NATIONAL QUALITY FORUM

CONFERENCE CALL FOR COMMON FORMATS EXPERT PANEL GROUP B

August 25, 2011

Group B Members Present: John Clarke, MD (group lead); Scott MacLean (HIT advisor); William Munier, MD, MBA (liaison member)

Other Panel Members Present: David C. Classen, MD, MS (co-chair); Henry C.L. Johnson, Jr., MD, MPH (co-chair)

NQF Staff Present: Melinda Murphy, RN, MS; Lindsey Tighe, MS; Jessica Weber, MPH

Others Present: Amy Helwig, Peter Goldschmidt, Sue Terrillion, Ira Yanowitz; AHRQ representatives

PURPOSE
The purpose of this meeting was for the group to consider and make recommendations on comments received about Common Formats reporting forms for the Skilled Nursing Facility (SNF) Beta and Hospital Version 1.1:

- Device or Supply Event Reporting Form,
- Surgery or Anesthesia Event Reporting Form.

Comments to be considered were those received through the National Quality Forum (NQF) Common Formats commenting tool as of July 12, 2011, which included 15 comments on the SNF Beta forms and 6 on the Hospital Versions 1.1 forms.

WELCOME AND INTRODUCTIONS
Dr. Clarke welcomed the Group B members and thanked them for their participation on the call. Ms. Murphy oriented the group to the documents provided for their review.

DISCUSSION AND RECOMMENDATIONS
Dr. Clarke introduced the topic areas to be discussed. Comments and recommendations related to all individual items discussed are included on the attached spreadsheet.

NQF MEMBER COMMENT
No comments were offered.

NEXT STEPS
Group B requested that the comments and responses be reviewed by Debra Bakerjian, due to her nursing home expertise. Ms. Murphy stated that the meeting minutes and comment table would be sent to Group B for review and comment as soon as possible. It will then be sent to the entire Expert Panel for discussion. The next Expert Panel is scheduled to meet via conference call on Friday, September 9, 2011 at 10:00am ET.

Common Formats Expert Panel
Action Taken on Comments Triaged to Panel
Skilled Nursing Facilities

			Action			
Common Formats ED & (form) #	Device Event Description Item Title	NQF Member or Public Comment	To AHRQ	Group B Action Date	Expert Panel Action Date	Discussion & Recommendations
1.1.1.2 (5.b.)	Medical equipment (e.g., walker, hearing aid)	do you want to include an example such as "urinary catheter used as a rectal or feeding tube"		8/25/2011		**Discussion**: The group determined it best not include devices being used as other than as intended in part to avoid having such practices appear to be acceptable. **Recommendation**: No change.
1.2.1 (1.c.)	Device failure or use error	if the event relates to a contracted service, like dialysis, how would Question 3, items a – f be answered? Only the contractor would know if a workaround, mis-programming, data entry error or inappropriate substitution or use of the device occurred.		8/25/2011		**Discussion**: For this and other comments about events related to contracted services, the group took the position that: 1) the nursing home remains responsible for the outcomes to patients; 2) nursing homes can/should include in contracts requirements that the contractor be part of the quality assurance efforts related to their services/devices; and 3) it is incumbent on the nursing home to develop and maintain positive relationships with contractors so they are aware that quality control is ongoing and any problems are brought to their attention and are appropriately addressed . **Recommendation**: No change.
1.2.1.2.3 (3.c.)	Mis-setting, mis-programming, or otherwise misusing a device, including an HIT device	Tracking system will require level of detail most likely not currently in place. Cost prohibitive?		8/25/2011		**Discussion**: The comment was taken to refer to end user applications rather than technical elements of devices. Nursing homes should be able, and expected, to track such events including those related to HIT. **Recommendation**: No change.
4.1 (Q.5)	Descriptive Information	Q5 appears to refer only to events instead of also including unsafe conditions. More clarity would be helpful, especially given that similar question on hospital form applies to both		8/25/2011		**Discussion:** AHRQ staff noted that the question could be stated more clearly and has taken steps to make the change. **Recommendation:** Group B supports the AHRQ change.

		categories.				
4.1.1.2	Not removed	Does it matter whether implantable device was "not removed" because it was left in the patient or because it was not yet implanted at the time of the event? Hospital form includes a question that allows for this distinction		8/25/2011		**Discussion**: Implantable devices are expected to be placed and removed in hospital thus the form does not need this option. **Recommendation**: No change.
4.1.3.1.2 (20.b.)	Registration/ appointment scheduling system	...nursing facilities do not use, in daily practices		8/25/2011		**Discussion**: Nursing facilities do need to use scheduling and appointment systems of some type for appointments both inside and outside the nursing home. **Recommendation**: No change.
4.1.2.2 (19.b.)	Automated dispensing system	The majority of SNFs/NFs do not use 4.1.3.2 Automated Dispensing Systems and if they do, these systems are owned and stocked by an independent pharmacy. Considering this, the follow sections need to be eliminated or modified: HIT Devise-Related Events (4.3.2.1, 4.3.2.2.1, 4.3.2.2.2, 4.3.2.2.3, and 4.3.2.2.4), Ergonomics (4.3.2.6.1 – 4.3.2.9), and Questions 19. 20, 21, 23, 24, and 25. …if they do, these systems are owned and stocked by an independent pharmacy.		8/25/2011		**Discussion**: The group discussed the fact that some nursing homes do have automated dispensing systems and that the number will continue to grow thus should be captured. They also noted that ownership of the devices are not germane to the need for reporting based on the nursing home responsibility for the patient and the need to include contractor services in relevant quality control/assurance efforts. **Recommendation**: No change.
4.1.3.3.1 (21.a.)	CPOE system	many facilities do not use		8/25/2011		Discussion and recommendation related to automated dispensing systems applies to CPOE.
4.1.3.3.4 21.d.)	Clinical decision support system	nursing facilities do not use, in daily practices		8/25/2011		Discussion and recommendation related to automated dispensing systems applies to clinical decision support systems.

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4.3.1 (Q.4)	Reuse of a device intended for single use	Q4 (to which this event description relates) refers specifically to incidents. However, this may be missed, as there are no instructions -- as is typically the format -- saying that this should not be answered for misses or unsafe conditions.		8/25/2011		**Discussion**: The commenter's point was appreciated; however, the group was not sure that change is needed. **Recommendation**: Request AHRQ review the question in terms of value of expanding or changing the questions and change only if it is determined that doing such would help capture the desired types of events.
4.3.2.6 (22.f.)	Ergonomics, including human/ device interface issue	Trip/Fall over device or electric cord a big problem		8/25/2011		**Discussion**: This is a common problem and should be acknowledged in an appropriate place. Falls would be captured on the fall form. **Recommendation**: In Question 13 on the SNF Fall form, include falls as a result of tripping on device cords/tubes among the examples to cue users that such should be captured.
4.3.2.9 (22.i.)	Unexpected software design issue…	This section at a lower priority in Nursing Home than other sections. Consider not introducing it until you gage how well the system can accommodate the other sections. FORM OVERLOAD WILL PARADOXICALLY HURT THE QUALITY OF CARE. Nurses will nurse the chart not the resident.		8/25/2011		**Discussion**: The group continues to be sensitive to the need for capturing the essential minimum detail on the reporting forms. However, this single response option was not seen as an element that would discourage completion of the form. **Recommendation**: No change at this time.
4.3.2.9 (22.i.)	Unexpected software design issue…	I am concerned with the collection detail needed for this event. While monitoring for mechanical failure of equipment is a priority, the level of detail expected with these measures will be cost=prohibitive for long term care industry to sustain		8/25/2011		See above.
General Comments		Make the Common Format more specific to the SNF/NF setting –		8/25/2011		The issues raised in this comment have been addressed earlier. See earlier comments and recommendations.

		•Identify in the format devices, supplies and HIT commonly used in nursing facilities. •Identify the SNF/NF responsibilities with regard to reporting device, supply and HIT events that are related to events by contractors who own and/or manage, and use the equipment to provide the service. .The Common Format is long and contains elements that are not common or used in the SNF/NF setting. .There are devices, supplies, and HIT used in nursing facilities that are owned and/or operated by a contract service. Laboratory, x-ray and dialysis testing and services fall into this category. Some facilities use contracted rehabilitation staff as well. Given this, and when reporting a device, supply or HIT failure, the Common Format falls short in identifying who is responsible for reporting the event. For example, if the event relates to a contracted service, like dialysis, how would Question 3, items a – f be answered? Only the contractor would know if a workaround, mis-programming, data entry error or inappropriate substitution or use of the device occurred.				
		The Common Format for		8/25/2011		**Discussion**: In addition to discussion with

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		Device, Supply and HIT needs more analysis. AHCA will be happy to work with format developers in modifying the format to be more relevant to the nursing care setting. There are currently no plans or funding opportunities for nursing home adoption of HIT to fully integrated electronic health information, and as a result system integration cannot be accomplished in the short-term.				AHCA, AHRQ has been contacted by a University of California San Francisco representative with long-term care/nursing home expertise with whom they will meet to further inform their work. The group acknowledges the heavy reporting requirements of nursing homes, the concern that they have not had the support to acquire infrastructure that would facilitate some of the data collection and reporting envisioned and the concern that the addition of the common formats adds to their workload as well as the need to support local systems. However, the group views this voluntary reporting as an opportunity to address and fix problems locally and nationally.

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Hospitals

			Action			
Common Formats ED & (form) #	Device Event Description Item Title	NQF Member or Public Comment	To AHRQ	Group B Action Date	Expert Panel Action Date	Discussion & Recommendations
1.2.1.1 (6.a.)	Device Failure	How do 1.2.1.1.4 and 1.2.1.1.3 add anything since the event will be labeled as a near miss or unsafe condition, respectively? Also, I'm not clear on the distinction between 1.2.1.1.1 and 1.2.1.1.2. For example, let's say an implanted defibrillator stops working. The failure itself was silent, but the patient dies from an untreated arrhythmia. How important is to distinguish that from an implanted defibrillator that goes crazy and shocks the person into vfib? In short, just noting a device failure or defect seems sufficient to capture all the useful information here		8/25/2011		**Discussion:** The commenter makes a good point. The detail regarding type of failure can be captured in the narrative of the report. **Recommendation**: No change at this time. Reconsider after data from use is available and expect that narrative options allow for capture of unusual device failures/defects.
1.2.1.2 (6.b.)	Operator Error	How do you distinguish these three - 1.2.1.2, 1.2.1.2.1, 1.2.1.2.3? For example, isn't force-fitting or defeating a fail-safe (1.2.1.2.1) misusing the device (1.2.1.2.3)? The terminology overlaps too much. If you want to make a distinction (and I'm not sure exactly what you're trying to isolate with each question), these need to be worded		8/25/2011		Discussion: Sometimes the intent or what one is trying to do that result in error is not known; e.g., intentional override to overcome bad engineering in the product vs misbehavior. The response options may not provide the clarity that will ultimately be desired. However, the group decided it was too soon to make changes sans use information. Recommendation: No change at this time. Reconsider after data from use is available

		differently.				
4.3 (9)	Reuse of a device intended for single use…	You may want to consider "failure to maintain a device in accordance with manufacturer's recommendations which could include required calibration, balancing, ground checks, filter / battery changes etc. . I see this as more a failure of their preventive maintenance program as opposed to something just becoming broken		8/25/2011		**Discussion**: The group noted that if such a failure were discovered absent an incident, it would be considered an unsafe condition and if an incident had occurred, this would become a contributing factor which likely would become known during an RCA. In either circumstance, inclusion in the module at this time was considered adding an unnecessary level of detail. **Recommendation:** No change at this time.

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			Action			
Common Formats ED & (form) #	Surg-Anes Event Description Item Title	NQF Member or Public Comment	To AHRQ	Group B Action Date	Expert Panel Action Date	Discussion & Recommendations
4.1.3.3 (5.c)	After procedure started (incision) but before procedure ended (closure	Note that the definition for procedure end used in NQF's serious reportable events is being changed. It is better to use the NQF definitions rather than these (4.1.3.2 and 4.1.3.3) … the proposed definition was: "Surgery ends after all incisions or procedural access routes have been closed in their entirety, device(s) such as probes or instruments have been removed, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded and the patient has been taken from the operating/procedure room." So 4.1.3.3 would be "after an incisions or procedural access routes have been started but before all incisions or procedural access routes have been closed in their entirety and device(s) such as probes or instruments have been removed"		8/25/2011		**Discussion**: The surgery-related SREs are designed to capture "wrong" surgeries – patient, site procedure while the Common Formats capture a wider range of surgery related events. However, uniformity/consistency in definitions is desirable. **Recommendation**: Request that AHRQ review the definitions in light of the comment to determine if there are changes that should be made and report back to the Expert Panel about its determinations.
4.1.3.5 (5.e.)	After procedure ended, but before patient left operating	Same comment here as at 4.1.3.3. Perhaps this can be worded differently to avoid confusion. The part of the proposed NQF definition that		8/25/2011		See above.

	room or other procedure area	most closely tracks what you are trying to capture here is "all incisions or procedural access routes have been closed in their entirety and device(s) such as probes or instruments have been removed" but before patient left operating room or other procedure area.				
4.1.8 (11)	Medical or surgical specialty of the provider (or team)…	it's very helpful to know the general type of the procedure (from the ICD 9 codes), but not very important to know the specialty of the provider/team. … we learn more from knowing that retained objects are more common in hysterectomies than in spinal cases than we do from knowing about procedures (in general) performed by OB's vs orthopedic surgeons. By knowing the type of procedure, you can develop more useful guidance for providers on potential risk points with certain procedures.		8/25/2011		**Discussion**: This matter was previously addressed by Group B and the Expert Panel **Recommendation**: No change at this time.