducing morbidity and mortality associated with breast cancer in Metropolitan Chicago. All information, reports or other data of the Consortium or [Participating Healthcare Provider] used or created pursuant to the Agreement in order to undertake medical study of breast cancer screening and treatment for the purposes of quality and patient care improvement, and of reducing morbidity and mortality, shall be used only for medical research, the evaluation and improvement of quality care, all within the meaning of the Illinois Medical Studies Act (the "MSA").

The Task Force and the Consortium, in providing the services described in the Agreement, will be a "medical organization" under contract with "health care delivery facilities" ([Participating Healthcare Provider]), all within the meaning of the MSA. [Participating Healthcare Provider] shall act through its Medical Staff Committee in order to undertake medical study of breast cancer screening and treatment for the purposes of quality and patient care improvement, and of reducing morbidity and mortality, all within the meaning of the MSA. The Medical Staff Committee of [Participating Healthcare Provider] shall adopt this statement to express its intentions that [Participating Healthcare Provider] is participating in the Consortium for the sole purpose of improving the quality of breast health services provided in Metropolitan Chicago and reducing morbidity and mortality associated with breast cancer in Metropolitan Chicago. [Participating Healthcare Provider] and the Task Force each intend that the information, reports and other data described in the Agreement are to be privileged, strictly confidential and protected under the MSA.

**Adopted By:** \_\_\_\_\_  
[Title]

**[Name of Participating Healthcare Provider]**

**Date:** \_\_\_\_\_