NATIONAL QUALITY FORUM

COMMON FORMATS EXPERT PANEL IN-PERSON MEETING

August 1-2, 2011

Expert Panel Members Present: David Classen, MD, MS (Co-Chair); Henry Johnson, MD, MPH (Co-Chair); Debra Bakerjian, PhD, RN , FNP; Matthew Grissinger, RPh, MS; Helen Lau, RN, MHROD, BSN; Shannon Phillips, MD, MPH; Nancy Ridley, MS; Heather Sherman, PhD; William Munier, MD, MBA (liaison member)

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

Others Present: Amy Helwig, Peter Goldschmidt, Susan 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:

- HERF
- PIF
- SIR
- Fall
- HAI
- Medications
- Perinatal
- Pressure Ulcers
- General Comments

The Expert Panel's list of Parking Lot Issues was also reviewed. Comments to be considered were those received through the National Quality Forum (NQF) Common Formats commenting tool as of July 5, 2011.

WELCOME AND INTRODUCTIONS

Drs. Classen and Johnson welcomed the Expert Panel members and thanked them for their participation. Those present introduced themselves.

Dr. Bakerjian oriented the group to the nuances of patient care in a Skilled Nursing Facility (SNF) and Nursing Facility (NF) environment. Dr. Bakerjian noted the following in particular about SNF/NFs:

- SNF Residents are covered by Medicare Part A and require more complex care than NF patients (24 hour care)
- SNF residents' average length of stay is 14 days
- NF residents are long stay residents whose daily rate is not covered by Medicare
- The Resident Assessment Instruction /Minimum Data Set (RAI/MDS) manual provides guidance from the federal level for minimum care requirements
- Dr. Bakerjian noted that the Common Formats should align with terms and reporting requirements from RAI/MDS wherever possible

DISCUSSION AND RECOMMENDATIONS

Subgroups A, C and D met and discussed the comments triaged to their groups, making preliminary recommendations. In doing so, each group had consultation from Dr. Bakerjian and other available panel members. The entire Expert Panel then convened to review the comments and preliminary

recommendations of the groups, review the general comments, and finalize recommendations. Comments and recommendations related to all individual items discussed are included on the attached spreadsheets.

NQF MEMBER COMMENT
No comments were offered.

FUTURE WORK FOR COMMON FORMATS
Group B will meet by teleconference during August and bring its recommendations to the full panel at its September meeting. Dr. Helwig stated that the Venous Thromboembolism (VTE) module for Common Formats was in its final stage of review with the AHRQ work group. AHRQ expects to release the module with a Federal Register in September at which time NQF will post the module for a 30-day Member and public comment period.

The updated Nursing Home and Hospital Versions of Common Formats, reflecting Expert Panel input is expected to be released in mid-2012. Prior to the release, AHRQ plans to fund a task order to look at the current AHRQ Harm Scale and revise it based on feedback. Usability testing and inter-rater reliability will also be tested; this may take approximately one year.

NEXT STEPS
The Expert Panel will review and approve the recommendations at its regularly scheduled conference call on Friday, September 9, 2011 at 10:00am ET.

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Common Formats Expert Panel
Action Taken on Comments Triaged to Panel
HERF/PIF/SIR
Skilled Nursing Facilities (SNF) and Hospitals, v.1.1

			Action			
Common Formats ED & (form) #	Device Event Description Item Title	NQF Member or Public Comment	To AHRQ	Group A Action Date	Expert Panel Action Date	Discussion & Recommendations
		SNF				
1.0 (HERF Q.6.c. includes HIT)	Type of Event	Compared to the hospital form, there are no questions for (1) whether HIT was implicated in the event and (2) whether it was an NQF SRE. This information is still important to have about the event. In particular, several of the serious reportable events clearly apply to NH residents.		7/21/11	All group recommendations addressed on 8/2/11	**Discussion**: AHRQ plans to add NQF SREs to SIR after appeals are addressed. Questions related to HIT will be added to the hospital HERF form. The fact they are not included now is a function of timing of the development and testing of the HIT component. Recommendation: No change needed.
1.1.3 (HERF Q.1)	Unsafe Condition	May be the same as a near miss - could either double report or under report		7/21		**Discussion**: SNF staff will not have same skill/knowledge as hospitals' staff. "Incident" will resonate in terms of incident reports; near miss and unsafe condition will not be recognized. AHRQ reports a separate SNF Users and Quick Guide is/will be available. **Recommendation:** Add a few classic examples to the 1.b and 1.c. response options and/or include links to Users' and Quick Guide to educate SNF staff.
1.2 (HERF Q.6)	A patient safety concern is identified as one or more of the following categories	This question is overly complicated. The asterisks (*) and plus (+) symbol descriptions are lost in the question instructions. Recommend placing those items beneath question text.		7/21		**Discussion:** The mix of regular and bold face type, symbols, and alpha ordering makes the response options a bit confusing. While it is understood that the electronic form will overcome these concerns, the paper forms would benefit from additional clarification in the instructions. Users Guide does

						speak to this. **Recommendation**: AHRQ should consider reordering the response options, grouping either in columns by relevance to event type or some other schema to make paper forms more clear. Also, in combination, rethink the instruction following the question to improve clarity.
1.2.1 (HERF Q.6.a.)	Abuse or neglect	not all concerns related to possible neglect are filed on incident reports. May not capture true volume.		7/21		**Discussion**: Response option 6.a. was included in the SNF beta version with the expectation that abuse or neglect might be more relevant in facilities with long stays. AHRQ staff appreciates the comment and would like a specific recommendation on this. The group noted that abuse or neglect is well understood in NF and that this and other potential criminal events will most often be addressed through personnel action rather than event reporting. AHRQ will capture the information through the SREs. **Recommendation:** Remove the response option.
1.2.3 (HERF Q.6.c.)	Device or Supply, including HIT	Need to define HIT as an incident		7/21		**Discussion**: HIT will not be recognized as an event in nursing homes and will require education on this point. **Group A would like Group B to address this issue** as it considers HIT during the discussion of the Device/HIT form. Is the definition on the specific Device/HIT form sufficiently clear to allow SNF personnel to identify an HIT related incident?
1.2.4	Elopement	Unsafe wandering should be		7/21		**Discussion**: Unsafe wandering can be

(HERF Q.6.d.)		considered a safety concern				viewed as wandering in unsafe areas (e.g., stairwells) and moving about without appropriate assistive devices. The group agrees that it is important to capture, that it can be captured in the "Other" response category as well as in Q.4 & Q.5 narratives as well as SIR. **Recommendation**: Add example(s) to response option 6.i. "Other" to suggest types of wandering that might be included. This might be done using a link to the Users' and Quick Guide to educate SNF staff. (Same as the suggestion for Unsafe condition above). Beyond that, evaluate frequency of occurrence once reports begin to be made and make any additional adjustments based on that data.
1.2.6 (HERF Q.6.f.)	Healthcare-associated infection	Need to define. Is any infection in a nursing home resident considered "healthcare associated". People get sick and that should not be construed as a negative incident.		7/21		**Discussion**: The group noted that HAI is defined on the HAI event description (ED) and form. Members also noted that some, but not all of the terms used on the forms, are included in the glossary and suggested a few options for improvement. These included, adding all defined terms to the glossary; this could be done by a) integrating into the current list or by development of "chapters", one for terms not used on the ED/forms and one for terms included on the ED/forms; b) including the term in the glossary and referring the user to the relevant ED/form for the definition. SNFs likely will not be familiar with all terms and would benefit from simple explanation with reference to full

						definition if definitions are not included in all relevant locations. Group A recognizes that first time users will have a learning curve vis a vis such things. Once in electronic form, links to such things as definitions will resolve this concern. **Recommendation**: With respect to definitions on paper documents generally, standardize the placement for consistency. **Group A would like Group D to address the specific comment/Group A suggestions.**
1.2.7 (HERF Q.6.g.)	Medication or Other Substance	Medication incidents might be its own category. Medication incidents can include wrong medication, administration, reconciliation.		7/21		**Discussion:** Since there is a form and event description that captures the information, the group believes it possible that the commenter had not reviewed those event-specific documents prior to commenting. **Recommendation**: No change.
1.2.8 (HERF Q.6.h.)	Pressure Ulcer	if tracking via incident reporting system - will not collect all data. will require our company to modify incident reporting system		7/21		**Discussion**: The concern is noted. Nursing homes track pressure ulcers (PU) through a QA program and assess PUs weekly. AHRQ staff noted that they have discussed with CMS and others the desirability of having a single system (Quality and Safety) to which reports could be made from which relevant information could be pulled or routed to other systems, which require the information. A group member noted that the PU Common Formats and SRE should be reconciled. AHRQ staff advised this has been done. **Recommendation**: No change specific to the comment.

1.2.9 (HERF Q.6.i.)	Other	Resident Self Injurious Behavior should be considered for Inclusion. Resident to Resident Behavior should be considered for Inclusion. Significant Contracture should be considered for Inclusion (loss of previous range). Significant Unplanned Weight Loss should be considered for Inclusion.		7/21		**Discussion**: The group agrees that injury to self or others are safety events; however, while contracture and weight loss are important concerns they are quality issues rather than safety. **Recommendation**: Consider including injury to self or others as examples of 6.i. "Other". Beyond that, reevaluate need for further change once the form is in use and data to indicate prevalence is available.
1.3 (SIR pending)	An event meeting NQF definition of SRE	Relationship to federal regulatory required reporting of reportable event or stand-alone?		7/21		**Discussion**: The group requested additional detail. Request has gone to the commenter. If the Commenter's issue is whether reporting to this system (PSO) suffices for regulatory reporting requirements, it does not. This system is voluntary and confidential. NQF staff note: Additional detail requested. No response to date; if received, will provide to the Panel and to AHRQ. Absent the detail, Panel cannot address.
2.1.1(HERF Q.2.)	Date the event was discovered	It may be more helpful to move Q12 (report date) up next to this question (event discovery date), or reference the two together to help ensure that these dates do not get confused with each other.		7/21		**Discussion**: The group briefly discussed the comment. Also, see below. **Recommendation**: No change.
2.1.2 (HERF Q.3.)	Time the event was discovered	The "unknown" category creates a problem when doing an investigation. If the time of the actual event is unclear then the time the Staff/Charge		7/21		**Discussion**: Event Discovery date/time is not necessarily the same as the Event Occurrence date/time. AHRQ staff noted that the guide for use has been improved and should be helpful.

		Nurse was made aware of the event is the time that should be recorded.				**Recommendation**: No change
2.2.2 (SIR 2.b.)	Toileting, bathing, showering, room	These are very different types of areas. Suggest separating into resident bathroom (including toilet, bath, or shower), common bath/shower area, common toilet area.		7/21		**Discussion**: While these are different areas, they have some important commonalities related to risks; i.e., water, position change with greater opportunity for slip / fall. In most nursing homes, residents share bathrooms (could be two to four sharing) and have common shower areas. **Recommendation**: Apart from considering including examples to clarify, no change.
2.2.3 (SIR 2.c.)	Indoor activity area (e.g., TV room, gym)	A SNF does not normally have a "gym". "Gym" would be confused with a PT treatment area. If you are trying to describe a "common" area where residents may socialize or meditate, perhaps state-- Indoor activity area such as TV room, activity room, library, game room. Keep in mind that SNFs have "multi-purpose" common areas that are used for dining as well as group events/meetings/entertainment.		7/21		**Discussion:** The group agrees that SNFs do not usually have gyms but do have common activity rooms. Also, they do not typically have a pharmacy but do have medication rooms and their treatment/ procedure room uses are quite different from the physical therapy area. They also discussed the potential confusion associated with the use of multiple “other” responses; this issue is relevant for both the SNF and hospital Common Formats. Within use of “other”, the issue of what circumstance is to be captured was raised. Also, the group noted that hospitals have both pharmacies and medication rooms. **Recommendations**: 1) SIR 2.c., remove “gym” and add “activity room” as an example; 2) SIR 2.e., replace “Pharmacy” with “Medication Room”; 3) SIR 2.g., remove “physical therapy” as

						an example and add it as a separate response option; 4) reconcile/clarify use of multiple "others" in the response options for both SNF and the hospital version and in so doing, consider circumstances such as event occurrence vs discovery, events precipitating in products, broader use of "outside area", and consider providing examples of "other area within…" and "outside area" specific to each setting to assist the user to appropriately document the information. In addressing recommendation 4) consider the differences between SNF and hospital and within SNF also consider the potential for error by contractors.
2.2.5 (SIR 2.e.)	Pharmacy	if meant to reflect a location, our facilities do not have internal pharmacies		7/21		See discussion at 2.2.3 comment above.
2.2.7 (SIR 2.g.)	Treatment or procedure room (e.g., physical therapy)	recommend therapy space be a dedicated location as events do specifically occur in this area and would want to track therapy versus nursing supervised space		7/21		See discussion at 2.2.3 comment above.
2.2.8 (SIR 2.h.)	Other area within the facility	Add hallway, stairs		7/21		**Discussion**: The suggested additions are examples of 2.h. "Other area within the facility" that as well as in Q.5 narrative. **Recommendation:** Add example(s) to response option 2.h. to suggest the suggested additions as areas that might be included. This might be done using a link to the Users' and Quick Guide to

						educate SNF staff. Beyond that, evaluate frequency of occurrence once reports begin to be made and make any additional adjustments based on that data.
2.3 (SIR Q.9)	Factors contributing to the event known at the time of the initial report	The response category of "equipment/device" does not appear in the SNF beta version, but it does in hospital v1.1. I understand that this information is being captured in a different format in the new device (with HIT) form. Still, it is a concern that such an important response category is missing from the overall "contributing factors" question. Plus, it will be difficult to compare events across settings if these response category differences persist in the hospital (v2.0?) and SNF (v1.0?) versions available at the same time.		7/21		**Discussion**: Form content in this regard will be reconciled in the next version of the hospital and SNF sets. The Device form, which includes HIT, collects greater detail and would be completed for an event that involved HIT. **Recommendation**: No change
2.3 (SIR Q.9)	Factors contributing to the event known at the time of the initial report	Vendor related Factors should be considered for Inclusion (many LTC Pharmacies, supplies, staff are provided through contracts to the facilities). Facility Systems status should be considered for Inclusion -some Facilities do not have capacity for their systems 24/7.		8/1		**Discussion**: Information could be added to the Users' Guide to clarify where vendor related factors might be captured. **Recommendation**: No change at this time. Reevaluate after form is in use and data is available.
2.3 (SIR Q.9)	Factors contributing to	Why is equipment/ device not considered a contributing factor		7/21		**Discussion**: Questions related to HIT (1.0 and 2.3) will be added to the HERF

	the event known at the time of the initial report	as in acute care?				and SIR forms. The fact they are not included now is a function of timing of the development and testing of the HIT component. **Recommendation:** None
2.3.3 (HERF Q.17; SIR Q.3; SIR 9.c., 9.d.)	Staff qualifications, competence (e.g. qualifications, experience)	To answer this question would take an in-depth analysis of the situation. For example, for a fall in a patient room - there is no staff competence. from 2.3.3 through 2.3.6 need to be completed after an analysis of the event, not at the reporting stage.		8/1		**Discussion**: Issues of staff competence likely to be determined later in process; i.e., RCA. If it is known, it can be recorded at Q.9.c. **Recommendation**: No change at this time.
2.3.3 (HERF Q.17; SIR Q.3; SIR 9.c., 9.d.)	Staff qualifications, competence (e.g. qualifications, experience)	Unless there are standardized competency criteria, this data collection point may not be valid		8/1		See discussion and recommendation above.
2.3.8 (SIR Q.9.h.)	Policies and procedures, includes clinical protocols: Clarity of policies	The clarity of the policy would be established after the investigation of the event, not to report the event. The first part of this section is for event reporting. The 2.3 section is for analysis of the event. I think they should be reported separately		8/1		**Discussion**: The issue is similar to those immediately above and would be recorded if known. **Recommendation**: No change at this time.
2.3.13 (SIR Q.9.m.)	Communication: Among staff or team members	Will this include SBAR		8/1		**Discussion**: SBAR (situation, background, assessment, recommendation) is included. **Recommendation**: No change.
2.3.15 (SIR Q.9.o.)	Human factors: Fatigue	Inappropriate data collection item		8/1		**Discussion**: This and the following two comments relate to terms in common use in hospital settings. Staff in

						SNF/NF have not yet begun use and will have a learning curve. **Recommendations**: 1) Check Users' Guide to determine if the human factors items are clear and improve if needed to facilitate SNF/NF staff education; 2) reevaluate with data after in use.
2.3.16 (SIR Q.9.p.)	Human factors: Stress	Inappropriate data collection item – how measured?		8/1		See discussion and comment related to Q.9.o. immediately above
2.3.17 (SIR Q.9.q.)	Human factors: Inattention	Inappropriate data collection item – how measured?		8/1		See discussion and comment related to Q.9.o. above.
2.5 (SIR Q.10)	Preventability of incident	Somewhat subjective. Some root cause analysis could get to real issue but many are not trained well enough in this area to get to that point		8/1		**Discussion**: The issue is valid for SNF/NF. Education may be needed to address a learning need. **Recommendation**: Review guidance to educate and ensure there is an explanation of why this is included.
3.0 (HERF Q.7 – 11)	Patient Information	Asks for Patient information, but Q7 asks for a specific name while Q11 asks about the number the incident reached. Which name do you pick? Should also mention/remind user to fill out PIF if they are filling in this section (one for each person represented in Q11?) Note: here it asks for gender, and DOB. The PIF form does not ask for both of those.		8/1		**Discussion**: The comment is likely related to unfamiliarity with the forms, their relationships and the intent to capture, in addition to name of each person to whom event occurred on separate forms, the number of individuals affected by an incident. **Recommendation:** No change at this time.
3.0 (PIF)	Patient Information	Noticed that "principal diagnosis" is not on this form (it is for hospital patients). Seems that this information could still be relevant to understanding the circumstances of a patient		8/1	8/2/2011 & 9/9/2011	**Discussion**: The majority (70 – 90 percent) of NF patients will not have a "principal diagnosis" recorded per se. Expert Panel discussion added the suggestion that "relevant diagnostic information" would more likely resonate

		safety event.				with NF staff **Recommendation**: Provide guidance to users, in an appropriate location, that relevant diagnostic information related to the resident's medical condition should be recorded in narrative sections of HERF or SIR.
3.1(HERF Q.7 – 11)	Identifying information about patient(s)/ resident(s) affected	How will this and other PHI information be protected outside the facility?		8/1		**Discussion:** Introductory information on the form addresses this matter. **Recommendation**: No change.
3.1.4 (HERF Q.7 – 10; PIF Q.1)	Age range	On the HERF Q7 asks for a name, gender, and DOB, but this form does not. Are these necessary on the HERF, or are they needed here? How are different patients affected by the same event kept separate or linked to appropriate patient information on HERF?		7/21	8/2	**Discussion**: AHRQ staff noted that this will be reconciled. This will become a non-issue once the forms are available in electronic format **Recommendation**: No change.
3.1.4.4 (PIF Q.1.d.)	Adult (18-64 years)	Why is it adequate for this category to cover a nearly 50-year age span? There is huge variation in this group, based on age. Most other response categories represent 10 year age groups. Why not allow a more detailed age-related analysis of "adults"?		7/21, 8/1	8/2	**Discussion**: The need for any of the age groupings was questioned based on the fact that date of birth is collected and from this information groupings of various types could be constructed that might or might not correspond those on the form. Institutions collect and retain name and date of birth, which can then be grouped by age based on analysis desired. AHRQ staff noted that the information is needed for required reporting and that the bands displayed on the form are illustrative and will be auto-populated when the forms are

						automated. AHRQ notes the ranges can be auto-populated at tech spec level. **Recommendation**: Collect date of birth without querying for age groupings. If age groupings are needed on paper forms, consider using deciles rather that the current groupings.
3.2.1 (PIF Q.6.)	Degree of Harm – AHRQ Harm Scale	Occasionally difficult to determine until some time in future		8/1	8/2	**Discussion**: Since the SIR is the summary document for event reporting, it is likely that it will be finalized by an RN. To the extent that reporters are competent/ comfortable in responding to the question, they should be encouraged to do so. **Recommendation**: No change at this time. Reevaluate after have date from use.
3.4 (PIF Q.8)	Notification of patient/resident, family or guardian	Notification to attending physician should also be considered		8/1	8/2	**Discussion**: Notification of the attending physician is considered to be the professional standard of practice. **Recommendation**: No change.
4.2 (HERF Q.12; SIR Q.1.)	Report date	the wording says "What is the date of this report". Is Q1 asking for today's date (our assumption) or the report date? The wording should match the HERF form if it is asking for the same information. If not, they should use different wording for "report."		8/1	8/2	**Discussion**: AHRQ staff noted they agree with the comment and are addressing the issue by changing the stem of the question. **Recommendation**: The group supports the AHRQ action.
4.3 (HERF Q.13 – 17)	Reporter information	The common format should clearly show the individual reporting the episode that the event pertains to their practicing setting of care and		8/1	8/2	**Discussion**: There is no intent to either blame the reporter or to limit potential reporting. The recommended change could do so. **Recommendation**: No change.

		their patient population.				
4.3.5	Are there elements missing from this event description? If so, please list the elements.	want to include as healthcare professional: direct care workers? administrator/manager? speech therapist/PT/OT? Dietary? housekeeping, maintenance?		8/1	8/2	**Discussion**: The group agreed that until the form is in use and prevalence of disciplines is determined, those not listed can be captured in the "other" categories. **Recommendation**: No change at this time.
4.3.5	Are there elements missing from this event description? If so, please list the elements.	A Conclusion Statement should be considered as a separate Element as a review of all data and impressions must be conducted by the supervising person so a conclusion regarding the occurrence of Abuse, Neglect, Mistreatment or Misappropriation of Property can be determined and documented to meet regulatory compliance and Resident safety goals.		8/1	8/2	**Discussion**: Drawing a conclusion at the time an event is first reported may be premature. **Recommendation**: No change at this time.
	Comments on reporting form	I commend the authors of the form, it is well done. Unfortunately I predict that mandatory use of this form will require so much time that the licensed staff will have significantly less time to care for residents and the overall effect will be negative. The form should initially be introduced as background/ teaching information only to allow familiarization. It should then be extensively piloted monitoring for the indirect		8/1	8/2	**Discussion**: The sentiment is appreciated. Many of the questions have been piloted in settings prior to their inclusion in the Common Formats. **Recommendation**: No change at this time.

		displacement of other important tasks the overloaded staff must perform.				
	General comments on the event description	The purpose of the HERF, PIF, and SIR report is not clear as well as how it relates to the specific Common Formats for Pressure Ulcer, Fall, HAI, Medication and Other Substance, and Device, Supply and HIT. Is this report intended to be an aggregate report for reporting Serious Reportable Events? The HERF, PIF and SIR report includes categories associated with abuse and neglect. It is not clear how this will be defined and determined. States define abuse and neglect differently and we are not aware of any one definition that can be applied nationally		8/1	8/2	**Discussion**: The Users' Guide speaks to the use and relationship of the forms. Issue related to abuse and neglect addressed in separate comment above related to 1.2.1 (HERF Q.6.a.) **Recommendation**: No change.

		Hospitals v.1.1				
2.3.1 (SIR Q.9.a)	Environment: culture of Safety, management	"Culture of safety" is a very broad term and means somewhat different things to different people. It also overlaps significantly with other factors in this list. The strongest overlap is with 2.3.16-2.3.18. And "Management" is similarly problematic. How is that compared to 2.3.5 and 2.3.6? And wouldn't 2.3.7 and 2.3.8		8/1	8/2	**Discussion:** Include as a parking lot issue to be watched and evaluated with use.

		be a measure of management?				

Common Formats Expert Panel
Action Taken on Comments Triaged to Panel
FALL

			Action			
Common Formats ED & (form) #	Event Description Item Title	NQF Member or Public Comment	To AHRQ	Group C Action Date	Expert Panel Action Date	Discussion & Recommendations
		SNF				
1.0 (introductory information)	Definition of Event	Use the RAI Manual definition for fall so that a recognized definition is used and to ensure all falls considerations pertaining to nursing facility patients are captured and examined.		All comments addressed on 8/1/11	All comments addressed on 8/2/11	**Recommendation:** Modify examples of falls to align with the RAI Manual.
1.0 (introductory information	Definition of Event	The definition does not coincide with CMS definition of falls which includes near fall "a resident lost his/her balance if not for staff intervention" for example.				**Discussion:** This would qualify as an assisted fall which would be reported. **Recommendation:** Include a question capturing who assisted the fall.
1.1 (introductory information)	A fall is a sudden, unintended, uncontrolled, downward displacement of a patient's/resident's body to the ground or other object (e.g., sink, table, surrounding furniture).	Section 1.1 Definition of Event for Fall is not totally consistent with the MDS 3.0 RAI Manual, Section J 1700 definition of fall. The Common Format definition does not include the following items contained in the RAI Manual: 1. If the nursing home resident is found on the floor/ground (not witnessed), this is considered a fall. 2. A falls is any fall no matter whether it occurred at home,				**Discussion:** This is captured under the observation of a fall (staff, visitor/family, another patient or resident, unknown). **Recommendation:** No change.

		while in the community, in the hospital or nursing facility. Many nursing home patients leave the facility for outings, specialist appointment, specialized medical tests, etc. Given this, the fall definition falls short with regards to scope of provider accountability and State required reporting. 3. Falls are not a result from an external force like a push. 4. An intercepted fall, when the patient would have fallen if he/she had not been caught by self or intercepted by another person is considered a fall.				
1.1.1.1 (Q.1.a.; Q.3)	A fall not known to be assisted	Along with unassisted fall, need to know if fall was witnessed or unwitnessed. If witnessed, by whom:_____				See above. More important to capture who assisted the fall.
1.1.2.1 (Potential new question)	A fall resulting from a purposeful action or violent blow	Unwitnessed fall, it is often impossible to determine if fall was purposeful for a resident with dementia. Example: "I was crawling on floor to get the baby chick from over there". In his mind he had a purpose, in reality there was no purpose. How would you code this type of event?				**Discussion:** No recommendation necessary. The example cited is not necessarily something to be captured nationally.
1.1.2.2	Near fall - loss of	Eliminate 1.1.2.2 from the				**Discussion:** Near fall is not

(introductory information)	balance that does not result in a fall	Exclusion list since the Near Fall definition is contrary to the RAI Manual definition of fall.				considered a fall. **Recommendation:** No recommendation necessary.
1.1.2.2 (introductory information)	Near fall - loss of balance that does not result in a fall	This is very difficult to determine what is near fall and what is the "usual gait pattern" i.e. resident usually walks on toes at a rapid pace and leaning very far forward over walker. This looks unstable and like every step he is going to fall, but he doesn't. Would like to see this category removed.				**Discussion:** The definition excludes near falls. Near falls caused by unsafe conditions would be captured on the HERF; however, if the patient did not actually fall, the fall module would not be filled out. No recommendation necessary.
1.2 (Q.9)	Processes of Care: None specified	There is no assessment information regarding whether the staff member took a blood pressure (to assess orthostasis), conducted a neuro assessment, and check their blood sugar if they have diabetes, for example.				**Discussion:** This is captured in whether a fall risk assessment took place pre-fall; post-fall this would be captured in an RCA. Common elements that arise through reporting will be added to future versions of Common Formats. No recommendation necessary.
1.3 (Q.5)	Patient/resident Outcomes: Fall, including any physical injury sustained (most severe)	Section 1.3 Patient/Resident Outcomes: notes any physical injury sustained (most severe) which includes dislocation, fracture, intracranial injury, laceration requiring sutures and skin tear/avulsion or significant bruising. This “most severe” list is inconsistent with the RAI				**Discussion:** Definitions are consistent. No recommendation necessary.

		which includes bone fracture, joint dislocation, and closed head injuries with altered consciousness, and subdural hematoma.				
1.3 (Q.5)	Patient/resident Outcomes: Fall, including any physical injury sustained (most severe)	I would put this at the end of the document to fit better chronologically. Falls in line with what happened, how did it happen, and what was the outcome. Also, there is no assessment information regarding the outcome. The first page states whether the patient sustained an injury but does not assess the appropriateness of treatment. Collecting process, rather than outcome information, is crucial for quality improvement efforts which I believe it the intent of this reporting scheme				**Recommendation:** Unnecessary to move the question. The form is not designed to lead reporters through an investigative process. Treatment is out of scope of the Common Formats.
1.3 (Q.4; Q. 5)	Patient/resident Outcomes: Fall, including any physical injury sustained (most severe)	Combine question 4 & 5 by adding a line to #5. No apparent injury sustained.				No recommendation necessary.
1.3.1 (Q.5.a.)	Dislocation	This is a diagnosis that an LPN is not qualified to make. Could question be about ROM WNL without pain?				**Discussion:** The form is filled out retrospectively; as such, the diagnosis would be available. Diagnostics would need to be performed regardless of the qualifications of the clinician present.

						Recommendation: Include instructions clarifying the above information. Recommend no change to the form.
1.3.2 (Q.5.b.)	Fracture	Unable to determine at the nursing home, usually requires x-ray and physician consult. would prefer to have question regarding ROM WNL, shortening or rotation of limb and question about pain				See above.
1.3.3 (Q.1.c.)	Intracranial injury	Again, too clinical when doctor is not onsite. Question should read: Did resident hit his/her head? If yes, is bruising/ hematoma/swelling, pain at impact site present?				See above.
2.0 (Potential addition to Q.2; Q.6)	Scope of Reporting: Patient safety concerns for the "Fall" category include only incidents that occur in a skilled nursing facility.	Section 2.0...only references incidents that occur in a skilled nursing facility. The RAI Manual assesses for falls in and outside of the nursing facility. A SNF/NF nursing home patient can participate in outings, doctor visits, etc. that take the patient outside of the facility. It is not clear under the Common Format, if the fall occurring during the time away from the facility is considered under the Patient Safety Reporting effort.				**Discussion:** This would be captured under the HERF and SIR (on the grounds, outside the facility or other). **Recommendation:** No change.
3.1	Patient/resident	Type of assessment: tool,				**Recommendation:** Consider for

(Q.7)	assessed for risk for fall prior to the fall	clinical judgment or falls history				future data collection-it was noted that there is not strong information about the validity of the assessment tools in use. History of falls is captured in risk assessment section.
3.1 (Q.8)	Patient/resident assessed for risk for fall prior to the fall	Q8 about whether patient was at risk for fall is worded slightly differently than hospital form ("increased" was added to SNF form). How does that affect the comparability of this information about events across settings?				**Discussion:** AHRQ does not plan to map between settings with Common Formats. This is worded differently as the majority of residents (due to age) will already be at an already increased risk of fall; as such, looking for risk factors that put them at an even greater risk of fall. **Recommendation:** No change.
3.1 (Q.7)	Patient/resident assessed for risk for fall prior to the fall	Fall risk assessments are preformed at the time of admission and quarterly. The answer to this question is always going to be yes. Why ask it?				AHRQ will be changing all instances of the word “performed” to “documented.”
3.1.1 (Q.8)	At increased risk for fall	Don’t really see the advantage of asking this question. What information is gained?				**Discussion:** Question is asked to see whether there are patterns in the people who are falling. For example, if they were identified to be at risk, were there prevention measures in place? **Recommendation:** No change.
3.2 (Q.10)	Fall prevention protocols or other interventions that were	Also add: exercise program, hip/joint protectors, Vitamin D/Calcium levels				AHRQ will add exercise program to the list of answer options.

	instituted prior to the fall	assessed/replaced.				The remaining interventions will prevent injury, not falls. (With respect to floor mats-need to change the language to reflect non-slip floor mats)
3.2 (Q.10.a.; Q. 10.h.)	Fall prevention protocols or other interventions that were instituted prior to the fall	There is no information on possible cause (even if unknown), location, footwear during the fall, and if the resident was sitting in a wheelchair (which accounts for 30% of all falls).				**Recommendation:** Rewrite Q.13 to "Which, if any, of the following physical factors contributed to the fall?" Include footwear, wheelchair/walker, and physical devices. AHRQ to consider wording of question and answer options.
3.2.2 (Q.10.b.)	Bed or chair alarm	Delete 3.2.2 and Protocol/Intervention Question 10 (b) from the format since bed and chair alarms can be used as restraints and can contribute to fall risk.				**Discussion:** Common Formats are designed to capture what is in practice; the aim is not to change behavior or practice. Inclusion of alarms is not an endorsement of their use; the intent is to capture data. **Recommendation:** AHRQ include a statement that these questions are not necessarily indicative of best practices, just current use/current practices. The list needs to evolve as current practice evolves.
3.2.3 (Q.10.c.)	Bed in low position	Section 3.2.3... lists the use of bed and chair alarms. Nursing home improvement goals focus on the elimination of restraints. While a bed or chair alarm is not considered a restraint, it may be used in that capacity if the alarm restricts				See above.

		independent movement – meaning the alarm singles the nurse who instructs the patient he/she cannot get out of the bed or the chair without first calling for nurse assistance and regardless if the patient is a fall risk or not. *The nursing home Interpretive Guidance for F 222 Restraints identifies that restraints should not be used for "convenience." Convenience is defined as any action taken by the facility to control a resident's behavior or manage a resident's behavior with a lesser amount of effort by the facility and not in the resident's best interest. Unless the patient has a recent history of falls or his/her condition and treatment put the patient at risk for falling, the use of bed and chair alarms are not in the patient's best interest. Efforts to restrict movement negatively impact patient strength, balance and respiratory capacity.*				
3.2.4 (Q.10.d.)	Call light/personal items within reach	This is a standard of practice, not an intervention.				**Discussion:** Protocol is encompassing of a standard of practice. **Recommendation:** Reword question to "which of the following were in place and being used…"
3.2.6	Fall alert	Need more clarification as to				AHRQ will remove fall alert from

(Q,10.f.)		how a fall alert is different from an alarm				both hospital and SNF Common Formats, as it is covered more specifically by chair/bed alarm and other data elements. Recommend inclusion of video surveillance as a protocol/intervention in use. This technology is emerging.
3.2.7 (Q.10.g.)	Floor mats	Eliminate 3.2.7 and Question 10 (g) - floor mats as a preventive action since floor mats can be a trip hazard and particularly for individuals who have a shuffling gate.				**Recommendation:** Clarify to "non-slip floor mats."
3.2.8 (Q.10.h. though applies to all response options given the question)	Non-slip footwear	This doesn't say it was actually being used just that they were part of the plan of care. *There is published research to suggest that even if these are care planned, they are still not being used. Or they may be used but not appropriately. For example- what if the bed alarm wasn't functional at the time of the fall- the nurse could say the alarm was in use or care planned but this reporting system doesn't prompt him/her to state whether it was appropriately working. Same goes for footwear or any of these other interventions.*				**Recommendation:** Change the wording of the question to "which of the following were in place and being used?"
3.2.8 (Q.10.h.)	Non-slip footwear	This is a standard of care not an intervention. It is				See above.

		expected that a resident will use non-slip footwear.				
3.2.10 (Q.10.j.)	Patient/resident situated close to the nurses' station	Eliminate 3.2.10 and Question 10 (j) pertaining to Preventive Action of changing the patient's room and moving it closer to nurses station. *Patient/resident situated close to the nurses' station, suggests that changing the patient room to afford closer nurse surveillance is a good preventive action. However, this is not easily accomplished in the nursing facility setting. Nursing facilities have rules and regulations on certified bed/units. And resident rights related to bed changes. In addition, emerging nursing facility models do not have traditional nursing stations where a nurse is always stationed to provide individualized patient surveillance.*				**Recommendation:** Clarify that the patient be closer to staff location (activity room, nursing station, etc.) Intent is whether the patient is close to the staff location (in a wheelchair), not to have their room moved.
3.2.11 (Q.10.k)	Physical/occupational therapy	Remove 3.2.11 and Question 10 (k), the provision of Physical Therapy from the Preventive Actions since this recommendation is not one easily accommodated in nursing facilities. *Section 3.2.11 suggests that the use of therapy is a good preventive action. While we agree with the*				**Recommendation:** Broaden this provision to "exercise or mobility programs" and note that this includes occupational therapy, physical therapy, other less formal programs, etc.

		potential benefits of providing physical therapy following a fall, nursing facilities are limited by the Medicare caps for Part B and if the patient is not a candidate for rehabilitation services. These situations place the burden of expense on the patient; many of whom may not have the independent resources for therapy services.				
3.2.12 (Q.10.l.)	Siderails	Eliminate 3.2.12 from Preventive Actions and eliminate Question 10 (l) since siderails are considered restraints in nursing facilities.				AHRQ has removed this.
4.1.1 (Q.6)	Patient/resident activity immediately prior to the fall	4.1.1.10 Recent acute illness; 4.1.1.11 Raised bed rails				**Recommendation:** Include of response capturing patients "navigating" bed rails. AHRQ to consider wording of response. Bed rails are often the cause of falls, not a prevention mechanism. This should also be considered for the hospital CF. Recent acute illness to be captured with "Risk Factors" section, Q.9.
4.1.1 (Q.6)	Patient/resident activity immediately prior to the fall	Compared to the hospital form, this question on SNF does not include response categories for a diagnostic or treatment procedure preceding the fall. *This information would be equally useful to understanding falls in*				**Recommendation:** Address with "Risk Factors" category, Q.9. Common Formats will not be used for mapping across settings.

		the NH context. Also, different response categories makes it harder to compare event characteristics across settings.				
4.1.1.2 (Q.6.b.)	Ambulating with assistance and/or with an assistive device or medical equipment	If this includes a fall from a wheelchair (either while being transported [with or without staff present] or from a stationary position) it should be indicated.				Captured with other physical devices contributing to the fall.
4.1.1.8 (Q.6.h.)	Toileting	Continence status				**Recommendation:** Address with other "Risk Factors," Q.9.
4.1.2 (Q.3)	Observation of fall	Add 4.1.2.4 Self-reported				**Recommendation:** Capture this information in both SNF and Hospital forms. AHRQ to consider where to capture this and its relevance in hospitals.
4.2 (Q.9)	Risk Factors	4.2.4 Lack of Sleep Short sleep duration and poor sleep efficiency were associated with increased risk of falls in women. *A study based on a cohort of 2,978 community-dwelling women (mean age 84 years) followed for 1 year found that sleep ≤ 5 hours per night was associated with increased risk of ≥ 2 falls compared to sleep 7-8 hours Reference - Arch Intern Med 2008 Sep 8; 168(16):1768 full-text Sleep apnea may be associated with increased risk of falls based on cohort of 1,952 persons aged 60-97 years followed for 10 years. Snoring was reported in*				**Recommendation:** AHRQ consider categorizing common physiological factors (orthostatic hypotension, hypoglycemia, metabolics, gait abnormalities, in addition to the other citations listed). Recommend inclusion in the next version of SNF Common Formats.

		69% and witnessed episode of sleep apnea reported in 8.3%. Reference - J Am Geriatr Soc 2007 Jul; 55(7):1149 4.2.5 Chronic Pain Chronic pain associated with increased risk of falls in elderly *based on population-based cohort study of 749 adults ≥ 70 years old with recorded falls on monthly survey for 18 months. 1,029 falls reported age-adjusted rate of falls per person-year 1.18 with ≥ 2 sites of joint pain. The more severe or disabling pain at baseline associated with higher fall rates. Reference - JAMA 2009 Nov 25;302(20):2214 4.2.6* Malnutrition may be associated with increased risk of frail mechanical falls in elderly *based on a cross-sectional study convenience sample of 126 patients ≥ 60 years old (median age 74 years) admitted to emergency department in Australia. Subjects were categorized as nonfallers, frail mechanical fallers or active mechanical fallers based on self-reported falls in previous 6 months. All patients given Malnutrition Screening Tool and Subjective Global Assessment tool indicated a prevalence of malnutrition of 15%. Malnutrition was associated*				

		with higher risk of being a frail mechanical faller. Compared to nonfaller active mechanical faller, malnourished patients had increased risk of self-reported falls over 6 months. Reference - Emerg Med Australas 2009 Oct; 21(5):386 4.2.7 Postprandial hypotension was associated with increased risk of falls *in a prospective cohort study of 499 nursing home residents ≥ 62 years old. Subjects were followed for 29 months with falls occurring in 199 persons (40%). Independent risk factors for falls included decrease in postprandial systolic blood pressure and prior falls. Reference - J Am Geriatr Soc 1997 Sep;45(9):1051 4.2.8* Depression *was associated with history of recurrent falls based on prospective cohort study 134 persons ≥ 65 years old were asked about history of falls in previous year and evaluated on 30-point Geriatric Depression Scale (GDS). Reference - J Am Geriatr Soc*				
4.2.3 (Q.9.c.)	Sensory impairment (vision, hearing, balance, etc.)	4.2.3.1 Loss of Binocular Vision Binocular visual-field loss *may increase the risk of falls in elderly women based on prospective cohort study of 4,071 community-dwelling white women ≥ 70 years old. 643 patients (16%)*				See above.

		experienced frequent falls (defined as ≥ 2 falls/year) within 1 year after eye exam result of severe binocular field loss. Reference - J Am Geriatr Soc 2007 Mar; 55(3):357 4.2.3.2 Multifocal Glasses *Multifocal glasses were associated with falls. A prospective cohort study 156 community-dwelling adults aged 63-90 years were evaluated. 87 persons (55.8%) regularly wore multifocal (bifocal, trifocal or progressive lens) glasses and were more likely to fall than nonmultifocal glasses wearers. The falls were due to a trip when outside of home or when walking up or down stairs Reference - J Am Geriatr Soc 2002 Nov;50(11):1760 4.2.4 Acute Confusion*				
4.3 (Q.13)	Contributing Factors	Also add facility-level issues: uneven floor, construction				AHRQ captures this in environmental contributing factors on the SIR.
4.3 (Q.11.a.; Q.13)	Contributing Factors	Additions are needed to the Contributing Factors section of the Common Format to make it more pertinent to the nursing facility setting. Not listed, but common contributing factors for falls in SNFs/NFs, are environmental condition like wet floors, adverse drug reactions, medication side-effects, dehydration,				These will be captured as discussed in a previous recommendation of other risk factors, Q.9.

		infections and delirium. *These medical issues are listed in the RAI Manual, J1800 planning for Care.*				
4.3.1 (Q.11)	Patient/resident on medication known to increase risk of fall and medication considered to have contributed to fall	Will nursing staff be provided with a list? Otherwise, they may not know this information off hand.				**Discussion:** There are existing sources in the nursing home; nurses working there are fairly expert in the risk of falls, including medications that increase risk of falls. It would be impractical to try to provide a list. No recommendation necessary.
4.3.1 (Q.11)	Patient/resident on medication known to increase risk of fall and medication considered to have contributed to fall	This is a difficult question. Almost any medication can cause a side effect that leads to a fall. Many of these medications are needed so the benefit > risk. You may want to include a list of medications that are related to falls, so the reporter would know exactly what medication to review.				See above.
4.3.1 (Q.12.a.)	Patient/resident on medication known to increase risk of fall and medication considered to have contributed to fall	Will there be a list OR perhaps the list will be too long to be helpful. I don't know the best answer.				See above.
4.3.1 (Q.12.a.)	Patient/resident on medication known to increase risk of fall and medication considered to have contributed to fall	Is there a recognized and standard listing of these meds or med classes?				See above.
4.3.2	Use of restraints,	You should reword this to				This has been addressed in previous

(Q.13)	bedrails, or other physical device considered to have contributed to fall.	say something like "was the bed rail or restraint or wheelchair IN USE at the time of the fall".				comments.
	Are there elements missing from this event description? If so, please list the elements	Members of the interdisciplinary team involved in addressing the assessment, prevention and intervention surrounding falls. *Reference: von Renteln-Kruse, W., Krause, T. (2007). Incidence of in-hospital falls in geriatric patients before and after the introduction of an interdisciplinary team-based fall-prevention. JAGS, 55(12): 2068-2074.*				**Discussion:** It was noted that a number of research studies have shown improvement in the number of falls with the use of a falls specific interdisciplinary team as an intervention. **Recommendation:** Consider in future versions of Common Formats. AHRQ to research.
	Comments on reporting form	Where do you enter vitals- hypotension or orthostatic hypotension is a CAUSE of falls. Also- delirium- is a CAUSE of falls- where is that entered?				Addressed in previous comments (Q.9, Risk Factors).
	General comments on the event description	I would add a question: Was the patient sent to the ED?				The PIF addresses this.
		Hospitals v.1.1				
4.1.1.9 (Q.6.i.;Q.6.k.)	Undergoing a diagnostic or therapeutic procedure	We have seen multiple cases of falls off of operating room tables and radiology tables which I assume would go here. Also falls in PT.				This would be captured on the falls form.
4.3. (Q.11; Q.6)	Contributing Factors: Patient on medication known to increase risk of fall and medication considered to have	While medications are a key to falls the timing of the meds such as Lasix prior to bedtime can be critical . Other contributing factors				**Discussion:** Timing of meds is captured in an RCA; not necessary for reporting. No recommendation necessary.

	contributed to fall.	may be ambulating in TEDS, ambulating in gowns that are too long for short statured patients.				

Common Formats Expert Panel
Action Taken on Comments Triaged to Panel
HEALTHCARE ASSOCIATED INFECTION

			Action			
Common Formats ED & (form) #	Event Description Item Title	NQF Member or Public Comment	To AHRQ	Group D Action Date	Expert Panel Action Date	Discussion & Recommendations
		SNF				
1.0 (introductory information)	Definition of Event	Modify or find a definition of HAI that applies to other settings of care; not just acute care. Modify the Common Format for specific use by SNFs/NFs that allow event criteria and definitions to similar to those found in the RAI Manual. *The Common Format definition of HAI is taken from the CDC/National Health Safety Network (NHSN) July 2010 Surveillance for Acute Care. As previously mentioned, to eliminate confusion and to motivate providers in settings other than acute care to participate in the Patient Safety Reporting effort, it is important to clearly indicate the settings where the HAI Common Format applies. As currently written, it can be construed that* *1) the HAI format only applies to acute care, or* *2) the acute care HAI format is inappropriate being used for other settings.*		All comments addressed on 8/1/11	All group recommendations addressed on 8/2/11	**Discussion**: The definition has been reconciled with NHSN. Based on the fact that some 25 states mandate use of NHSN at present and others are expected to be required to do so, the NHSN definitions and requirements are expected to result in adjustments to the RAI manual. **Recommendation**: No change.

		Considering issues with the definition of fever, the latter assumption appears to be valid and that the format has not adequately considered the elderly population.				
1.2.6 (HERF Q.6.f.)	Healthcare-associated infection	Need to define. Is any infection in a nursing home resident considered "healthcare associated". People get sick and that should not be construed as a negative incident.				Group A asked that Group D address the comment and review Group A suggestions below. *Group A noted that HAI is defined on the HAI event description (ED) and form. Members also noted that some, but not all of the terms used on the forms, are included in the glossary and suggested a few options for improvement. These included, adding all defined terms to the glossary; this could be done by a) integrating into the current list or by development of "chapters", one for terms not used on the ED/forms and one for terms included on the ED/forms; b) including the term in the glossary and referring the user to the relevant ED/form for the definition. SNFs likely will not be familiar with all terms and would benefit from simple explanation with reference to full definition if definitions are not included in all relevant locations. Group A recognizes that first time users will have a learning curve vis a vis such things. Once in electronic form, links to such things as definitions will resolve this concern.* *Recommendation: With respect to definitions on paper documents generally, standardize the placement for consistency.* **Discussion**: Issues identified in the comment and Group A discussion have been addressed elsewhere. See discussion and recommendations throughout including recommendation to include definitions on the SNF form and to ensure alignment with NHSN.
1.1 (Q.1)	A healthcare-associated	Need to clarify "no evidence" that it was				**Discussion**: NHSN definition should be used.

	infection (HAI) is ….	incubating at time of admission - i.e. 72 hours - I see 48 hours in exclusion section but I believe CDC definition looks at 72.				**Recommendation**: Ensure consistency with NHSN.
1.1.1 (Q.1 - Q.6)	Inclusions	Do reporters need a table at the top with NHSN definitions, as on hospital form v1.1? *I would think SNFs and their staff may be less familiar than hospital staff with these conventions.* Also, was it intentional to no longer ask the qualifications of the person who identified the HAI?				**Discussion**: Inclusion of definitions and web location for additional information as is done with the hospital set would be useful to SNF/NF reporters. There is an expectation that there will be individuals who meet infection control practitioner guidelines available in/to nursing homes to help ensure accurate categorization and reporting. **Recommendation:** No change
1.1.1.3.1 (Q.3; Q.21; Q.22; Q.24)	Symptomatic urinary tract infection	Add purulent urethral discharge around the catheter as a criteria for diagnosis				**Discussion**: Presence of purulent discharge does not necessarily mean UTI. The NHSN definitions won't include this. **Recommendation**: No change
1.1.1.3.2 (Q.3.a.; Q.21; Q.22; Q.24)	Asymptomatic bacteremic urinary tract infection	Say locally asymptomatic				**Recommendation**: No need for change.
1.1.1.4 (Q. 2.d.)	Clostridium difficile infection (CDI) - gastrointestinal system infection	Incubation period may be up to 3 months				**Discussion**: Incubation period may be longer. This would not affect the question. **Recommendation**: No change.
1.1.1.5 (Q. 2.e.)	Type of infection that developed during admission, not further validated	Is it intentional that there is not a response category for SSIs? These would seem plausible since PIF Q5 about rescue actions				**Discussion**: While surgery is not done in SNF/NF, infection could develop after admission from acute care. To determine attribution, the date of surgery and of the event

		includes surgical intervention.				would be important. **Recommendation**: Ensure alignment with current NHSN requirements for nursing homes.
1.2.1.2.1.1 (Q.15.a; Q.21.a.; Q.22.a.; Q.24.a.)	Fever (>38 degrees C core)	Common Format Section 1.2.1 Process of Care, defines fever as >38º C core. …recommend that the format use the RAI Manual definition and replaces the format definition of >38 C core at sections 1.2.1.2.1.1, 1.2.2.1.1.1, and at Questions 15 (a), 21 (a), 22 (a), and 24 (a).*According to the AMDA, Clinical Practice Guideline (CPG), Common Infections in the Long Term Car Setting, the criteria for defining fever is: 1. Increase in temperature ≥2º F (1.1º C) from baseline. 2. Two or more measurements of oral temperature ≥99º F (37.2º C) or rectal temperature ≥99.5º F (37.5º C). 3. Single measurement of temperature ≥100º F (37.8º C). The AMDA CPG goes on to explain that 1/3 of elderly patients with acute infections may present without a robust febrile response since basal temperature in frail elderly may be lower than 98.6º F (37º C). Thus, the absent of*				**Discussion:** The concept to which a part of the comment relates is that of neurodeficits. However, as noted earlier, 25 states currently require NHSN and the others are expected to join its use. **Recommendation**: Ensure alignment with NHSN.

		fever, as defined as 38º C core, is not adequate to rule out fever. The RAI Manual, Section J 1550 Fever, defines fever as 2.4º F higher than baseline and the patient's baseline needs to be established prior to the Assessment Reference Date (ARD). Considering the definitional issues, more work is needed to modify the Common Format for use by SNFs/NFs and PSOs.				
1.2.1.2.3 (Q.14)	Common skin contaminant (e.g. S. epidermidis) is cultured from two or more blood cultures drawn within two days of each other	Specify that this constitutes a BSI.				**Discussion**: There was considerable discussion about the number of questions overall and the questions and construction of those questions with respect to blood stream infections. AHRQ staff noted that a number of the questions were included in an effort to deconstruct the complexity of the assessments/determinations required by asking a series of specific component questions determined to be likely to be answered accurately and in ways that allow comparability across reports. The group noted that the placement of the questions would benefit from reorganization. With respect to the specific comment, there is not a similar question in the hospital set and skin contaminant would not result in a report. **Recommendation**: Overall:

						Reorganize the questions so that Q. 7 – 17 fall under Q.2.c. The specific comment: Evaluate question in terms of NHSN requirements and hospital set alignment.
1.2.1.3 (Q.19.b.)	For patients less than or equal to one year of age (on or before first birthday), CLABSI confirmed via clinical signs/symptoms and laboratory	Eliminate criteria for pediatric patients *The Common Format lists considerations for pediatric acquired infections. The pediatric format information is confusing to read and adds unneeded complexity.* Since there are few SNF/NF pediatric patients, we recommend omitting the pediatric elements from the format. These elements include 1.2.1.3, 1.2.2.1, and 1.2.2.3. If needed, consider developing a specific format for pediatric HAIs.				**Discussion**: Since there are pediatric patients in nursing homes, it is appropriate to collect the information. **Recommendation**: 1) Do not eliminate criteria for pediatric patients. 2) Do align hospital and SNF/NF forms and ensure alignment with NHSN. 3) Leverage e-version of the Common Formats to show only the relevant questions as has been discussed by AHRQ.
1.2.2.1 (Q.19.a.)	For patients/ residents greater than one year of age (after first birthday), symptomatic CAUTI with a current indwelling catheter is indicated by both of the following	*The Common Format lists considerations for pediatric acquired infections. The pediatric format information is confusing to read and adds unneeded complexity.* Since there are few SNF/NF pediatric patients, we recommend omitting the pediatric elements from the format. These elements include 1.2.1.3, 1.2.2.1, and 1.2.2.3. If needed, consider developing a				See discussion and recommendation immediately above.

		specific format for pediatric HAIs.				
1.2.2.1; 1.2.1.3; 1.2.2.3 (Q.19.b.;Q.20; Q.21; Q.25)	For patients/ residents greater than one year of age (after first birthday), symptomatic CAUTI with a current indwelling catheter is indicated by both of the following	Not applicable in this environment.				See discussion and recommendation above.
1.2.2.1.1.1 (Q.15.a.; Q.21.a.; Q.22.a.; Q.24.a.)	Fever >38 degrees C core (if patient less than 65 years of age)	*Considering the definitional issues, more work is needed to modify the Common Format for use by SNFs/NFs and PSOs.* … recommend that the format use the RAI Manual definition and replaces the format definition of >38 C core at sections 1.2.1.2.1.1, 1.2.2.1.1.1, and at Questions 15 (a), 21 (a), 22 (a), and 24 (a).				**Discussion**: See earlier discussion regarding use of NHSN across the states. **Recommendation**: Ensure alignment with current NHSN requirements.
1.2.2.1.1.3; 1.2.2.2.1.6 (21.c.; Q.22.c.)	Costovertebral angle pain or tenderness	Add scrotal/prostate swelling tenderness.				**Recommendation**: Align with NHSN requirements.
3.0	Risk Assessments and Preventive Actions: None specified.	[add] Risk assessment immediately known upon admission with a catheter or recently discontinued catheter				**Recommendation**: Align with NHSN requirements.
4.2.1.1 (Q.9)	Type of central line	Why is "tunneled/implanted"				**Discussion:** The documents should align.

		language in event description but not in questionnaire? The lack of this explanation -- and that wording is different than on hospital form -- may prevent comparisons of events across settings.				**Recommendation**: AHRQ will ensure alignment.
4.2.2 (Q.4)	Pneumonia - ventilator status (within 48 hours prior to onset of symptoms)	The difference between wording of this question on SNF form vs. hospital form may prevent comparisons of events across settings.				**Discussion**: As in earlier discussions, wherever appropriate, the two sets should be aligned. **Recommendation:** Ensure appropriate alignment.
4.2.2.1 (Q.4)	Patient/resident on ventilator	Is it intentional that there are not more questions about VAP?				**Discussion**: The level of detail in the hospital set is not needed in the SNF/NF setting. **Recommendation**: No change.
4.3	Contributing Factors: None specified. Are there elements missing from this event description? If so, please list the elements.	Add a Prevention Section that addresses Immunizations. …recommend the format be modified to include this information with particular consideration to immunizations, isolation, cohorting, hand-hygiene, and use of personal protective equipment (PPE).				**Discussion**: The comment is related to outbreaks, which may be more likely to become clear with RCA; however, this issue should be further considered. **Recommendation**: Consider this topic in general discussion by the full panel.
Q.19	Comments on the aggregate report	If this is for the long term care environment, remove references to <1 year of age - not applicable. Definitions or qualifying criteria should in all cases mirror standards defined				See earlier discussion and recommendation.

		by CDC.				
	Comments on reporting form	The form is easy to follow, but has many different infections listed. Consider separate forms for each infection. The person completing the form will know what the infection is and the task will not seem as daunting.				See earlier discussion and recommendation related to reorganization of questions to facilitate responses.
	General comments on the event description	The inclusion of blood stream infections (bacteremia) is important, but I think will give few data. If a patient is suspected of bactermia, they probably will be in the acute hospital.				See earlier discussion and recommendation related to reorganization of questions to facilitate responses. Reevaluate after have data from use.

Common Formats Expert Panel
Action Taken on Comments Triaged to Panel
MEDICATION OR OTHER SUBSTANCE

			Action			
Common Formats ED & (form) #	Event Description Item Title	NQF Member or Public Comment	To AHRQ	Group D Action Date	Expert Panel Action Date	Discussion & Recommendations
		SNF				
1.1.1.1.1 (2.a.)	Prescription or over-the-counter	Should there be further delineation of over the counter and homeopathic		All comments addressed on 8/1/11	All group recommendations addressed on 8/2/11	**Discussion**: Examples of OTC might be useful in the SNF/NF setting without being needed in the hospital setting. **Recommendation**: Consider including "herbal or homeopathic medications " in parentheses after "OTC".
1.1.2 (Q.1.e.; introductory information)	Exclusions	… Consider and address medications, resulting in negative outcomes, given prior the SNF/NF admission but outcomes noted after SNF/NF admission. *While we find the format to be comprehensive, it does need to include consideration of medications prescribed and administered to patients prior to admission to the nursing facility where adverse events resulting from these medication or substance have occurred or been noted after patient admission. It is not clear how these events are to be considered by the nursing facility for PSO reporting.* We recommend adding the following to 1.1.2				**Discussion**: Comment overall focuses on addressing manifestation of events that were present on admission (POA). **Recommendation**: Since this is an issue that can cross the Common Formats topic areas, included this for discussion of general comments.

		Exclusions: •Drug-to-drug interaction as a result of a prescription and/or administration of drugs prior to SNF/NF admission. •Drug-to-food interaction as a result of the administration of a drug and food prior to SNF/NF admission. •Adverse drug reaction from a drug prescribed and administered prior to SNF/NF admission. A related question also needs to be developed like: Which of the following best characterizes the negative drug event resulting from prescribed and administered drugs and substances prior to SNF/NF admission? 1.The drug(s) and/or substance issues were identified on admission. 2.The drug(s) and/or substance issues were identified after continued course of medication. 3.The drug(s) and or substance were prescribed and administered before admission. 4.The drug(s) and or substances was prescribed before admission but administered while a				

		SNF/NF patient.				
1.1.2 (Q.1.a.)	Exclusions	List as exclusion a medication (usually an OTC medication) that is self-administered by the resident (following appropriate confirmation of the resident's ability for this task by the facility)				**Discussion**: This is a risk point that should be captured. **Recommendation**: No change; do not add this as an exclusion.
1.2.9 (8.i.)	Incorrect strength or concentration	Eliminate. I believe this is an uncommon issue.				**Discussion**: This can/should be captured. **Recommendation**: No change
1.2.13 (Q.15)	Medication or substance that is known to be contraindicated…	Need to add drug-gene For examples 2C19 poor metabolizer and Plavix.				**Discussion**: The concern is appreciated but should be further assessed prior to adding it. **Recommendation:** No change at this time. Reassess after have data from use.
4.3	Contributing Factors: None specified. Are there elements missing from this event description? If so, please list the elements.	Add Preventive Actions. ...We recommend that the format be modified to include the medication issues common to SNF/NF care and patients where Preventive Actions will improve outcomes. The MDS 3.0, Section N, Medications, identifies the following medications as those needing assessment for the geriatric population: insulin, antipsychotic, anti-anxiety, antidepressant, hypnotic, anticoagulant, antibiotic and diuretic. *These drugs, while commonly*				**Discussion**: The comment is appreciated; however, the Comment Formats are intended to capture events rather than provide quality improvement preventive action recommendations. The Users' Guide or other educational material could include clarifying information. **Recommendation**: No change.

		prescribed and administered to elderly patients, are known to present health and safety risks, cause negative side-effects and are often found to be the basis of drug-to-drug interactions like the concurrent administration of an antibiotic and anticoagulant. Some Preventive Actions for elderly patients may include: •Monitor patients admitted with a prescription or history of being given antipsychotic medication. •Monitor off-label use of antipsychotic medication. •Monitor INR for patient taking anticoagulants. •Identify and discontinue the use of concurrent administration of anticoagulants and antibiotics. •Daily weights and intake and output (I&O) for patient taking diuretics. •Monitoring blood sugar levels and adjusts insulin level as needed.				
(Q.2.a.;Q.2.c.; Q.17)	General comments on this event description	Modify some terminology to be more consistent with the SNF/NF setting. The Common Formation uses terminology like over-the-counter and investigational drugs. While these are				**Discussion**: See earlier discussion of similar/related comments. **Recommendation:** No change at this time.

		known terms, they are not commonly used in the SNF/NF setting. Nursing facilities do administer over-the-counter drugs like Tylenol but they are considered Stock Drugs – administered by the clinician upon physician orders or from routine orders for specific conditions. Nursing facility Standing Orders are limited to pneumonia and influenza vaccines. We are not aware of any investigational drugs being used for elderly patients.				
	General comments on this event description	Very detailed. I do not think that it would take long to complete for one incident. I like the form.				No action required

		Hospitals v.1.1				
1.2.10 (Q.8.j.)	Incorrect preparation, including inappropriate cutting of tablets, …	It would be really useful to distinguish between incorrect compounding in the pharmacy and incorrect compounding in the patient care area. We don't have really good statistics on this.				**Discussion**: This can be captured on the SIR. **Recommendation**: No change.
1.2.13 (Q.15)	Medication or substance that is known to be contraindicated for the patient	Need to add drug-gene. For examples 2C19 poor metabolizer and Plavix.				See earlier discussion and recommendation on this matter.

4.2	Risk Factors: None specified	The literature has rather interesting discussions of risk factors, including juxtaposed storage of look-alike-sound-alike drug products, similarity of labeling and packaging, understaffing, encouraging overtime, encouraging/ permitting avoidance/misuse of medication safety technology, poor lighting, inadequate space/facilities for dose preparation, etc. These should be enumerated and captured as part of this form.				**Discussion**: These are issues that form users may not think about in capturing an event though they should be considered in event analysis during RCA or management review. **Recommendation**: No change at this time. Reevaluate with data from use.

Common Formats Expert Panel
Action Taken on Comments Triaged to Panel
PERINATAL

			Action			
Common Formats ED & (form) #	Event Description Item Title	NQF Member or Public Comment	To AHRQ	Group D Action Date	Expert Panel Action Date	Discussion & Recommendations
		Hospitals v.1.1				
1.1 (Q.2.)	A perinatal event involves an adverse outcome occurring to the mother, fetus(es) or neonate(s)…	AHRQ would like the NQF Panel's opinion on adding a "Neonate" only answer option to Question 2 "Who was affected by the event?". The thinking behind the current version is that the mother (a patient) is always affected, even if just emotionally, when an event affects her neonate. More than one PSO has noted that they would like a "Neonate" only answer option.		8/1/11	8/2/11	**Discussion**: The group agreed that "neonate" only should be added. As part of the overall discussion, they discussed whether "mother and neonate" was an appropriate response option and after considering various examples determined that it too is an appropriate response option. **Recommendation**: Add "Neonate" to the hospital Common Formats Perinatal module Q.2. as an additional response option.

Common Formats Expert Panel
Action Taken on Comments Triaged to Panel
PRESSURE ULCER

			Action			
Common Formats ED & (form) #	Event Description Item Title	NQF Member or Public Comment	To AHRQ	Group C Action Date	Expert Panel Action Date	Discussion & Recommendations
		SNF				
1.0 (Q.1; introductory information)	Definition of Event	Use the RAI Manual definition for pressure ulcer and the stages. These definitions are used every day in nursing facilities, are easily recognizable, and their use will reduce reporting time and nurse burden. *The Common Format pressure ulcer definition contains a brief definition with more information describing the pressure ulcer stages including Unstageable and Suspected Deep Tissue Injury. The definitions start with the NPUAP definition but leaves off the last sentence related to contributing factors.* *•Stage 1 - definition does not use the NPUAP definition but is consistent with the RAI Manual definition. However, the format definition excludes the reference to identifying pressure ulcers in individuals with dark skin.* *•Stage 2 - definition is consistent with NPUAP and the RAI Manual definitions.* *•Stage 3 and Stage 4 - definitions are not NPUAP or RAI Manual definitions.* *•Unstageable - definition is close to the NPUAP definition but not the RAI Manual definition. The format definition again excludes reference to detecting ulcers in patients with dark skin.* *•Unstageable related to deep tissue injury – the first line of the given definition appears to be the same as the NPUAP's definition for Deep Tissue Injury. The source of the*		All comments reviewed 8/1/11	All comments reviewed 8/2/11	**Recommendation:** Harmonize with NPUAP/EPUAP definitions in the next version of SNF Common Formats. Common Formats are currently following MDS 3.0 definitions. Recommend a table be provided demonstrating the relationship between the MDS 3.0 definitions and the NPUAP/EPUAP definitions. It was noted that NPUAP/EPUAP guidelines are considered the standard of care for clinical practice by the RAI Manual. It was also noted that CMS does plan to

		second line is unknown. Considering the above, the Common Format definitions appear to have components taken from different definitions and omit reference, in Stage I and Deep Tissue Injury, to detecting ulcers in patients with dark skin. The Common Format definition also omits from Stage 1 the notation that "a number of contributing factors are also associated with pressure ulcers and the significance of these factors is yet to be elucidated." The format section, Questions on paper…., associated with 1.0 Definition of Event, offers questions to help explain the nature of the ulcer and the severity of the event. It is important to note that many of the listed items are part of MDS 3.0, Section M - Skin Conditions and the questions are already found in the RAI Manual.				evolve to NPUAP/EPUAP definitions.
1.1 (Q.1; introductory information)	A pressure ulcer is localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with sheer and/or friction…	These are different stage definitions/ typology than used for hospitals, yet they are not clearly laid out on the form. Instead the form refers to a CMS website, which has a series of downloads requiring reporter to know in advance which document to find this information in.				**Discussion:** Common Formats won't duplicate MDS information. They are meant to be a reporting form. The event description will have more information than the reporting form. If previous recommendation is followed, there will be no need to refer

						to the CMS website.
1.1 (1.f.)	A pressure ulcer is localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with sheer and/or friction…	Question 1; Answer f should not be there. They are not pressure ulcers.				**Discussion:** This question likely stems from unfamiliarity with the form. Answer F is an exclusion; users will stop using the form if answer F is selected.
1.1.1.1 (Q.1)	A pressure ulcer that advances to stage 3 or 4 or becomes unstageable and that was at stage 1 or stage 2 or was not present on admission	A pressure ulcer that was at stage 1 or 2 or was not present on admission that advances to stage 3 or 4 or becomes unstageable. Also Rephrase the point below.				AHRQ to consider rephrasing.
1.1.2 (introductory information)	Exclusions	Add to Exclusions – A pressure ulcer, any stage, first detected in patients who are in active death				**Discussion:** These patients are not being treated for their pressure ulcers with the exception of keeping the patient comfortable/giving them palliative care. The pressure ulcers may still progress as

						the patient is declining without this being a patient safety event. Concern was raised that patients receiving palliative treatment only for pressure ulcers should also still benefit from prevention interventions and that these events should be reported. **Recommendation:** Exclude patient/resident who is receiving palliative care for a pressure ulcer.
1.1.2 (introductory information; Q.3)	Exclusions	Instructions specifically exclude certain types of ulcers. The description at the top of the page says that to be included it must not be present on admission or it must have worsened. Similar to the HAI form, why not reduce burden on both ends. For instance – the form could read "STOP – you do not need to complete this form" rather than "Stop: This form is complete." Or does AHRQ want to know the amount of Stage 1 or 2 pressure ulcers etc? Also, If the most advanced stage of the pressure ulcer is a stage 4,				AHRQ to look at reporting diabetic foot ulcers in future versions of Common Formats. **Recommendation:** no change to where the "Stop" is in the form-goal is to get information. Recommend

		but it is a Stage 3 at admission, do you really want to exclude it? Currently, the user would stop the form and it would be complete.				capturing information about progression of Stage 3 PU to Stage 4 in this version of Common Formats. There is a major difference in treatment, outcomes, risk, etc. between the two stages.
1.1.2 (introductory information)	Exclusions	Will this include patients who are end-stage or on hospice?				Addressed in a previous comment.
1.1.2 (introductory information)	Exclusions	How will increase in stage due to surgical debridement be captured?				**Recommendation:** Capture whether there was physical debridement associated with progression of the PU stage.
1.1.2.3 (Q.3)	A pressure ulcer that was not present on admission and that does not advance to stage 3 or stage 4, nor become unstageable	Many stage I or II are preventable in the nursing home and may reflect the same system break down that results in stage II and IV. I agree that separating stage I and II from Stage III and IV makes sense but not sure why stage I and II that were acquired in the nursing home were excluded from reporting.				**Discussion:** AHRQ to consider including acquired Stage I or II PU in future versions of Common Formats. Stage I and II were initially excluded due to current reporting requirements of CMS. However, it is important to send

						the message that acquired PU are serious and preventable.
1.3.1.3.3 (2.c.)	Related to suspected deep tissue injury	Prior to admission?				**Discussion:** AHRQ to consider implementation concerns-idea of treating Pressure Ulcers as "episodes of illness," when the PU should be reported, how to capture when it first happened, how it progressed and how it resolved. Recognize that this is problematic for nursing homes, as patients are there for longer periods of time.
1.3.3 (Q.14)	Development of a secondary morbidity (e.g., osteomyelitis or sepsis) attributed to the presence of a pressure ulcer.	This question (Q14) differs from hospital version by not referring to suspected deep tissue injury. The difference in wording may prevent comparisons of events across settings.				**Discussion:** Common Formats are not intended for use in comparisons across settings.
1.3.3 (Q.14)	Development of a secondary morbidity (e.g., osteomyelitis or sepsis) attributed to the presence of a pressure ulcer.	Listing of potential morbidities should be available - and should include pressure-ulcer infection, need for surgical debridement, reconstructive surgery. Pain secondary to the ulcer may be included by some as a secondary morbidity.				**Discussion:** Cited examples are treatments, not secondary morbidities. The PIF asks what intervention or

						treatment was done and includes surgery. **Recommendation:** Include of tunneling and fissure development as a secondary morbidity.
3.1 (Q.4)	Documented skin inspection performed on admission	Required elements of a skin inspection should be defined.				**Discussion:** No recommendation necessary. These are already routinely done.
3.1 (Q.4)	Documented skin inspection performed on admission	This is good data item for pressure ulcers that form in residents shortly after admission but what about residents who have been in facility for some time and are high risk for PU? They need to have frequent skin inspections.				**Discussion:** AHRQ to consider adding a question capturing when the last skin inspection was performed prior to discovery of the PU and by whom.
3.3 (Q.5)	If risk assessment(s) performed	All residents should have a standardized risk assessment performed at admission and periodically thereafter. This both good clinical practice and required for Medicare/Medicaid certification. Also, data suggests that many new pressure ulcers occur in residents with acute changes in status (e.g. they get sick, exacerbation of COPD/CHF) but no new risk assessment is performed and thus no changes in preventative efforts are undertaken.				**Discussion:** AHRQ to consider incorporating content capturing assessment performed upon change of condition.
3.3.1.1	Formal assessment (e.g.,	Would it be helpful to reporters for AHRQ				**Recommendation:**

(Q.6)	Braden, Braden Q (pediatric version), Norton, Waterlow)	to address approach to pediatrics, i.e., when the SNF CFs pertain to infants/children and when they do not. There are a lot of CFs that (in comparison to hospital form) no longer refer to this age group, yet occasionally it appears. Not clear whether this is intentional or not.				Someone with pediatric expertise review the Common Formats for unique issues related to peds (future versions of Common Formats).
3.4 (Q.9)	Pressure ulcer prevention intervention(s) implemented	[add] Moisture, Shearing?				Recommend that skin care practices used to prevent moisture and shearing be captured.
3.4 (Q.9)	Pressure ulcer prevention intervention(s) implemented	What about the basics of skin care, hydration?				**Recommendation:** Hydration can be captured with nutritional support.
3.4 (Q.8; also Q.5; Q.9)	Pressure ulcer prevention intervention(s) implemented	Does not capture changes in any of the three options when the residents risk status for pressure ulcer increased during their stay. A common problem in nursing homes is that the intervention plan and risk assessment done at admission does not change over time as the resident's status changes. It is during these changes in status that the resident develops new pressure ulcers. This data collection would not capture this concept only if the resident had any intervention of pressure relief or repositioning at all. Similarly, repositioning of feet is key to prevent pressure ulcers on heels but one could answer these questions in the affirmative by having plan for turning resident but no plan for repositioning				Addressed in a previous comment.

		their heels.				
4.0 (Potential new question)	Circumstances of Event	[how are the following addressed] • resident insists on a maintaining a certain position for comfort, mobility, or function • upright position required to prevent reflux/regurgitation/aspiration?				**Discussion:** AHRQ will potentially address this in a future version of Common Formats as a contributing factor (incontinence, patient choice on mobilization). This could be considered under resident behavior as a contributing factor.
4.0 (Q.10; Potential new question)	Circumstances of Event	[how are the following addressed] Again, assume a device caused pressure ulcer when most are due to either failure to follow the intervention plan consistently or more often modify the intervention plan when the resident's mobility changes due to a change in their status (e.g. exacerbation of underlying illness such as CHF or they develop an illness such as URI).				Addressed in previous comments.
4.3	Contributing Factors: None specified.	There may be multiple contributing factors based on co-morbid conditions, end of life status				Addressed in a previous comment.
	Are there elements missing from this event description? If so, please list the elements.	Not all pressure ulcers are avoidable/ preventable. There needs to be an assessment that, in the opinion of the reviewer, that there was a high likelihood of development of a pressure ulcer due to the co-morbidities of the patient.				**Discussion:** The SIR captures how preventable the event was.
	Comments on the aggregate report	Would be helpful to have total beds, total admissions stratified by SNF vs. non				**Discussion:** Recommendation to

		SNF to help understand the report. The report only has numerator data. Some type of denominator data will be helpful even if risk adjustment is not possible.				be considered by AHRQ. Noted that this would be difficult given the voluntary nature of reporting. CMS captures this data through quality measurement.
	Comments on reporting form	Dying patients on hospice often develop ulcers as their organs fail; it's the normal dying process. Also, their nutritional status is failing as part of the natural dying process. I am concerned that we- as LTC professionals will feel pressured to 'force feed or force supplements' on the hospice/ dying patient. Where do you comment that the patient is on hospice? Where do you enter other contributing factors? Ulcers are a sign of skin as an organ is failing and the whole patient must be evaluated to optimize healing - not just pressure relief and nutrition. Other factors that must be addressed- moisture, infection (cellulitis and osteomyelitis), sheering, smoking, anemia, meds (steroids or other immunosuppressive meds), poor arterial blood flow, blood sugars >150, and toxic topical treatments-for example wet-to-dry; dansk's solution				Addressed in previous comments.

Common Formats Expert Panel
Action Taken on Comments Triaged to Panel
GENERAL COMMENTS

			Action			
Common Formats ED & (form) #	Event Description Item Title	NQF Member or Public Comment	To AHRQ		Expert Panel Action Date	Discussion & Recommendations
		SNF				
	… Overall, what would improve usability of the common formats in your organization?	*We have identified a number of issues that need to be resolved before the Common Formats can be used effectively in nursing facilities. The identified concerns, if not addressed, will lead to confusion, questionable results and will dissuade providers in engaging in the patient safety effort. More specifically,* the following issues need to be resolved before we can comment on the use or appropriateness of an aggregate report: •It is not clearly stated if both SNFs and NFs are included in the Common Formats. *We are assuming that both patient types are included due to the prevalence of patients who are duel-eligible and reference to Medicaid in the SNF definition.* •Many format definitions are inconsistent with those used in nursing facility regulation. •Event reporting is duplicative of requirements already mandated by insurance and Federal and State regulation and in its current form, adds to			8/2/11	All items have been addressed by previous comments with the exception of use of contracted services. Expert Panel acknowledges that the use of contractors is taking place but maintains that the healthcare setting is responsible for the event/the reporting of the event.

		system complexity and provider burden. Reporting simplification is needed. •*For the most part, nursing facility care is tertiary; in that care is delivered after home physician care and hospital care and thus,* it cannot be assumed that all SREs can be attributed to the setting of care identifying the issue and completing the report. •Consideration of event-reporting for care and services provided by contactors is not developed in the offered formats and contracted services need to be addressed before the reporting system is offered to PSOs. …recommend that the safety program developers meet with long term care stakeholders to refine the Common Formats and aggregate report to improve program clarity and to ensure that reporting tools meet the goals of the safety program without adding system complexity and provider burden. *We believe that modifications can be made to simplify the format and report, make them more pertinent to nursing facilities, and motivate providers to engage in the safety*				

		and quality improvement program.				
	Overall, what would improve usability of the common formats in your organization?	For it to be linked electronically to our medical records system and for it to replace state specific required reporting formats.			8/2/11	Expert Panel appreciates the comment. This will continue to evolve.
	Overall, what would improve usability of the common formats in your organization?	The series of forms that need to be completed seem unwieldy given the current environment in nursing home. *Nurses are currently required to complete a facility incident report and possibly others depending on the incident (FDA if there is a device involved). When multiple reporting methods are employed, the likelihood of success is small.*			8/2/11	The Expert Panel acknowledges that this is an issue.
	Overall, what would make the aggregate reports more useful to your organization?	Other events to include: hospital transfers, use of palliative care and hospice/end of life care, aspiration. Each of these underlie quality issues in long-term care and would benefit from aggregate measurement.			8/2/11	These issues have been addressed in other comments.
	Overall, what would make the aggregate reports more useful to your organization?	Will this reporting replace reporting that nursing homes have to report to their State DOH? What about to the FDA for devices? Also, will this replace what they have to report within their own facility? How will that be done easily with the lack of flow from the various forms (complete HERF			8/2/11	This reporting will not replace reporting to State DOH or to the FDA for devices. It may replace what has to be reported within facilities.

		then go to the individual report)? Nursing homes don't have time to go through all of this; they need something simple!				
	General comments on these forms.	Patient safety reporting should not duplicate other patient safety reporting requirements and be constructed in such a way as to motivate provider engagement in the program. •Eliminate from the definition the reference to "A facility within a hospital." •Decide if the common formats and reporting include both SNFs and NFs patient events and if so, combine the statutory definitions and cite the basis for such definition. •... Recommend that NQF adopt the revised definition in their next update to the Patient Safety Taxonomy Report and for other SNF/NF related report. •Where possible, (Pressure Ulcers, Falls, and Medication or Other Substance) the common formats need to be modified to be consistent with SNF/NF MDS 3.0 definitions and data element language. •The format should be designed in such a way that the common format data			8/2/11	

		elements, for both MDS and PSO reporting, are the same so that it is easier for nursing facility software developers to extract the needed data into a specific report for PSO reporting. •For Common Formats, such as Device or Supply and HIT, where there are no direct linkages to the MDS, need to be simplified by making it more SNF/NF specific. •To reduce burden and complexity, eliminate Common Format sections on pediatric patient reporting since this SNF/NP population is very small. •To encourage those few facilities with pediatric patients to participate with the PSO, develop a Common Format just for SNF/NF pediatric patients. *Note: See AHCA attachment for additional detail about a number of the foregoing*				
	General comments on these forms	Several of the comments submitted here are about question wording/structure differences between hospital and SNF versions. It would be VERY helpful to the NSPD analysts if the experts advising AHRQ clarified which differences did (or did not)			8/2/11	

		affect the ability to compare events across these settings. Other HHS entities have indicated that understanding how errors occurring in non-hospital settings compare to those occurring in inpatient settings is of specific interest.				
		Hospitals v.1.1				
	What, if any, patient safety events should be added? Please include rationale for suggestions.	We have seen airway management issues outside of the OR such as a head/ facial/ neck trauma patient in the ED still under assessment and work up but not intubated and swelling increased overtime making intubation difficult if not impossible.			8/2/11	AHRQ staff note that this could be captured in the surgery and anesthesia form.
	General comments on these forms	Very comprehensive. Would be ideal in the perfect world, but question feasibility to apply in real world. Staff currently resistant to report on simple format (not enough time for ONE MORE THING) and facilities do not currently have manpower to implement usage.			8/2/11	Expert Panel appreciates the comment.
	General Comments on these forms	... Moving HIT-related misadventures from “causation code” to “event” has the advantage of allowing these events to be measured and reported. The process (questions 20 through 26) built into the Patient Safety Event			8/2/11	AHRQ staff note that currently reporting allows for the device to be reported as involved with the event or reported as the primary event. When the forms are used electronically, the user will be prompted to move from form to form rather than fill out individual

		Report "Device or Medical/Surgical Supply, including Health Information Technology Device" helps unearth specific details which can be used to inform system-level solutions. The experience of our members suggests the event category "Device" should be established as a primary event code, and it should also remain a choice for "contributing" or "causation" factors for other event types. *Training for end users should be able to capture "HIT" for both primary events and contributing factors.* Additional work to standardize definitions and gain uniformity in reporting should be undertaken. *Concerns with the documents reviewed include the need for dual-reporting (suggested in Item #19 of Patient Safety Event Report "Device or Medical/Surgical Supply, including Health Information Technology Device"). In the event example provided, a medication error (set-up by a HIT system error) ultimately results in a fall. This appears to generate 2 events (medication error and fall) with a contributing factor of HIT. The sample identifies categories of "Device," "Fall," and "Medication." Is the intent of this event reporting*				event forms.

		process to have the end user complete 3 reports? If one event must be reported as an HIT-related event; a medication event; and a fall (using separate forms or reporting screens), the fitness of the system for handling large volume reporting would be questioned.				

Common Formats Hospital Versions 0.1 Beta – Version 1.1
Parking Lot Issues

GENERAL

Item	Date	Status
Consider harmonization/alignment with ICPS	Various; 8/2/2011	**Keep in parking lot** and revisit over time; ICPS now very different from initial. US has not embraced it as much as other countries in part due to fact that other countries did not have
AHRQ should review "connectivity", "linkage" across forms and between paper and electronic forms	02/09; 2/10; 8/2/2011	Full tech specs published 3/10 address these issues in full. Continue to strive to address alignment of content. **Keep on list** while await standardized coding and model.
The term "other" appears as a response choice in multiple items across the forms. The responses to this item, each place it appears, should be analyzed to determine what items should be added in future iterations.	2/09; 8/2/2011	PPC will be able to address this after receive data. **Keep on list.**
Usability testing and data coding/mapping (ICD, SNOMED, etc.)	09/09; 02/10; 05/10; 8/2/2011	V1.1 can have more SNOMED mapping. Some usability testing has been done. The general issue of mapping is still undergoing refinement. Usability testing contingent on having data entered into the Common Formats. **Keep on list.**
the language of the statement on forms related to "public reporting burden" could have a chilling effect if reporting individuals interpreted that to mean that the results of the report would be publicly reported. AHRQ will flag the fact that this statement does not mean that reports will be made public.	11/09; 8/2/2011	This is the OMB burden statement. AHRQ will pursue with OMB to add a caveat. This will disappear with electronic forms. **Remove from the list.**
Revisit all reporting form content and structure based on user feedback	11/09; 8/2/2011	User feedback pending. AHRQ does get feedback form PSOs and Expert Panel. **Remove from list.**
Events that occur across settings (i.e., occur in one, discovered in another)	8/1/11; 8/2/2011	Transitions. **Keep on list.**
Outbreaks: should they be addressed in Common Formats and if so, how.	8/1/11; 8/2/2011	May be more appropriate for RCA when it is promulgated. **Keep on list.**

Common Formats Hospital Versions 0.1 Beta – Version 1.1
Parking Lot Issues

Should parties external to AHRQ take a major role in educating SNF/NF personnel on use of Common Formats? If so, what characteristics should these parties possess?	8/1/11; 8/2/2011	Users Guide related to SNF should include additional educational information including as related to safety culture. This is big role of the PSOs. **Keep on list.**
Absent definitions, terms mean different things to different people and in different settings; e.g., culture of safety as a contributing factor on SIR. How should this be addressed?	8/1/11; 8/2/2011	See above. Combine and **Keep on liat.**
When different organization specify/define topics/terms differently…	8/1/11; 8/2/2011	Is a real issue and will likely continue. Definitions should be consistent – representational words can be different. **Keep on list.**

HERF/PIF/SIR

Item	Date	Status
Clear delineation of location of event occurrence on the forms: • Type of facility (e.g., hospital, nursing home, etc. w/or w/o facility code designations by such organizations as CMS, AHA); • location within the facility (e.g., hematology, 4-East); and • provider/provider type (e.g., physician, nurse)	10/08; 8/2/2011	**Remove from list.** Has been addressed.
PIF – • Retain Principal Dx and Principal Procedure at present and include spaces for both free text description as well as ICD codes with notation the latter should be added when or if codes are available later in the process. • Add an option of "Unknown" for both dx and procedure. • Define Principal Dx and Principal Procedure in Users Guide glossary.	01/09; 8/2/2011	**Remove from list.**
PIF – there is value in determining increased costs in terms of resources and patient impact including breaking down to capture number of days discharge was delayed.	02/09; 8/2/2011	It is captured on the PIF. **Remove from list.**

Common Formats Hospital Versions 0.1 Beta – Version 1.1
Parking Lot Issues

PIF – • Consider addition of admission date and discharge date (to calculate LOS) • If this is readmission within 30 days? Admitted from where- another facility, home, ER etc. DRG code (if known) - for risk adjustment purposes	02/09; 8/2/2011	Since get info re increased LOS, this may not be needed. Discharge date is questionable need and is a burden. Review after use. **Retain on list** for Group A next round.
Two or more events, including or various types (e.g., incident, near miss, unsafe condition) consideration concerning linkage of different categories of events to a single patient should be explored once automation occurs.	11/09; 8/2/2011	Revisit after automation. Linking re multiple patients is provided for in tech specs. For multiple events with single patients, prompts to other appropriate events. Tech team might consider linkage diagrams. **Remove from list.**
PIF - AHRQ Harm Scale – Use of the terms "harm" and "rescue" should be reevaluated after feedback from users and PSOs	02/10; 8/2/2011	Usability testing to be underway soon w/contract that will include harm scale. **Keep on list.**

Blood or Blood Products

Item	Date	Status
tissue, and gene therapy removed for Version 1.0 and AHRQ will consider reintroducing in future versions with defined data fields and discrete elements. (Organ transplant to Surgery form)	07/09; 8/2/2011	Potential future module. Look at HL-7. **Remove from list.**

Perinatal

Item	Date	Status
Consider whether changes related to inclusion of amniotic fluid embolism should be made in a future iteration. (deferred until after v.1.1 posting)	02/10; 03/10; 8/2/2011	**Keep on list** for use information.