

FINAL MINUTES

MEETING OF:

PATIENT SAFETY AUTHORITY

TED GLICK BUILDING
WILDWOOD CONFERENCE CENTER
HACC DRIVE
HARRISBURG, PENNSYLVANIA

TIME: 11:20 A.M.

DATE: September 11, 2007

Agenda

- I. Call to Order
- II. Approval of July 10, 2007 Meeting Minutes
- III. Report of the Board Chair
- IV. Report of the Board Executive Director
- V. Committee Reports
- VI. PA-PSRS Update
 - Presentation - "Update of Wrong-Site Surgery Guidance Project", John Clarke, MD
 - Presentation - "Obstructive Sleep Apnea", Mary Blanco, RN, MSN
- VII. Old Business
 - Patient Safety Authority Budget Update and Confirmation
- VIII. New Business
 - Presentation - "Implementation of Recently Enacted Laws Concerning HAI", Mike Doering, MBA
 - Confirmation of HAI Advisory Panel Candidates
 - Summary of Anonymous Report Review
- X. Public Comments
- XI. Adjournment

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PATIENT SAFETY AUTHORITY

September 11, 2007

Ana Pujols-McKee, M.D., Chair
Mike Doering, Executive Director
Laurene M. Baker, Communications Director
Anita Fuhrman, R.N., B.S.
Roosevelt Hairston, Esquire
Stanton Smullens, M.D.
Gary A. Merica, R.Ph.
Cliff Rieders, Esquire
Marshall Webster, M.D.
Lorina Marshall-Blake [telephone]
William Goodrich, Esquire [telephone]
Barbara Holland [telephone]
Joan Garzarelli, RN, MSN [telephone]

Also Present

John R. Clarke, M.D., PA-PSRS Clinical Director
Mary Blanco

1 PATIENT SAFETY AUTHORITY

2 SEPTEMBER 11, 2007

3 ***

4 The regularly scheduled meeting of the Patient
5 Safety Authority was held on Tuesday September 11,
6 2007. Ana Pujols-McKee, Chairperson, called the
7 meeting to order at 11:20 a.m.

8 ***

9 Report of the Board Chair

10 Ms. Ana Pujols-McKee gave a brief opening welcoming
11 everyone back from the summer break of the month of
12 August. She also asked everybody to take a look at
13 the minutes of the previous meeting and then asked for
14 approval of the minutes. It was moved and seconded
15 and the minutes stood approved. Mr. Rieders asked if
16 there could be a moment of silence for September 11.
17 This was accepted and a moment of silence was
18 observed. Ms. Pujols-McKee then took a roll call for
19 attendance. She first spoke about having an in-
20 service with CDC coming to speak to the group, rather
21 than individually, to explain their data base and its
22 capabilities as CDC's data base is going to be the
23 common data source for reporting under the new Act 52.

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1 Also an update that she has been working with Carolyn
2 Scanlyn and her team from HAP on getting on board.
3 One of the discussions and meetings was with Dr. Kuhns
4 from the Institute of Governors. Dr. Kuhns's work has
5 been quite extensive on education of Boards. She
6 discussed a little bit about some of Dr. Kuhns's work.
7 They are trying to create an educational program on
8 safety for the Boards that would address accreditory
9 issues, state issues, CMS issues, and for it to be as
10 broad and to be sort of a one-stop solution for a
11 Board rather than create something independent that
12 may be redundant with many other agencies. The next
13 step would be for a proposal, a recommendation, or an
14 update on what it looks like in terms of direction to
15 go in.

16 ***

17 Report of the Board Executive Director

18 Mr. Doering went over a few things that were in the
19 document previously sent out to the Board members. A
20 new release of PSRS was implemented on August 13 and
21 everything went very smoothly. Mr. Doering will be
22 giving a presentation to executives and staff of
23 Shriners Ward General [ph] in Erie on September 17,

1 2007. It's a general presentation focusing on the
2 work being accomplished by the Authority. Nashby [ph]
3 is holding a forum called Focus on Pennsylvania and
4 this will be in Harrisburg, invited are the Department
5 of Health, the governor's Office of Healthcare Reform,
6 PSA, PHC4 and also peers from other states. The focus
7 will be on how things are done in Pennsylvania. Dr.
8 John Clarke and Mike Doering will be giving the
9 presentation on the 19th and 20th. He will also be
10 talking to the Pennsylvania Nurse Anesthetist
11 Association or Pennsylvania Association of Nurse
12 Anesthetist on Saturday, October 6 in Philadelphia.
13 There has been a lot of time spent on Act 52 since the
14 last meeting. Some of the things that have been
15 accomplished are that work plans have gone out, we've
16 put together the sub-committee made up of the
17 initiative Board champions, we've talked with DOH to
18 discuss initial plans, we have attended the HAP
19 conference call, we've solicited the HAI Advisory
20 Panel nominees and developed a slate of candidates,
21 and contact change requests are almost complete, we've
22 sat down with DOH looking at the NHS end product of
23 CDC and went through a webinar on exactly what it did

1 and how it worked and that was very interesting. So a
2 lot of work has been done around Act 52 there are
3 plans for going forward. Also included in the binders
4 everyone received were some of the little work plans
5 for some of the strategic plan initiatives and one on
6 the Patient Safety knowledge exchange was also
7 included. This is an example and smattering of some
8 of the stuff that has been worked off of. Mr. Doering
9 noted on page five of his report the two top
10 paragraphs on page five were left in there from the
11 last report and they can be marked out. There is one
12 financial chart which is the unaudited balance sheet
13 of July 31, 2007. At this time it shows a \$3.7
14 million balance. Some of that will get applied to
15 invoices from last year so it's more in the range of
16 about \$3.2 million. This is not enough to cover the
17 expenditures for this year. To point out the terms of
18 the primary contract with Ekrey [ph] Institute in '06-
19 '07 based on the base budget and some change orders
20 put through we had a total expenditure for \$2.87
21 million. We ended up spending \$2.83 million. So
22 remaining balance basically of about \$44,000, \$45,000
23 so we came in under on the whole Ekrey Institute

1 contract for last year. The '07-'08 budget has been
2 amended. This will be discussed later on.

3 ***

4 PA-PSRS Update

5 Dr. John Clarke talked about the original wrong side
6 surgery investigation and the subsequent articles in
7 the Advisory are now available and this has prompted
8 us to do something about this problem. We have a two
9 prong attack. One is to get some more information.
10 This will be done by visiting five hospitals and
11 gathering information. This information will be used
12 to tailor and modify our other initiative which is
13 already ongoing as well and that is to do an intense
14 follow up on each near miss and actual wrong side
15 surgery report we get. We get about two reports a
16 week, although for the most part these are near
17 misses. Mary Blanco is spearheading this part of the
18 project and has been very good at working with these
19 institutions to get compliance. By the end of this
20 calendar year we hope to come up with some refined
21 recommendations to institutions about what actually
22 works and what doesn't work.

23 ***

1 Obstructive Sleep Apnea

2 Mary Blanco, RN started by letting everyone know there
3 were handouts given to the Board members on this
4 presentation. It was noted first that this problem
5 may block the path to positive operative outcomes.
6 This is based on an article that will be out in
7 September 2007. Ms. Blanco discussed what obstructive
8 sleep apnea is. She noted it's a very common sleep
9 disorder. It's a complete and/or partial airway
10 collapse during sleep. In the United States it
11 affects two to four percent of the population. A
12 study by the Medical College of Wisconsin showed nine
13 percent of men have some moderate obstructive sleep
14 apnea; four percent of women have moderate obstructive
15 sleep apnea. It often occurs most in the 40 to 65
16 year old range and the incidence increases with age.
17 She went on to discuss the problem with patients that
18 have obstructive sleep apnea. Patients are at greater
19 risk for respiratory and cardiopulmonary complications
20 during surgical procedure, there are certain
21 complications that you are more prone to.
22 Approximately 80 to 90 percent of patients with
23 obstructive sleep apnea are undiagnosed. It was noted

1 that folks with this problem can have operative
2 complications and get into trouble very quickly. A
3 brief summary of the kind of things we see in PSRS is
4 a majority of the reports indicate sleep apnea was
5 noted in the medical history; post operatively they
6 may need to be reintubated and transferred to a higher
7 level of care; need for reversal agents; overall an
8 increased hospital stay, people have procedures in
9 ambulatory centers then have to be transferred to the
10 hospital for observation, at least 24 observation
11 overnight. So risk factors need to be identified
12 preoperatively. Obesity, age over 65, short thick
13 neck are some of the factors. Also some of the
14 comorbidities would include hypertension, heart
15 failure, and cardiac arrhythmias. The use of a
16 screening tool a short questionnaire, self
17 administered could help give doctors and
18 anesthesiologists a good idea that a person may indeed
19 have an undiagnosed obstructive sleep apnea.
20 Anesthesia traditionally does their perioperative
21 assessment of a patient and their focus has usually
22 been on heart disease, lung disease. The joint
23 commission actually proposed that universal screening

1 for all patients in the preoperative area be a
2 national patient safety goal. It hasn't been adapted
3 yet but could be on their list of potentials. She
4 went on to discuss if patients are identified as
5 potential or suspected of having obstructive sleep
6 apnea there are different ways to manage this. Their
7 airway is key, the choice of the anesthesia to use,
8 use of sedatives and opioids, and obviously the
9 patient monitoring. In summary, the identification of
10 these patients in the pre-operative assessment is
11 critical. And although it isn't a definitive
12 diagnosis certainly a suspected obstructive sleep
13 apnea patient does warrant a little bit different
14 treatment and that the surgical team should be aware
15 of this and standardize their approach with some of
16 the tips just highlighted in the intraoperative and
17 postoperative areas. Hopefully these strategies can
18 improve quality and safe care for our patients. In
19 relating to the bariatric surgery population it was
20 noted that this is an area that needs to have focus on
21 as more and more bariatric surgery takes place. It
22 was noted that not necessarily more training is needed
23 as there is more heightened awareness of what to look

1 for.

2 ***

3 BUDGET

4 Mr. Doering stated the budget has been updated to
5 include costs for implementation of Act 52 and also to
6 develop programs for the education of facility Boards.
7 This brings the total to approximately \$5.4 million
8 for this year. Mr. Smullens moved and Mr. Webster
9 seconded the motion to accept the budget. There was a
10 roll call vote taken and the motion stood approved.
11 It was noted a modest enhancement of \$300,000 in terms
12 of budget expenditure is in the budget figures. This
13 is for the Authority to be able to spend in case more
14 things come down due to the passage of Act 52.

15 ***

16 Old Business

17 On the Just Culture Model Mr. Merica wanted it noted
18 on the record there will be three workshops in the
19 State of Pennsylvania in the month of October for
20 healthcare leaders, one in Pittsburgh, one in
21 Philadelphia, and one in State College. It was noted
22 the session in Philadelphia has a waiting list. There
23 is the possibility of adding some other sessions to

1 try to accommodate the facilities so that no one will
2 be denied these sessions.

3 ***

4 Implementation of Recently Enacted Laws Concerning
5 HAI/Confirmation of HAI Advisory Panel Candidates

6 Mr. Doering gave a short summary of Act 52. He had
7 previously attended a presentation that HAP did and so
8 he gave the group just a brief summary of what is
9 going on. Act 52 is all about healthcare acquired
10 infection and arose out of Senate Bill 978. It was
11 signed into law the 20th of July and became effective
12 on August 18. This Act 52 takes Act 13 of 2002 and
13 adds Chapter Four which is related to the reduction of
14 healthcare acquired infection. As a note Chapter Six
15 is also reserved for future additional requirements
16 for long term care nursing facilities. Some of the
17 things that a facility has to do in Act 52 are related
18 to having infection control plans and hospitals,
19 nursing homes, and ASCs need to do those. Included in
20 those plans there has to be multidisciplinary
21 committees, infection control protocol, et cetera.
22 Then one that has to do with PSA and it's procedures
23 for distributing Patient Safety Advisories. In terms

1 of the facility, HAI reporting requirements, nursing
2 homes will be required to electronically report
3 patient specific HAI information to DOH and PSA and
4 hospitals will be reporting HAI information to the
5 Center for Disease Controls National Health Safety
6 Network beginning no later than February 14 of 2008.
7 And Act 52 also says that the facilities must
8 authorize DOH, the Authority, and PHC4 to have access
9 to all of their data within NHSN. The Department of
10 Health has some duties including implementing public
11 health awareness campaign, developing and recommending
12 best practices to improve screenings and cultures.
13 The Authority and Department of Health needs to work
14 with PHC4 and PSA to determine what the rate of health
15 care associated infections are in facilities and do
16 some comparison statewide and nationally, and also
17 develop benchmarks with PHC4 and PSA to measure
18 progress. The law establishes HAI as a serious event.
19 So what's going to happen is healthcare acquired
20 infections are going to be defined by the CDC, if it
21 meets CDC's definition then it is an HAI, and if it is
22 an HAI it is a serious event. This does need to be
23 reported to the Authority and DOA. The Patient Safety

1 Authority must publish uniform definitions for HAI
2 reporting by hospitals. That's going to be fairly
3 easy because it is all about what the CDC's
4 definitions are. A webinar was attended at the
5 Department of Health to look at the CDC system. It is
6 fairly robust and provides a lot of good information.
7 Answers are wanted to questions about types of
8 processes and procedures so we can talk to people to
9 find out what works, what doesn't, and what guidance
10 is needed. We want information on what's happening
11 where there might be an outbreak, what types of
12 infections, how do we keep it from occurring again.
13 From a legal standpoint we need to know that we, as
14 well as DOH, can get the information within 24 hours
15 because it is a serious event according to the law.
16 But we need to know what information we want to see.
17 It doesn't do a lot of good just to know these types
18 of infections occurred at these facilities without
19 proper and complete information being supplied. Also
20 DOH would have to define in regulations about the
21 amount of time in which a serious event must be
22 reported. Ms. Pujols-McKee stated that if the goal is
23 to collect data that becomes meaningful information

1 for hospitals and nursing homes to work towards
2 improving then how we create questions for this has to
3 be well thought out. Because a year from now we want
4 to hear from hospitals that unlike information they
5 were getting before on infections from PHC4, which
6 left them somewhat confused, they are now getting a
7 meaningful very precise data that is flexible enough
8 for them to apply improvement strategies in their
9 organization. So the need to be thoughtful and make
10 it as efficient as possible and not have duplicate or
11 triplicate reporting when we can get the data from one
12 source. The Advisory Panel, the infection control
13 experts, who are appointed to assist not only PSA but
14 DOH and others in carrying out requirements of the law
15 including the content and format of nursing home HAI
16 reporting, developing rates and benchmarks for HAI,
17 Patient Safety advisories saying what types of things
18 should we be addressing, what should be analyzing,
19 what should we be reporting on, or providing guidance
20 on to the facilities, and help develop a training
21 program. Folks were contacted for input or asked for
22 nominations from the Department of Health, PHC4,
23 governor's Office of Healthcare Reform, all of the

1 APIC Chapters, from HAP, from three nursing home
2 industry groups, from PRHI, HCIF, and from our own
3 Board members and from others. Today there is a slate
4 of 13 people nominated for the Advisory Panel.
5 Another issue brought up was PSRS versus NHSN on
6 timing associated with comment notification periods
7 for the hospitals and for the nursing homes. Talking
8 about HAI, we have to put out a 30 day comment period
9 for whatever we're going to do, allow an opportunity
10 to respond for 30 days, and then address those
11 responses. Also we have to publish something in the
12 Pennsylvania Bulletin and that's approximately 120
13 days that a facility has to comply with whatever we
14 are putting into the bulletin. We want to have
15 whatever the method of reporting to us will be
16 completed sometime in the spring. As far as nursing
17 homes a little bit more identification development of
18 what is really needed has to be done and we will try
19 to have that implemented next summer. Finally content
20 and format of nursing home HAI reporting is a joint
21 DOH and PSA responsibility and we need to determine
22 how and what to report. So it must be clarified what
23 nursing homes will need to do, whether to have

1 additional reporting types. This could possibly be a
2 significant addition to the PSRS system in terms of
3 the high number of facilities and users that we would
4 maintain. It was further noted that October 2 there
5 will be a kick off for the facility training of the
6 NHSN. And there will be a kick off in which CDC is
7 going to be participating live along with the
8 Department of Health and HAP will be proposing a
9 recommended road map for them to have all the training
10 done by the end of November. So in theory they could
11 actually go live effective 1/1/08. From HAPs vantage
12 point this makes a lot of sense because it gives a
13 full year's worth of data that would go into NHSN. As
14 well as we're doing some education around the
15 electronic surveillance systems which will also take
16 place in October. Mr. Doering then gave a background
17 of what happened in terms of identifying the panel. A
18 list of qualifications looked for in the nominees was
19 put together. We had to have one representative of a
20 non rural hospital, one person from a rural hospital,
21 one person for profit nursing home, one person not for
22 profit nursing home, and one person county nursing
23 home. Those are the only requirements per the Act.

1 Per a phone conversation with some of the Board
2 members they wanted to have some balance in terms of
3 the different folks that they had on the panel. The
4 following were chosen for the Advisory Panel: Erick
5 Bergquist, Medical Director for Epidemiology at
6 Indiana Regional Medical Center, Dorothy Borton, RN,
7 Infection Control Practitioner from Albert Einstein
8 Healthcare Network, Patrick Brennan, M.D., Chief
9 Medical Officer and Senior Vice President University
10 of Pennsylvania Health System, Professor of Medicine,
11 Kenneth Brubaker, M.D., Director of Geriatric Program
12 Willow Valley Retirement Community and several others,
13 Susan E. Coffin, M.D., Medical Director Department of
14 Infection Prevention and Control at Children's
15 Hospital of Philadelphia, Daniel Haimowitz, physician
16 and Medical Director of Geriatric Program Attleboro
17 Retirement Campus and several other places, Sharon
18 Jacobs, RN, Manager of Infection Prevention and
19 Control at St. Clair Memorial Hospital and also
20 president of APIC-Three Rivers, Emily McCracken, MPH,
21 Hospital Epidemiologist and Director of Infection
22 Control for Hamot Health System, S. Candy Mulholland,
23 RN, Infection Control Coordinator for Kane Nursing

1 Homes, Carlene A. Muto, physician, University of
2 Pittsburgh Medical Center, Medical Director Department
3 of Hospital Epidemiology and Infection Control,
4 Stephen Ostroff, physician and Bureau Director of the
5 Bureau of Epidemiology, Pennsylvania Department of
6 Health, Abby Weand, nurse and HAI Project Leader,
7 Pennsylvania Health Care Cost Containment Counsel,
8 Linda Winston, MSN, Infection Control Officer for
9 Altoona Regional Health System. It was moved and
10 seconded to approve the nominations of the candidates
11 as the Advisory Committee. A roll call vote was taken

12 ***

13 Summary of Anonymous Report Review

14 Dr. John Clarke noted there's a provision for
15 anonymous reporting of patient safety concerns about
16 serious events in the law. A report was received this
17 summer about a patient who was a minor in the
18 behavioral health unit. The concern was that one of
19 the non professional staff of the unit had a romantic
20 relationship with a parent of the minor. The patient
21 safety officer at the institution did a follow up on
22 this. It was found the staff member had contacted the
23 Human Resources Department of the institution about

1 the appropriateness of having a relationship with a
2 parent and human resources advised the person there
3 was no organizational policy prohibiting dating of a
4 patient's family member. On further investigation a
5 departmental policy for the inpatient behavioral unit
6 said that all relationships with patients and their
7 families had to be related to their professional
8 duties. Once this became known -- and this was at the
9 staff worker's instigation well before our
10 investigation -- the human resources, the behavioral
11 unit and the supervisor of the individual met with the
12 individual and came upon an agreement for future
13 behavior which was should the patient be re-admitted
14 to the hospital that person would be isolated from any
15 contact with the patient. In response to our request
16 about the appropriateness of reporting this as a
17 serious event the institution did a further
18 investigation through the Patient Safety Office. The
19 facility found no evidence either documented or verbal
20 in their discussions with the individuals that they
21 contacted to support any diagnosis of emotional
22 distress from breach of therapeutic boundaries. Also
23 none of the physician care providers expressed any

1 concern that the patient had experienced emotional
2 distress. On this basis the facility determined there
3 was no harm and therefore that this did not constitute
4 a serious event as defined by the M-Care. It was
5 suggested that the Authority do an independent review
6 just to validate there was no harm to the child. Dr.
7 Clarke said there would be an independent verification
8 and a follow up report.

9 ***

10 Adjournment

11 Ms. Pujols-McKee asked for a motion to adjourn. This
12 was done and seconded.

13 ***

14 [Meeting adjourned at 12:40 p.m. on September 11,

15 2007]

16 cmf