NQF Process to Receive Comments on Common Formats
Meeting of the Expert Panel

February 25 – 26, 2009

Marriott Metro Center Hotel
Washington, DC

MEETING SUMMARY

Panel members present: David C. Classen, MD, MS (Co-Chair); Henry Johnson, MD, MPH (Co-Chair); John R. Clarke, MD; Diane Cousins, RPh; Peter L. Elkin, MD; Mark A. Keroack, MD, MPH; David L. Knowlton, MA; Mary E. Krugman, PhD, RN; Helen Lau, RN, MHROD, BSN; Arthur Levin, MPH; Marlene Miller, MD, MSc; Lori Paine, RN, MS; Shannon Phillips, MD, MPH; Nancy Ridley, MS; Heather B. Sherman, PhD; Liaison Member: William Munier, MD

Others present: Peter Goldschmidt, MD; Amy Helwig, MD; John Moquin; Marcy Opstal; Ira Yanowitz (AHRQ).[1]

National Quality Forum (NQF) staff present: Peter Angood, MD; Eric Colchamiro, MPA; Alexis Forman, MPH; Melinda Murphy, RN, MS, NE-BC

PURPOSE

The purpose of this meeting was to take action on the recommendations that were formulated by Expert Panel subgroups related to the nine Common Formats event-specific forms.

WELCOME AND INTRODUCTIONS

Dr. Classen welcomed the Expert Panel and guests. He then asked that all present introduce themselves and that the Panel make any relevant disclosures of interest. Dr. Keroack noted his organization has developed an online adverse event reporting system. Dr. Johnson noted that his organization makes software for hospitals, including patient safety-related products. Dr. Classen noted he works for a technology services company and is involved with a medical software company. Dr. Miller noted she has been a paid researcher for MedMarx, has published research related to error reporting systems and has previously worked at the Agency for Healthcare Research and Quality (AHRQ) as Director for the Center for Quality Improvement in Patient Safety.

The Panel was oriented to the materials being displayed on the screens in the room and to the plan for moving forward with the day's work.

[1] Others present in the audience for all or part of the meeting included: Kathy Barberio (IFMC); Russ Mardon (Westat); Geoffrey Rake, MD (DoD); Rita Munley-Gallagher and Patty Sokol (ANA) Susan Raetzman (Thomson Reuters); Sherrie Graham (Child Health Corporation of American) ; Sheila Warren (Indian Health Service); Dan Pollock, Centers for Disease Control and Prevention); Dan Cohen, MD (DATIX); Lisa Asatorian and Carol Vargo (AMA);

DISCUSSION AND RECOMMENDATIONS

OVERVIEW OF NQF ROLE WITH COMMON FORMATS

Ms. Murphy provided a brief overview of the NQF role stressing that the work is a collaboration between AHRQ and NQF by design and that the process being used to collect comments and provide input to AHRQ related to the Common Formats is an adaptation of the consensus development process. It does not include endorsement. Ms. Murphy noted that NQF had received over 700 comments specific to the 12 Common Formats forms and based on criteria set by the Expert Panel had triaged over 450 comments directly to AHRQ. Also, the Expert Panel had established criteria for how it would prioritize comments about which it would opine. Since the Expert Panel, through its subgroups, addressed all of the more 250 comments triaged to it, the criteria were not applied.

REVIEW OF COMMON FORMATS: HISTORY, CONSTRUCTION, TESTING, FUTURE

Dr. Munier provided information about the status of naming Patient Safety Organizations (PSO), a review of the Common Formats development and maintenance process, as well as the future including the plans related to automating the forms. He pointed out that: 1) the forms were designed for use by hospitals with the expectation of moving into other environments later; 2) the paper-based forms are as short and simple as possible to facilitate acceptance; and that 3) specifications for the forms' content are being developed to facilitate conversion into electronic formats by private vendors. He discussed modularization of the forms and noted that sets of Common Formats for three additional phases of the improvement cycle will be forthcoming overtime including sets for 1) root cause analysis; 2) improvement mechanisms that are instituted and 3) evaluation of outcome of improvement effort undertaken.

Dr. Munier noted that the Common Formats Version 1.0 will be revised based on feedback and comments received through the NQF and Expert Panel processes. The revisions will be made in the forms as well as the various support materials such as the Users Guide. The revisions and the creation of such things as the Expert Panel recommended "Quick Guide" should facilitate what will be initial use of the forms by healthcare institutions and PSOs. After release of Version 1.0, AHRQ expects to update the forms on an annual basis.

RECOMMENDATIONS RELATED TO HERF, PIF, AND FAF

On January 23, 2009, the Expert Panel convened to act on recommendations of the subgroup that review recommendations related to the Common Formats generic forms. At that meeting three items related to the PIF were held over for discussion at the February 25 meeting. They were 1) potential addition of a free text to Item 10 that would allow a reporter to use free text rather than principal diagnosis code with the proviso that the code be added when available; 2) potential addition of a free text to Item 11 that would allow a reporter to use free text rather than principal procedure code with the proviso that the code be added when available; and 3) potential change in

response options to Item 18 to simply indicate whether the patient or patient family were notified of the incident.

Additionally, in response to the group's suggestions for modification of current paper form Items 12 – 16 to replace the term "rescue" with one more commonly understood; delete the 24 hour timeframe in Item 13 and, if needed, replace with more flexible options; remove "residual" from Item 16; remove each use of "unplanned" in Item 15; and simplify the harm scale items, AHRQ provided revisions as noted in Attachment A. In so doing, AHRQ revised the response options for Item 18 as recommended.

It is the recommendation of the Panel that, with respect to the revised set of questions:

- Items 13 and 14 be reversed;
- the word "residual" be removed from Item 15;
- the word "rescue" be removed from each of the items in which it appears;
- the word "unplanned" be removed from Item 14 and response option 14.l.

GENERAL RECOMMENDATIONS

General recommendations approved on January 23 were touch upon briefly and are included below so that all recommendations are captured in this set of materials – these minutes and worksheets related to each of the 12 Common Formats forms.

Guides

- While information about when forms are to be completed and by whom is contained in the Users Guide, it is recommended that the information be more fully and prominently detailed both in the Users Guide and in a new, more accessible "Quick Guide".
- Expand the Users Guide by adding and clarifying items as noted below and in the attached worksheets.
  - Acknowledge that users may find the paper forms confusing because multiple forms are required and overlap occurs.
  - Provide additional guidance as to the connectivity among the forms.
  - Prominently clarify meaning of Final Assessment Form in both Users Guide and "Quick Guide" and possible additional information that may or may not be completed after FAF since users will not be aware or focused on fact that AHRQ expects to issue additional forms such as RCA which would occur after FAF is submitted.
- Add a "Quick Guide" and a set of "FAQs" to provide more quickly accessible references.
- Include in Users Guide, "Quick Guide" and/or FAQs information about transmitting the various forms to PSOs and NPSD in terms of such things as a) institutional options for how forms may be transmitted; e.g., singly or together and b) form completion options; e.g., who may complete various forms, how to address form completion when there are multiple reporters for a single event.
- For frontline staff, place extra emphasis about how to use the forms in both the Users Guide and "Quick Guide".

Forms

- Consider adding some schema, such as lettering (A, B, C, D) to the forms to help people know the sequence in which they should be addressed.
- Include, where appropriate "pointers" to assist users in locating places where information related to specific topic but not captured on the specific form is or can be found and captured. (added on February 26)

Pending general recommendations submitted by the subgroups and the related Expert Panel discussion are:

- **Medication Incident Reporting**
  1. AHRQ should consider what actions it can take in launching Version 1.0 of the Medication form that will encourage increased reporting of comparable information; e.g., work with PSOs to accept electronic reports from organizations that currently use such; point users of the form to reliable data dictionaries in the public domain; collect information about users in terms of types of reporting systems used and institution demographic, particularly size/complexity.
  2. AHRQ should consider suggesting to users that they report medication incidents through both the PSOs and MedWatch and in so doing, note the harmonization effort.

The Expert Panel approved the medication incident reporting recommendations. The point was made that the volume of medication errors argues for making the process of reporting as simple and similar in content and form as possible and to the extent possible mirror that of current and mandatory reporting systems to continue to focus on easing the reporting burden. The Panel also noted that falls are another group of high volume incidents that should be similarly addressed. Members also noted that other mandatory systems; e.g., States, FDA, etc. be considered in harmonization efforts.

- **HAI**
  1. Add information in the introduction to the HAI form that the entire form should be completed by trained ICP staff and include the rationale for this advice.
  2. AHRQ consider identifying (potentially with CDC) and flagging the small number of questions that could be expected to be accurately completed by non-ICP staff.

The HAI recommendations are addressed within the context of the specific HAI form; recommendations are included on the HAI worksheet.

An additional general recommendation that evolved from the discussion of both the HAI and medication reporting forms is that, where appropriate, AHRQ build the Common Formats forms in tiers or layers in groups of items based on who is expected to complete the items. This concept is further addressed in the recommendations for those forms.

CROSS-CUTTING ISSUES

The Expert Panel subgroups identified a number of cross-cutting issues for both information and discussion.

Informational Items

- **Capturing the "Right" Information.** Analysis of information received over the course of use of Version 1.0 will inform future versions so that, for example, if it becomes clear that there are items that should have been included that were not or should be differently worded, those changes will be made.
- **FAF Form Name.** AHRQ staff noted that because of the implication created by the name of the form – Final Assessment Form, AHRQ is considering changing the name to Summary of Individual Report (SIR).

Items for Ongoing Consideration

- **Paper-based vs. Electronic Forms**. All subgroups discussed the inherent limitations of paper forms and discussed with AHRQ staff the capabilities that will be available once the forms are put into an electronic format. AHRQ staff has noted that:
  - linking of forms and collection of additional detail will be enabled by electronic forms, the specifications for which will be available with the release of Version 1.0;
  - AHRQ has a library of items that it can bring forward for use in an electronic version of the Common Formats that are not feasible to include in the paper-based system;
  - some additional specific detailing beyond what is now included in the forms is possible but paper-based forms do pose limitations to the amount of detail that can be captured without making the forms off putting to users;

  The groups have agreed that it is appropriate to keep paper forms as simple as possible while capturing essential information and to continue to visit the issue of what and how much should be included going forward.

- **ICD-9 coding.** The issue of allowing ICD-9 coding in a free text field on both the PIF and the Surgery form has been discussed and recommended; however, this matter is a general concern. Once the forms are available in electronic format, importing ICD-9 codes from billing data or UB40 should facilitate obtaining correct information seamlessly.

- **"First Applicable Category" Instruction**. After considering this instruction across a number of questions, the group suggested this instruction should be further discussed in terms of the objective to be achieved by its use, the alternatives, and the implications of the term and alternatives, particularly "Most" and "All". This will be a discussion item related to specific forms and questions in Version 0.1 Beta and with future versions.

- **Work Around.** In discussing potential issues encountered with use of devices, Group B noted that some information should be captured regarding work arounds, including as it related to both on- and off-label actions. Since this situation can occur across multiple types of events, it was suggested that AHRQ consider addition(s) to the FAF and/or RCA to capture this information.

- **Consistency Across Forms.** This issue was discussed in various ways during multiple group meetings. In one specific instance, suggestion was made that the Surgery subgroup review Item 25 on the Perinatal form to ensure a smooth connection with a similar question on the Anesthesia form. While Perinatal Items 23 - 27 have been recommended for removal and held for inclusion in the RCA set in Version 2.0, the overall issue remains an item for the Expert Panel's consideration and AHRQ's ongoing action.

- **Root Cause Analysis (RCA).** During discussion of items on multiple forms, AHRQ noted that it expects to have a series of RCA forms available for use when Common Formats Version 2.0 is issued in Summer 2010. While those forms will be able to capture more detail than can be obtained on the current forms, issues for consideration include the following.
  - Careful thought must be given to the questions that are essential to understanding an event since they may not be captured later.
  - Provision should be made for a process to accept later information to amplify initial reports, such as in the form of an addendum.
  - Any information submitted subsequent to an initial report must be able to be linked to the initial report.

- **Burden of Reporting.** The issue of paper-based reporting burden was discussed in the context of medication error reporting. In response to a question regarding where responsibility for putting paper reports into a database will lie, Dr. Munier responded that because the Patient Safety Act is entirely voluntary, AHRQ has no authority to say how the work is to be done. The methods for building a database from reports is open to individual institutions, which have full latitude to design the way in which the reports are compiled into a database. They may choose to do it themselves, arrange with a PSO to accept paper forms and create an electronic database, etc. What has been arranged is that the PSOs will submit data to the Network of Patient Safety Databases (NPSD) in electronic form.

RECOMMENDATIONS RELATED TO EVENT-SPECIFIC FORMS HEALTHCARE-ASSOCIATED INFECTION; MEDICATION AND OTHER SUBSTANCES; AND PERINATAL

General and overarching issues are presented here. Item specific recommendations are presented in the attached spreadsheets.

HAI. The overarching issue of the preparation of the practitioner best prepared to respond accurately and consistently across settings, which had been discussed at length by the subgroup, was reiterated to the Expert Panel. The group feels that HAI incident reporters should be Infection Control Practitioners (ICP) trained in the CDC terminology. They also recommend that an early question be included in the HAI form that asks if the report is an ICP trained in CDC terminology. Dr. Clarke noted that the Pennsylvania reporting system requires people to use the CDC system. Dr. Munier noted that the form was prepared to be consistent with the CDC requirements but has been pared to a "Level 1" set of information reserving a

"Level 2" set of information for electronic forms that are consistent with the greater detail required by the CDC National Health Safety Network (NHSN) and can be used to electronically move the data between reporting systems. Dan Pollock, CDC, who was present at the meeting noted that CDC reports require attestation of accuracy by an ICP. He also provided information that over 2,100 (40 percent of US) hospitals across 19 states of varying sizes and population density are enrolled in NHSN.

It was suggested to AHRQ that the HAI form should be the first area for conversion to an electronic format so as to take move to a system completely interoperable with CDC system and to avoid a middleware solution that may or may not be compliant with the NHSN requirements. Further, institutions will likely want to have the full set of information about its infections in order to fully understand and design effective interventions. The challenges related to acquisition of systems, availability of trained personnel and the cost of such assets are a factor in how and when institutions will move to the ideal state, absent state or federal mandates.

A suggestion was made that AHRQ consider an intermediate position of offering the option of using the Common Formats HAI form or report directly to NHSN. Dr. Munier replied that the Common Formats are meant to be an integrated set of reports across the spectrum of patient safety and to take HAI or any other out would create an undesirable gap.

The Panel agreed that paper forms will be needed by institutions that do not yet have electronic capability but stressed that the information should be harmonized with the NHSN requirements and, where possible, be completely consistent so as to be transmitted to NHSN without further work.

Medication. Dr. Keroack introduced the discussion of the medication form by commenting that much of the discussion about this form related to the issues of the volume of medication events to be captured, precisely identifying the medication including the value of having a strong drug dictionary to which forms users are pointed, and the need for pharmacist involvement in reporting to ensure accuracy and consistency. The fact that forms completion is voluntary was also noted in terms of the limitation this poses related to being able to set requirements about both who should complete forms and how complete the information should be.

As in discussion of the HAI and other forms, the issue of using existing, accepted systems was raised. In the case of medication, RXNorm for drug name terminology and National Council for Prescription Drug Programs' (NCPDP) SCRIPT system were mentioned. Again, the limitation posed by paper forms and the desire that the forms be kept short and simple suggest that the systems and desired detail be held and revisited in the context of electronic forms.

A comment was made that human breast milk and contrast media should be included on an appropriate form. With respect to breast milk, errors related to its use have been reported as medication errors and as more in the area of blood products because it is serum-related. The issue was tabled for discussion later in the meeting. On Day 2 of the meeting, this item was further discussed and a recommendation made that the breast milk be placed on the Medication form. See that form for the specific recommendations.

A Panel member presented to the Food and Drug Administration (FDA) representative present at the meeting, the case for including over-the-counter , herbals, and items taken as part of cultural beliefs in any list of substances considered for reporting under medications.

Perinatal. At the conclusion of the discussion related to specific items on the form, Dr. Angood asked whether additional items related to the baby had been discussed. While such a discussion had occurred, the group consensus was that it was appropriate for this form to focus on birthing and delivery with the expectation that additional questions related to specific issues; e.g., infections, be included on existing forms or a form related to neonatal events should be considered by AHRQ. As noted earlier, comments specific to the questions and response options are addressed on the Perinatal worksheet.

RECOMMENDATIONS RELATED TO EVENT-SPECIFIC FORMS BLOOD, TISSUE, ORGAN TRANSPLANTATION OR GENE THERAPY; FALL; AND PRESSURE ULCER

General and overarching issues are presented here. Item specific recommendations are presented in the attached spreadsheets.

Blood. Dr. Krugman opened by acknowledging that Dr. Liang, a blood bank director, had lead discussion of this form and has since resigned the Panel; therefore, she is presenting the recommendations that were formulated under his direction. Dr. Liang's view was that the Agency Information Management System (AIMS) used in Australia included detail and pathways for describing problems in blood product related processes that are not captured by the Common Formats form. Given the fact that AIMS is a proprietary system which AHRQ has in its inventory but for which it does not have detail; therefore, was not able to consider during development of the form. The classification tree, absent details, from the International Classification for Patient Safety (ICPS) which mirrors that of AIMS was made available to the Panel by Dr. Sherman. Dr. Munier noted that, while AHRQ did not have access to the details of AIMS, he appreciates that it is a very sophisticated system that meets or exceeds the level of the most highly developed systems. He also noted that Prof. Bill Runciman of the Australian Patient Safety Foundation and a member of the Expert Panel, has indicated that AIMS is not a practical solution for paper-based forms. Dr. Munier was asked if AHRQ considered the Medical Event Reporting System – Total HealthSystem (MERS-TH) during development of this form; he responded in the affirmative. A suggestion was made that it would not be appropriate to recommend endorsing a proprietary system such as AIMS when it cannot be made available to the Panel; rather it was suggested that tools in the public domain should be drawn upon. Dr. Sherman noted that the concepts that are included in AIMS and the ICPS are captured in the blood form. In response to a question about what AHRQ wants to achieve with this form, Dr. Munier noted that AHRQ is striving to set up an adverse event-reporting system rather than a supply chain quality control mechanism.

The question of including human breast milk on this form was raised in terms of identifying the links to body fluid, nutrients and the need to make the location in which it is placed intuitive to the form user. The Panel determined it is not appropriate for this form.

Pressure Ulcers. Dr. Krugman presented a set of revised questions that address both the comments and the group's desire to present the items in sequence that follows what would occur in practice. (See Attachment C) The suggested set of questions are both revised and reordered. Reordering began with a question about whether a standard skin assessment was done from which issues of skin breakdown would flow. The revision includes, in addition to

Braden scale, query regarding Norton and "other" skin assessment tools though the group recommends that while Braden and Norton would include a score, other would not since there would be no standardization for scores in this response. Suggestion was made to stay with Braden noting that it has become the gold standard. In response to this suggestion, a member of the audience from Department of Defense (DoD) cautioned that both Braden and Norton are used across, and sometimes within, DoD facilities.

Dr. Classen proposed that the discussion of this form be deferred until February 26 to afford the subgroup an opportunity to further refine their recommendations. Also, he asked that they focus on the front end user and bring items related to the event, rather than the institution, to the fore. Dr. Krugman expressed willingness to refine the wording noting that the group would continue to follow a logical sequence and a panelist voiced opinion that the recommendations are solid and will require little additional work.

On February 26, the work of the group was reviewed and acted upon; action is reflected in attached worksheet.

Fall. Dr. Krugman presented a set of questions that included items revised further from what was provided to the Panel in preparation for the meeting. All items previously addressed are included. In the ensuing discussion, AHRQ provided input related to some of its deliberations and the rationale for some items; e.g., 4. and 5, that were recommended for deletion. Also, it was suggested that medication be included as potential contributing to falls as well as modification of medications being included as a prevention strategy. In response to Panel discussion, Dr. Krugman suggested that further discussion of the Fall recommendations be deferred to give the group an opportunity to further review its recommendations. The Panel agreed.

On February 26, the work of the group was reviewed and acted upon; action is reflected in attached worksheet.

RECOMMENDATIONS RELATED TO EVENT-SPECIFIC FORMS ANESTHESIA; DEVICE AND MEDICAL OR SURGICAL SUPPLY; AND SURGICAL AND OTHER INVASIVE PROCEDURE (EXCEPT PERINATAL)

General and overarching issues are presented here. Item specific recommendations are presented in the attached spreadsheets.

Dr. Clarke briefly reviewed the various overarching issues that are included in the **Items for Ongoing Consideration** in the *Cross Cutting Issues* section above that were brought forward by this group.

GENERAL COMMENTS

The Panel reviewed the general comments submitted in response to questions about whether there are topics that should be added to the Common Formats; what would improve usability of the forms within institutions; and overall general comments. The discussion of these is reflected in the worksheet titled "CF General Comments".

In conversation with the audience, the following items were discussed without specific recommendations:

- Handling of incomplete forms – all reporting is voluntary; all input will be accepted. The Panel does project that moving to electronic reporting will increase reporting and eventually reporting will become mandatory at which time reporting will further improve.
- Confidentiality of information vs transparency – a number of pros and cons of each were discussed with the underlying perspective of a balance that would allow the public to have information needed for decisionmaking and providers to have a measure of protection that will encourage reporting to learn and improve.

PROJECTIONS FOR RELEASE OF VERSION 1.0

Dr. Munier stated that the paper form of Version 1.0 is expected to be released in June 2009 with the technical specifications and other support items released in July or August at the latest. Thereafter, annual updates are planned. In the fall of 2009, AHRQ will begin developing the new content for Version 2.0

In addition to addressing the recommendations from the Expert Panel, AHRQ has other items for inclusion in Version 1.0. As previously noted, forms for root cause analysis are expected to be included in Version 2.0.

AHRQ envisions a continuing role for NQF in the process though collecting comments about experience with Versions 1.0 and those that follow and vetting those comments through the Expert Panel. To the extent permitted by federal guidance, AHRQ staff will share Version 1.0 with NQF as soon as possible.

Over the next few months, AHRQ will be addressing the Panel comments as it works to refine the Common Formats into Version 1.0. During this period the Panel will have a quiet period.

The PSOs will be meeting immediately following the AHRQ annual meeting; sessions will be held on September 16 and 18 (in open session) and on September 17 (in focused PSO work). The Expert Panel is invited to attend this meeting in order to develop an appreciation of the PSO work with the Common Formats and reporters as they think forward to the Panel's future work.

PATIENT SAFETY EVENT TAXONOMY

A minor part of the work of the Expert Panel is to continue to follow the progress of the International Classification for Patient Safety (ICPS) in order to make a recommendation to the NQF Board at some appropriate point about the continued endorsement of the PSET. Dr. Sherman is a member of the group that drafted and has been shepherding the ICPS and provided an update of its current status.

PSET has been incorporated into the ICPS and is no longer separately supported. The latest version of the ICPS is available on the website at http://www.who.int/patientsafety/taxonomy/en and has been forwarded to the Panel.

The latest version is being tested in France, Belgium, South Korea, and Canada. Also, IHI and NCC MERP are testing the ICPS harm scale alongside their harm scales. At present the ICPS is in the hands of the World Alliance and the Division of Health Management and

Information, the groups that oversee the ICD. Within the next several months, these groups will develop a knowledge infrastructure ontology which will eventually become part of the ICD. It is envisioned that the ICPS Drafting Group, of which The Joint Commission is a member, will serve as a technical expert panel in this process. Dr. Sherman reiterated that the ICPS continues to be in alignment with the PSET.

Having completed its business, the Expert Panel adjourned at 11:10 a.m., February 26, 2009.

Common Formats
Patient Information Form (PIF)
AHRQ Proposed Revision of Items 12 – 16 and 18

12. Following discovery of the incident, was any intervention attempted in order to "rescue" the patient (i.e., to reverse, reduce, or halt the progression of harm)? CHECK ONE: POA15

a. ☐ Yes

13. What was the apparent result of intervention (rescue)? CHECK ONE: POA31

a. ☐ Prevented harm
b. ☐ Reversed or reduced harm (severity and/or duration); includes halted progression of harm
c. ☐ Seemed to have no effect
d. ☐ Made harm worse
e. ☐ Unknown

14. Which, if any, of the following (unplanned) interventions (rescue) related to the incident were performed? CHECK ALL THAT APPLY: POU18

a. ☐ Transfer; includes transfer to a higher level care area within facility, or transfer to another facility, or hospital admission (from outpatient), etc.
b. ☐ Return to operating room, emergency department, or other procedure area (for any reason)
c. ☐ Tracheostomy
d. ☐ Ventilation
e. ☐ Intubation or conversion to general anesthesia (e.g., following high spinal)
f. ☐ Conversion of laparoscopy to open procedure
g. ☐ Repair of organ
h. ☐ Removal of organ
i. ☐ Amputation
j. ☐ Mechanical circulatory support; includes any such support not present before procedure
k. ☐ Medication therapy; includes administration of antidote, and change in pre-incident dose, route, etc.
l. ☐ Other unplanned intervention: PLEASE SPECIFY _____

c. ☐ No
d. ☐ Unknown

15. Approximately when after discovery of the incident was the (residual) harm assessed? PHP35
CHECK FIRST APPLICABLE CATEGORY:

a. ☐ At about or before 24 hours
b. ☐ After 24 hours but before 3 days
c. ☐ At or later than 3 days after the incident was discovered
d. ☐ Not assessed
e. ☐ Unknown

16. What was the extent of harm to the patient (i.e., extent to which the patient's functional ability is expected to be impaired subsequent to the incident)? CHECK FIRST APPLICABLE CATEGORY: PHP31

a. ☐ Death

b. ☐ Severe permanent harm – severe life-long bodily or psychological injury or disfigurement that interferes significantly with functional ability or quality of life

c. ☐ Permanent harm – life-long bodily or psychological injury or increased susceptibility to disease

d. ☐ Temporary harm – bodily or psychological injury, but likely not permanent

e. ☐ Additional treatment – injury limited to additional intervention during admission or encounter and/or increased length of stay, but no other injury

f. ☐ Emotional distress or inconvenience — mild and transient anxiety, pain or physical discomfort, but without the need for additional treatment other than monitoring (such as by observation; physical examination; laboratory testing, including phlebotomy; and/or imaging studies)

g. ☐ No harm – event reached patient, but no harm evident

h. ☐ Unknown

18. After the discovery of the incident, was the patient or patient's family or guardian notified? CHECK ONE: PAA18

a. ☐ Yes

b. ☐ No

c. ☐ Unknown

Common Formats
Medication & Other Substances Form
Recommended Replacement for Item 3

3. Please identify the product involved in the event:

Brand name (if available)	Generic name	Strength	Dosage form
If the product was an investigational drug, please provide the name/identifier.			
If the product was a compounded preparation, please list all ingredients.			

Draft Pressure Ulcer Question Revisions

Note: Group C concurs with the use of definitions from the National Pressure Ulcer Advisory Panel.

Question Revision	Previous Question Number	Rationale	Public Comments
1. Does the facility use a standardized skin assessment tool for assessment and rating skin integrity? ☐ Yes …… 2. Identify the name of the assessment tool: ☐ No a. Braden b. Norton c. Other:_____	# 7 **NOTE**: most acute care hospitals using Braden or Norton to do **all** skin assessments using their established criteria, not just staging of Pressure Ulcers, so all providers recognize that an evidence-based tool was used *at all times consistently* for benchmarking, from integrity to breakdown. Note: We thought questions #1 and #3 on current form could be captured by new # 10 and final question # 16	We believe it would be important to know up front if they do/do not use an evidence-based assessment and rating tool. Braden is the gold standard. NDNQI also acknowledges Norton. The 'other' could be a default and no score is permitted, but It would be a way of tracking what facilities are using when submitting forms to AHRQ.	Several of the public comments noted there are 'many' tools for skin assessment and rating. I do not believe we can get into the varieties that are used for PU staging, other than the acknowledged standard tools approved by the Expert PU Panel and NDNQI. Note: Lori and I disagree w/the public comment that states a pressure ulcer that worsens during facility stay should not be reported because of complications, pt condition. There is evidence demonstrating that skin integrity can be impacted by nursing care. Skin integrity is considered a valid measure for the quality of nursing care provided. There are always exceptions, but those should be the variance, not skin breakdown the variance.
3. On admission to the facility, was a skin assessment performed using this rating tool? ☐ Yes …… 4. Was the presence of any pressure ulcer or area of deep tissue injury ☐ No noted [alternative question: how many pressure ulcers or areas of deep ☐ Unknown tissue injury were noted on admission? None (if checked move to 7), 1, 2, 3, 4, 5, more] ____ ____ ☐ Yes ……. 5. Identify stage(s): ____ ____ ____ ☐ No 6. Final Stage of Community Acquired ulcer(s) or DTI on discharge:____ ____ ____ ____ ☐ Unstageable	Moved question # 4 and # 5 to #3.	Rationale: sequential responses to questions help user move from general to specific questions. Starting with admission is less confusing that starting with the 'end' of the story. Starting with staging on entry to facility is important, since it distinguishes community acquired versus hospital acquired. User of form	While we know AHRQ is only interested in nosocomial pressure ulcers, we thought questions related to this would help to clarify the difference.

Question Revision	Previous Question Number	Rationale	Public Comments
		may confuse the 2 sources so by this question along with question #	
7. Was the patient determined to be at risk for pressure ulcer/deep tissue injury during the facility stay? ☐ Yes ☐ No ☐ Unknown	Question #6 modified		
8. Was a risk score calculated by a standardized tool? ☐ Yes…… 9. Enter risk score ☐ No ☐ Braden ____ ☐ Unknown ☐ Norton ____ ☐ Other: Score_____ 10. Did this risk score change during patient stay? ☐ No… remained the same ☐ Yes... patient skin condition improved ☐ Yes… patient pressure ulcer(s) worsened during stay	Question #7 …not just Braden noted per above.	NDNQI requests the time frame that the risk assessments were carried out prior to ulcer being detected. This does not seem to be asked here? Eg 0-12 hours, 12-24 hours, 24-48 hours, greater than 48 hours, unknown. Since question was not asked on this PU form, Lori and I substituted #10, new question. **Issue is: were there regular skin assessments conducted?** Hard to capture? There may be more than one pressure ulcer that developed.	A question could be also put in here per public comment: Is it a new pressure ulcer or worsening of an existing one" One Public Comment did not feel a score was necessary. Usually a score is included to determine if the risk rating indicated risk and need to intervene. Public Comment also wondered why we did not ask the question of skin assessments being conducted regularly. Please read our rationale and questioning this time frame also.
11. Were pressure ulcer preventions used to prevent the ulcer or deep tissue injury from either starting or getting worse? ☐ Yes …… 12. Pressure ulcer interventions used: (check all that apply) ☐ No ☐ Pressure Redistribution Surface ☐ Unknown ☐ Repositioning ☐ Nutritional support ☐ Other ☐ Intervention unspecified	New Question	We felt this question was important. NDNQI asks this question, and it seems to be an important aspect of how skin integrity PU's progress/are halted from further deterioration. Often our RNs through diligence can assess skin at the border line of deterioration and prevent it from worsening.	A Public Comment mentioned that other contributing factors could be a secondary question here, such as albumin, vasopressors, etc. We considered this but thought it might be too complicated to capture. The preventions were more important to capture, and the outcomes.
13. Did any pressure ulcer appear to be related to the use of a device, appliance or specific patient positional situation?	#10	Same question, but we did not think all types of	This raises the question of

Question Revision	Previous Question Number	Rationale	Public Comments
☐ Yes…… 14. ☐ Tube placement (eg endo, NG, GT, trach, other) ☐ No ☐ Ortho appliance (cast, splint, other) ☐ Unknown ☐ Urinary/fecal catheter ☐ Positioning during interoperative procedure		tubes needed to be asked individually. We added interoperative since long and complex procedures on a nutritionally deprived patient can result in skin breakdown from OR positioning.	whether or not there should be an additional question on location of pressure ulcer or DTI. Several Public Comments mentioned this.
15. During facility stay, did patient develop a secondary morbidity determined by the facility to be the result of the presence of a pressure ulcer or deep tissue injury? ☐ Yes _____ ☐ No ☐ Unknown	#12	We thought #12 and #13 could be combined, since if they did develop secondary morbidity, we would **only** be interested in this if it related to a pressure ulcer or deep tissue injury.	
16. Identify the total number of ulcers at the time of discharge:_____(Includes community acquired on admission) Total Number of **Facility acquired** ulcers = _____ **Number of Facility acquired Ulcers Staged/Unstageable: (These numbers identified in this section should match the total number of <u>facility acquired</u> ulcers)** Numbers of Stage I _____ Numbers of Stage II _____ Numbers of Stage III _____ Numbers of Stage IV _____ Number of Unstageable/Deep Tissue Injury _____	New Question	We thought it would be important to capture total number of ulcers, and then facility acquired, since some facilities would not just report one ulcer, but may report several at the same time. The number of total numbers could then be compared to the number on admission.	NDNQI captures this in their PU data.