

CENTERS FOR MEDICARE AND MEDICAID SERVICES

**SPECIAL OPEN DOOR FORUM ON
MINIMUM DATA SET, VERSION 3.0 (MDS 3.0)**

**Conference Lead: Robert Connolly
Moderator: Natalie Highsmith
January 24, 2008
1:00 pm ET**

Operator: Good afternoon. My name is (Rebecca), and I will be your conference facilitator today. At this time, I would like to welcome everyone to the Centers for Medicare and Medicaid Services Special Open Door Forum on Minimum Data Set Version 3.0.

All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question and answer session. If you would like to ask a question during this time, simply press star then the number 1 on your telephone keypad. If you would like to withdraw your question, press the pound key.

Thank you. Ms. Highsmith, you may begin your conference.

Natalie Highsmith: Thank you (Rebecca) and good afternoon for joining - thank you for joining us for this special Open Door Forum on the MDS 3.0.

During this special open door, CMS will report on the findings of a five-year CMS nursing home MDS 3.0 validation study. The changes to the MDS 3.0 have been designed to improve data assessment, care planning and quality measurement.

The changes were based upon various public meetings, provider feedback, technical data collection and research. The MDS 3.0 changes are scheduled to be finalized and implemented nationally on October 1, 2009.

Folks here in Baltimore, you did receive the presentation materials outside on the table. For people listening on the phones lines, the presentation materials are posted on the Special Open Door Forum Web site. That is www.cms.hhs.gov/opendoorforums with an s.

You'll see a link for Special Open Door Forums on the left. You click on that and there will be a download section. You will see the Power Point format, a Word format of the presentation, as well and then the fourth link is the timeline for this call today.

Secondly, we probably have some press folks on the phone lines, if not here in Baltimore, as well. All press questions should be directed to our CMS press office and that number is 202-690-6145.

The Special Open Door is focused towards the providers, the people who are directly affected by this MDS 3.0 and we will take their questions and comments first.

When we get to the question and answer session or the comment question and answer session, I ask that you limit your questions to one and limit your prepared comments to two minutes.

And in case we probably will not get to everyone's questions or comments, but to submit your questions or comments, there is an email address. That email is mds30comments -- with an s -- @cms.hhs.gov.
mds30comments@cms.hhs.gov.

And finally there will be an MP3 file posted on the CMS Special Open Door Forum Web page and that will be available starting January 30, and that will be available for 30 days.

Now I will turn the call over to Mr. Bob Connolly who is the CMS Project Officer for the MDS 3.0 validation contract. Bob?

Robert Connolly: Thank you Natalie. Good afternoon. We at CMS are very excited that people have come to Baltimore and there has been such a large response to this MDS 3.0 validation information by phone.

Before I introduce the main speakers, I'd just like to acknowledge the work that's gone into this. We started in 2003, as Natalie said, we had over 1,300 comments, we had technical expert panel meetings, we partnered with the Veterans Administration, Dr. Christa Hojlo and their research, as Dr. Saliba will tell you, was instrumental in doing a study that is the best it can be.

We also were out in the State of Colorado and eight other states doing onsite data collection. We had tremendous support from our Gold Standard nurses and our facility nurses. We've worked very closely (unintelligible) hope you will be, as well.

So I'd like to now first introduce Dr. Debra Saliba. She is a geriatrician. Works at the VA and is the Director Borun Center at UCLA. She is Principal

Investigator and has been instrumental in this work and a great leader in understanding MDS.

Dr. Joan Buchanan is at the Department of Healthcare Policy at Harvard Medical Center. She is very well known in doing research with MDS. And again, the team of Deb and Joan has been fantastic.

So, Dr. Saliba?

Debra Saliba: Hello. I want to thank you all for your interest in learning about the significant improvements that we're making in MDS 3.0. When we consider change, it is important that we really ask whether the challenges of change are going to make it - the gains that we're going to have from that change are worthwhile.

The main advances that we're seeing in MDS 3.0 are that it gives residents voice, it has increased clinical relevance for assessment, it has increased accuracy, both validity and reliability, it has increased clarity and it has increased efficiency. It has achieved these gains while reducing the average time for completion by 45%.

You have been asking for increased clinical relevance, accuracy and clarity and efficiency for over a decade. But why is resident voice important? First, it is essential for improving resident quality of life; a goal shared by all of us. CMS is increasingly focusing on promoting resident centered care.

Items that rely on resident self-report convey clear respect and for individual voice that is fundamental to high quality and to culture change. These type of assessment meets the expectations of residents and families. They want to be asked. They want their care to be individualized and accurate.

In addition, as you will see today, resident self-report improves accuracy and feasibility. We all know from our life experience that general unfocused questions do not elicit meaningful reports. A vague, “How are you today?” doesn’t really encourage us to specifically relate to how we’re doing.

Independent evaluations have shown significant under detection with unstructured observations. These items, it’s important to emphasize, have been tested in nursing home populations.

Direct interview is more efficient. Many MDS assessments now instructs the coder to review the record, interview staff across all shifts and interview the resident and the family. Evidence suggests that this rarely happens. Providers are not given tools that have been shown to work in obtaining important information.

Other items call for detailed daily observations and documentation of all behaviors for all residents throughout the day that is time-consuming and not feasible.

On the other hand, validated direct interview allows the resident self-report to become the primary and sole data source for the majority of residents allowing providers to target more time-consuming observations to those residents who are not able to self-report.

How do we identify and test these advances? Our evaluation team had six sets of players. You’ve been introduced to the lead team already. A national VA nursing home research collaborative included a large team from the Los Angeles VA. From the Philadelphia VA, our leads were Dr. Joel Streim, Ira Katz, Suzanne DiFilippo. From Atlanta the lead was Dr. Joe Ouslander with

input on pain methodology by Pat Parmalee. From Bedford, Dr. Dan Berlowitz and Elaine Hickey.

Our lead QIO is the Colorado Foundation for Medical Care. Instruction guides and form design had important input from Carelink, RRS Consulting and the Kleimann Communications Group.

We worked closely with folks at CMS who answered queries and used MDS for program function. We were also assisted by numerous workgroups, consultants and content experts, many of whom gave very generously of their time and experience.

MDS development proceeded in four phases. The first phase included a Town Hall meeting where we transcribed and reviewed all your comments and questions. In addition, we performed content analysis of almost 1,300 written comments received during open comment period.

Phase 1 also included a technical expert panel. The TEP reinforced your user requested goals of improving the MDS clinical relevance and accuracy, improving MDS efficiency to support clinical assessment. A separate validation panel used a structured methodology to rate validity and feasibility of current and candidate items. The names of those panel members are on the Web site that you were given the link for earlier.

Phase 1 identified several areas that needed significant development work so we added Phase 2 to our original work plan.

In Phase 2 the VA HSR&D funded a national consortium of nursing home researchers to improve and revise key MDS sections. This consortium focused

on mood, behavior disorders, mental status, delirium, pain, falls, customary routine and activities and diagnostic coding.

From mood assessment, this intensive VA evaluation showed that resident self-report is feasible and efficient, even in nursing home residents with cognitive impairment. It also yields more valid information than observations. For pain assessment, the VA research confirmed what several other studies have shown, namely that residents self-report attained is feasible and efficient, even in residents with cognitive impairment.

We showed that residents were able to recall pain experience over five days and that they were able to use items that report pain affect on function. These last items were drawn from a geriatric pain survey that's used in other settings.

We also saw that asking the resident about the importance of customary routine items and activities was feasible and had good test/retest reliability.

For many interview items, we tested resident understanding and use of response scales with a method known as cognitive testing. In the case of customary routine and activities, we learned that simple yes/no responses did not match resident narratives and that a more expanded response scale that included important but can't do actually made responding - the task of responding easier for the resident.

Across interviews, it became obvious that even cognitively impaired residents know what they want and how they feel and that they can report this information if well-designed interviews are used. Almost all residents with moderate cognitive impairment could respond and even many with severe cognitive impairment could be included.

For diagnoses items, improvements in instructions to include algorithms to better define active improves coding. In our VA study for delirium, we were able to revise the data collection protocols and instructions from an assessment tool that's used in other settings.

In cognitive assessment, testing showed that most staff welcomed, having specific questions to facilitate their assessment and that scores were highly correlated with Gold Standard measures. For behavior items, new items that considered impact on the resident were found to be reliable.

We moved on to Phase 3 where work providers, nursing home leaders and resident advocates reviewed the results of the VA research and advised us on its use in community facilities. In this phase, we also conducted common tests of combined items and instructions in six community and four VA nursing homes.

In this phase we also focused on design - on form design bringing in organizations with specific expertise in making forms more user-friendly. From our combined experience training folks to use forms, we know it is important as the updated form include definitions for items that have caused confusion. In addition, ease of use was enhanced by using larger fonts including fewer items to a page and inserting logical breaks.

Finally, items that were confusing, not valid when collected in this part in the MDS type format, are not needed for programming were deleted. Bottom line, the form looks like it takes more pages but it should be more clear and usable and efficient.

In Phase 4 we tested the draft MDS 3.0 and instructions in 71 nursing homes across 8 states. The facilities were a mix of profit and non-profit and included hospital based. 3,800 residents participated in different parts of the evaluations.

These residents ranged in age from 23 to 105 and were selected based on when they were scheduled for their MDS 2.0s, not based on clinical or cognitive states.

The VA also tested in a national sample of 19 facilities and 760 residents. Although we saw similar trends in our VA data as we saw in our community data, the results I'm going to present to you today are limited to the community sample.

We had two types of data collectors. Each state had two Gold Standard nurse data collectors and each nursing home selected one its own nurses to test MDS 3.0. We felt that it was particularly important to include actual facility staff to in addition to their regular duties completed the MDS 3.0.

The national task of MDS 3.0 considered reliability or the extent to which two data collectors achieved the same results when assessing the same event. This is an important measure of how clear and stable an item is. Many prior studies have shown stronger liability when they were collected by Gold Standard nurses, but much lower reliability when actual facility nurses collect the MDS 2.0 in more operational environments.

We therefore designed the study to collect both types of reliability. Because their Gold Standard to facility nurse reliabilities were as strong as our Gold Standard to Gold Standard reliabilities in our study analyses, the results I'll present to you today are limited to the ones that included the nursing facility

nurse. We also tested validity or the degree to which items measured the intended concept.

In addition, we measured the time to complete. We asked staff to record all start and stop times separately for working on MDS 2.0 and for MDS 3.0.

The actual experience in feedback of the nurses who tried out the MDS 3.0 was very important to us. We mailed anonymous surveys to all nurses to get their feedback. We used (unintelligible) response scales and also allowed for open comments.

Nurses answered in MDS 2.0 survey prior to the MDS 3.0 survey.

In the next few minutes, I'm going to review the rationale and some of the evidence for the five MDS 3.0 sections with major revisions. In MDS 3.0 the primary cognitive assessment is the brief interview for mental status or BIMS. This structured simple performance test is used to assess mental status for all residents who can be understood.

For those residents who are rarely or never understood or who are unable to complete the BIMS because of non-sensible answers, staff will use the old staff assessment from 2.0 for mental status. The confusion assessment method or CAM is a validated delirium assessment that replaces the MDS 2.0 delirium items.

Why did we consider these changes? Many clinicians are uncomfortable with the MDS 2.0 observation base scoring. Rating long-term and short-term memory Okay is not a standard approach to assessing cognition and is generally not recognized by providers in other settings.

Indeed, only 29% of the nurses we surveyed thought that the MDS 2.0 cognitive items were easy to complete accurately.

MDS 2.0 instructions encourage assessors to use a formal assessment but do not help the assessor by providing an actual assessment tool.

Finally, although MDS 2.0 summary cognitive scale, such as the CPS or the COGs, for the researchers in the crowd you may be familiar with those, they show good performance but the algorithms to create a CPS or a COG score are not readily scored by actual nursing home staff.

The MDS 3.0 BIMS directly test registration, orientation and recall; the domains common to both cognitive tests in other settings. To make more appropriate for nursing home populations, we selected item wording that gives partial credit for close answers and responses to prompting, which is commonly used to communicate with nursing home residents.

In addition, experts on delirium assessment emphasize the central role of a structured cognitive assessment in detecting delirium. The BIMS therefore serves to support the validated delirium assessment protocol.

Supporting delirium screening is important because it represents a serious condition with increased mortality, morbidity, cost and institutionalization. In some studies, the reliability of the old MDS 2.0 delirium items has been worst than chance.

In addition, independent evaluation shows significant under detection of delirium with unstructured observation. The confusion assessment method or CAM is increasingly recognized as a valid approach to identifying delirium. It

has been cited as an appropriate tool by the Royal College of Physicians, NCQA, and other guideline developers.

It has improved sensitivity and specificity for detecting delirium in frail older adults in hospitals and in post acute care settings.

As you recall, one important reason for replacing the MDS 2.0 cognitive item with staff discomfort with completing subjective assessments. So, what did the nurses who used them think? Their feedback was very positive. 80% thought that the BIMS improved their ability to calculate scores and trigger RAPS. 78% preferred the BIMS interview to the old assessment items. 88% reported that the BIMS provided new insight into the residents' cognitive abilities.

How did the BIMS perform in the nursing home population? The BIM showed excellent reliability on nurse agreements and 85% of non-comatose residents were able to complete the BIMS with scores ranging from 0 to 15.

As the data on this slide shows, the BIMS had excellent performance as a task to detect for liability. It was more highly correlated with Gold Standard measures of cognitive impairment and it is more accurate than the CPS MDS 2.0 measure relative to Gold Standard in classifying residents as cognitively impaired.

Another important reason for introducing a structured cognitive assessment was to improve delirium training. So what did the nurses who used the form think about the CAM? 85% found the definitions on the form were clear. 71% felt that the CAM helped them do a better job of screening for delirium.

As the CAM developer strongly advised us, improved performance did appear to be tied to structured interviews. 64% of the nurses reported that even in the sample of residents they assessed for this trial, the BIMS allowed them to observe new delirium behaviors that were missed by the medical record.

The MDS 3.0 delirium items had very good reliability and these numbers were significantly higher than had been achieved with the 2.0 in the past.

In independent evaluations of the hospitalized and post acute care older adults, delirium prevalence is typically between 11% and 16%. For delirium prevalence scored with MDS 3.0 CAM items was 7%, bringing us closer to prevalence that we would expect in nursing home populations with a mix of new admissions and follow-up assessments.

This compares to a 2% prevalence in MDS 2.0 in a sample that we compared these tools in.

The second section that I will highlight is the depression assessment which also introduces resident voice. The MDS 3.0 uses the PHQ-9 interview to assess remote symptom in all residents who can make themselves understood. A staff assessment, the PHQ-9 observational version, is used for those residents who cannot make themselves understood or who could not complete the PHQ-9 interview.

The observational version includes an irritability item as an observable find of possible mood disturbance in cognitively impaired adults.

Why was it important to revise this section? Independent evaluations have repeatedly shown significant under detection of depressed mood with unstructured observations, particularly in nursing home populations.

The 2.0 approach does not comport with accepted standard of self report. To do the 2.0 well comprised time-consuming systematic observations of all residents across all shifts. This is difficult to achieve in the realities of a busy nursing home environment. Indeed, only 22% of the nurses in our survey reported that the 2.0 section was easy to complete accurately.

Finally, the 2.0 item have questionable utility for gauging a resident's response to treatments. The PHQ-9 interview that is included in MDS 3.0 is based on DSM-IV criteria for depression if validity for identifying depression has been well-established in other settings.

The PHQ-9 is increasingly being recognized by clinicians in those settings. It has been used in outpatient elders, hospitals, rehabilitation settings, including post-stroke populations and in home health. In addition, it has also been used in younger adults.

It is now the standard screen in the VA system and is used by the Alzheimer's Centers at their intake interviews.

One reason it is gaining such wide-spread views is that it allows identification of threshold definition and allows the assessor to rapidly sum a severity score. It has also been shown to be sensitive to change over time. It remained to us to test whether it could be used in the frail populations that are in nursing homes.

So, our nurses used this and what did they think? Some, admittedly, were very hesitant initially to use the PHQ-9, in part because they felt the questions were too personal. However, once they tried the interviews, they found that the residents were frequently grateful that someone had finally asked them and they wanted to talk about how they felt.

Nurse feed-back on these items at the end of the study reflected this important transformation in their thinking. 87% of the nurses rated the mood section as improved over 2.0. 88% felt that the PHQ-9 interview was better than the MDS 2.0 for capturing residents' moods. 84% felt the items could inform care plans. 88% reported that items provided new insights into mood.

The nurses were also very positive about the new observational tool for those residents who could not self-report. 90% felt the detection in communication about mood would improve, as staff learned to watch for these signs and symptoms. 72% found the PHQ-9 observational version assessment easier than 2.0. The PHQ-9 shows excellent reliabilities with kappas greater than .9.

Residents were able to complete the PHQ-9 at high rates. 82% of non-comatose residents were able to complete the interview. Nursing home residents even with cognitive impairment can tell you how they feel.

In addition to excellent reliability and high completion rates, the PHQ-9 showed high correlation of .83 with an independent Gold Standard measure of moods. The observational version also showed strong correlation of .79. The MDS 2.0 measure showed only weak correlation of 0.23.

Another section with major improvements is behavior. MDS 3.0 moves these items from a symptom checklist and includes part of their definition on the form to aid the assessor in coding.

For the behavior items, the revised language is clearer and linked to operational definitions. Behavior symptom groupings were revised to match constructs. The term alterability is replaced with specific impact questions.

The label resist care was replaced with reject care and refocused on residents' goals of care.

Wandering was rated separately from the other behavioral symptom groups and impact, again, replaces alterability ratings.

Well, why were these changes important to make? The all behavior items groupings were not consistent with recognized factors. Indeed, only 41% of the nurses surveyed rated the MDS 2.0 items as easy to complete accurately. The all behavior item labels were viewed as pejorative by consumers and did not convey potential expression of unmet needs.

The new MDS 3.0 labels were agreed by providers and consumers. Staff varied widely in their definition of alterability in completing 2.0. In addition, mental health providers felt that it does not identify ongoing behaviors that required intervention.

The new MDS 3.0 specific impact items give insight into severity and the potential need for treatment or intervention. Again, the feedback was positive on these changes. Most rated the behavioral symptoms as easy to complete accurately.

91% preferred the 3.0 behavior item section. 90% to 94% rated new behavioral symptoms as clear. 88% rated impact items as providing important severity information. Again, measures of agreement or kappa were excellent for both the psychosis and for the behavioral items.

This slide shows how well the revised 3.0 behavior items agreed with the Gold Standard measure for behavior. As you can see, the agreement of MDS

3.0 ranged from .86 for physical towards others to .73 for verbal towards others to .53 for other.

On the other hand, the MDS 2.0 agreement was worse than chance with kappas ranging from .23 to .31.

When comparing the agreement between MDS 3.0 psychoses items and independent Gold Standard assessments, we see excellent agreement. MDS 2.0 kappas, again, were worse than chance.

This slide shows the distribution of the new impact items that considered whether behavior puts the resident at risk, interferes with care or interferes with activity, and it follows the pattern that we would have expected from the impact of behavior.

Another section with significant revisions is the customary routine and activity section. The MDS 3.0 Preference Assessment Tool replaces the 20 customary routine staff assessment items for residents who can be interviewed. An important ratings scale replaces the 2.0 check all that applied in the past year.

New interview for activities, preferences replaces 12 staff assessment items for residents who can be interviewed. We also tested the question that asks whether the resident wanted to talk to someone about returning to the community.

A staff assessment of activities and daily preferences only completed for those residents who cannot complete the interview. It instructs the assessor to observe the resident's response during exposure to the activity.

Why were these changes important to make? The old customary routine items were not perceived as helping care planning. In part, this is because prior practice could be related to ability, illness, access instead of actual preferences or what the resident would have wanted.

Only 30% of the surveyed nurses rated the 2.0 customary routine items as helping their care planning. Our early expert panel strongly recommended that we replace these items with items that ask the resident directly about importance.

The new preference assessment tool or P-A-T, PAT, as we call it, is grounded in residential care quality and maps to the University of Minnesota Quality of Life Domains. It focuses on resident voice as central to determining activities and daily routines.

Residents were able to complete these interviews. As you can see here, 85% of non-comatose residents were able to complete this section. Additional 4% were completed by their significant other. The remaining 11% were assessed with the staff report items.

Initially, our nurses, again, were a little bit unsure about the ability of residents to answer these items. However, once they interviewed the residents, they found these items worked. By the end of the trial, 81% rated the interview items more useful for care planning. 80% found the interview changed their impression of residents' wants.

Nurses also reported that the post-acute care resident appreciated being asked. Only 1% felt that some of the residents who responded didn't really understand the item.

Similarly, nurses were positive about the activity items. 77% rated them as useful for care planning, 83% found the interview changed their impression of residents' wants. They reported that post-acute care residents were equally likely to appreciate being asked when compared to long-stay residents.

None felt that some of the residents who responded didn't really understand the items. Agreement on these items was excellent with kappas greater than 0.9.

As a further test as whether residents with cognitive impairment responded differently to these items, we looked at main scores by cognitive level. We found no significant difference between intact and severely impaired residents who answered these questions in the main scores.

Pain assessment is the fifth MDS 3.0 section we will review today. In this updated section, we added items to report treatment. The resident interview replaces staff observation for residents who can report pain symptoms. The section was expanded to capture affects of pain on function. The staff assessment of pain was changed to an observational checklist of pain behaviors and is only completed for those residents who cannot self-report.

Why were these items changed? They were changed because the old pain item has been repeatedly shown to have poor correspondence with independent pain assessments in nursing home populations. The MDS 2.0 observational approach does not comport with accepted standards of self-report where pain is increasingly seen as the fifth vital sign.

To complete MDS 2.0 well, again, requires time-consuming systematic observations of all residents across all shifts. By interviewing some residents

and targeting our observations to those who most need them, we're able to be more efficient.

Particularly important, in 2.0, detection bias penalizes more vigilant facilities. So those who are doing a good job of trying to pick up the pain assessment look worse when you look at their pain prevalence than those who are less systematic in their pain observations.

In addition, providers and consumers have expressed frustration that the MDS 2.0 pain section addresses limited characteristics insufficient to capture pain experience.

In particular, the 3.0 severity response was viewed as insufficient and failing to match commonly used pain assessment scales. Providers and other experts wanted a severity response between moderate and horrible or excruciating.

We had a strong rationale for these revisions. CMS and providers requested items to capture pain therapy. CMS report - self-report is the Gold Standard for pain assessment. Pilot tests show that residents were able to recall their pain over five days. Providers are increasingly using the 0 to 10 scales in nursing homes and in other settings.

If we could show the 0 to 10 scale could be used in nursing homes, it could facilitate communications and comparison across settings.

Again, feedback was very positive and early nurse comments reflected a positive influence of the QIO program on pain assessment. Most nurses rated the pain management items as clear. 88% rated the MDS 3.0 pain items as an improvement. 94% reported the new pain items could inform care plans.

Even with prior national emphasis on pain assessment, 85% of the nurses reported that the MDS 3.0 interview items provided new insight into residents' pain. 90% felt that all residents who responded understood the items.

For the staff assessment, 85% felt that observable behaviors would improve the reporting of possible pain. Reliability or agreement was excellent for pain treatment, pain interview and the staff checklist of observable pain. Completion rates for resident interviews were high. 85% of non-comatose residents were able to complete the interview.

This slide shows the self-report of pain symptoms was higher in MDS 3.0 than in the sample with the MDS 2.0 approach, allaying to some degree the concerns of some that residents would be likely to deny significant pain.

We also looked at temporal reliability having a different assessor obtain the pain information 24 hours later. These tests showed excellent agreement between Time 1 and Time 2.

This slide shows the distribution of items for the observed behaviors checklist. With this list, 43% of residents unable to self-report had at least one pain symptom. Significantly increasing the pain detection for this subset of patients who could not self-report compared to the 2.0 prevalent.

I've shown you five significant updated sections. We made substantial improvements, as you see in the forum, in other sections. In the interest of time, I'm just going to mention some. If anyone wishes to review in more detail, we can do that during the Q&A.

We will not cover the small changes that were made to improve ease of coding and accuracy, although it is important to note that nurse satisfaction and the time savings likely reflect the cumulative effect of changes throughout the form.

Other sections with important changes include the pressure ulcer section, where we've reversed - we've eliminated reverse staging and we've added a column to note present of pressure ulcers on admission.

Balance, refocus on movement and transition, at times where folks are at highest risk for falls, the falls items introduced type of injury, which was reliability code by study nurses. The bowel and bladder item, we no longer rate catheter as continence, and we improved the toileting program item, as well, to allow documentation of toileting trials that were unsuccessful.

In the activities of daily living, we now have a single - recommending a single response scale, the 2.0 approach had the column A coded based on average performance, which was sometimes difficult for people to calculate. B was based on most dependent episode. The combined column, recommended, is now based on most depended for the entire assessment.

Goals of care item was added at the recommendation of providers. Oral/dental items were improved with significant input from the American Dental Association. The swallowing item is now a checklist of observable signs and symptoms of a possible swallowing disorder. And the restraints items separate out bed and chair.

Finally, in addition to this specific section feedback, we asked nurses to provide overall ratings of the revised MDS 3.0's clinical utility and clarity. 85% rated MDS 3.0 overall as likely to help identify unrecognized problems.

81% rated MDS 3.0 as overall more relevant than MDS 2.0. 84% reported the MDS 3.0 interview items improved their knowledge of the resident. 85% rated MDS 3.0 questions as more clearly worded.

We were a little surprised at how positive the response was because again, change is hard for folks and we felt that people would be sort of inclined towards the tool they were familiar with and had been filling out. Many of these nurses had been doing 2.0 for a decade. So we were very surprised at how positive the feedback was.

Nurses also rated MDS 3.0 overall validity as high. 89% rated MDS 3.0 as providing more accurate report of resident characteristics than MDS 2.0. 75% rated MDS 3.0 as better reflecting best clinical practices or standards.

There were some new items that we tested that got poor reviews from the nurse users. So they weren't just going through and marking everything positive, but we dropped those items, so that's why I'm not showing you. We listen to the nurse feedback, they were new items, they didn't work and we dropped them.

At the start, I reported that MDS 3.0 took 45% less time to complete than the MDS 2.0. Here you see the average completion times for MDS 3.0 of 62 minutes and for 2.0 an average of 112. This is particularly significant given that the nurses were new to the MDS 3.0 and probably had not achieved maximum efficiency. In addition, facility records and pre-population in the fields are often set up to accommodate MDS 2.0 but were not available for MDS 3.0.

All MDS 3.0 assessments were full assessments. This efficiency reassures us that resident voice does not impede the efficiency of evaluations. By

interviewing residents who can report their own preferences and feelings, staff can focus their time on the more complex observational protocols for the most vulnerable who cannot self report.

These time savings also likely reflect a more usable form and clearer items. These MDS 3.0 improvements also reflect the resources that were available to us in revising the tools. We were able to build on feedback from users and significant experience with the 2.0 tool.

MDS 3.0 benefited from input from experts. It also benefited from a decade of advances in assessment science that has positioned us to improve clinical care in nursing homes. A number of assessment items we're adopting are already in use in other settings.

We showed that they can be used in the vulnerable populations in nursing homes, which means when we call a provider in another setting on the phone, we can use the language that is common to them.

These standardized items could improve communication with providers and allow us to better track care and patient progress across setting.

So, are the challenges presented by change worth it? We believe the answer is a resounding yes. National testing showed increased resident voice and refined measures in MDS 3.0 had led to increased measurement reliability, increased validity and that these improvements together increased clinical detection and assessment accuracy.

Our evaluation also showed that nurses who use the MDS 3.0 reported higher satisfaction due to increased clinical relevance, increased clarity and increased

knowledge about their residents. As one nurse said, it reminds me of why I became a nurse.

Finally, MDS 3.0 makes these gains with reduced time but of completion by 45%. These efficiency savings may help offset the private provider cost of retooling to this new instrument in October, 2009.

I want to thank you for your attention and your interest today. I think we'll move on to the question and answer session.

Natalie Highsmith: Yes, thank you. Just to remind everyone in Baltimore that there is a microphone here in the middle aisle. If you have a question or a comment, please begin to line up at the microphone now.

Remember to limit your comments - your prepared comments to two minutes and your questions to one question. And we will be taking two questions from here in Baltimore and taking two questions from the phone lines alternating that way.

Robert Connolly: Before we begin -- this is Bob Connolly, again -- I'd just like to thank Deb Saliba for the report. To have an instrument that's more reliable, more valid and is less time in creates satisfaction is such a move forward, and it tells the story of the wonderful work that's going on in nursing home and it will affect our quality measures, it will affect care planning, it will help in many, many different ways.

I'd like to provide a context for our question and answers in a timeline of where we're going from here.

First, MDS 3.0 is only the clinical side. We have a national study, The STRIVE Study, that's looking at RUGs and payment. That will be coming later in the year. And so what we're telling you today is not final. We must await those analyses and results.

The second thing is that the RAND research is being reported on as we end the contract March 31, 2008. I'm sure you will find other things for us to look at and other ideas, but that will hopefully be another version as we move down the road and hopefully versions will not take as long between MDS 2.0 and 3.0 as they have.

Lastly is that we're consulting internally and externally to look at implementation issues. We've given you one form that has everything that we think is in there, but we need to think about some other things that we're really not prepared to discuss a number of topics today. First, we can't talk about RUGs or case mix. We must await the STRIVE study.

Second, we recognize training is so critical to what we will do with MDS 3.0, especially as we move with interview, but we're looking with many of you to come up with a training and train the trainer model.

We do not have detailed plans today for IT and yet we realize IT, all the vendors, all the different software, all the different uses by states are important, and how we support you if we change items are things that we'll work on down the road together.

The third thing is resident assessment protocols. We're really looking internally with ways to deal with this. We did not fund this in the RAND study so that we will need to look at this more and do not have any information today on RANDs.

Lastly, we're not prepared today to discuss the many different forms - and record types, not forms -- thank you (Ray) -- in terms of impact, submission, quarterlies, discharged, that again, are more things that we'll work on down the road.

So we have all of the information that we're talking about today. Also on the MDS 3.0 Web site that I think many of you are aware of and we'll be updating that with Deb's slides later this afternoon or this week.

So I'd like to now move to the timeline, and as you can look at the timeline, we've gotten to the Special Open Door Forum, we're now working and will have for you in spring an MDS 2.0 to 3.0 crosswalk and a transition plan. This will give you the detail that you need to look at of how these items have changed the MDS.

There will be draft specifications for vendors and providers in November, 2008, and this will have preliminary STRIVE information. It will not be final, but it will have some STRIVE input. The final specifications will come in February, 2009.

We're going to have a series of meetings. We're going to coordinate with the state Medicaid National Meeting in March, 2009. We're looking to have an RAI Conference and technical conference kind of back to back in spring of 2009 and we're looking to have two satellite broadcasts.

FY 2010 the SNF payment update in the federal register will talk about RUGs changes and that will be in July, 2009. As I said, we're going to implement MDS 3.0 October 1, 2009, and we'll begin using MDS 3.0 in the survey process that same month.

So in terms of the quality indicators, we will have to wait until the MDS data is - MDS 3.0 is entered and can be used in quarterly reports. So as you can see here, that really we will not have full MDS implementation for our quality indicators in Nursing Home Compare until October, 2011, and we'll be looking at new items to report quality measures during that time.

So I'll end now and turn it back to Natalie and look forward to your questions.

Natalie Highsmith: Okay, again everyone, we do have the microphone here in the middle aisle. If you have a question, please start to line up now. If you have a question, please limit it to one. If you have prepared comments, please limit it to two minutes. And (Rebecca), if we could go ahead and start people getting lined up in the queue on the phone lines, please.

Operator: At this time I would like to remind everyone, if you would like to ask a question, press star then the number 1 on your telephone keypad.

Natalie Highsmith: Okay, we'll take our first question here in Baltimore. Please remember to state your name and what organization or provider you're representing today.

(Deb Vandervele):Hi, this is (Deb Vandervele) and I'm representing SunBridge Healthcare, and my question is related to the completion in the time study. Was the completion only done by a nurse or was there inter-disciplinary team evaluation in there, as well and their time capture?

Debra Saliba: In the times that - hello, are you there? Okay. It didn't sound very loud. Okay, so the times that were recorded by the 2.0 - for the 2.0 were the times of people working on the form. It did not include the IDT meeting. It did not

include the RAPS. We clearly instructed them not to include those in their times.

The 3.0 form was in most cases completed by one facility nurse because that's who we train, but we did give them the option if they wanted to go back to their facility and deputize other team members to do their sections of the tool and train them on it, that they could do that.

So, there was a little bit of a mix in terms of the number of people completing that. So - and sometimes it was the nurse who normally doesn't complete the nutrition section and completing the nutrition section and other times it was the dietitian that completed the nutrition section for the 3.0.

(Deb Vandervele): Okay, thank you.

Debra Saliba: Okay.

Natalie Highsmith: Okay, we'll take a question from the phone.

Operator: Your first question comes from (Mary Weidner). Your line is open.

(Mary Weidner): Yes, I have a comment versus a question. Hello?

Natalie Highsmith: Okay, go ahead.

(Mary Weidner): Oh, I can hardly hear you. I'm sorry. I've been working in the MDSs for 11 years and I'm credentialed and certified by ANCC. I have never taken 112 minutes to fill out a 2.0 MDS. And if I did take over an hour to do it, it was completing the RAPS and a portion of the care planning. So I would like to know where they got this timeframe from.

Debra Saliba: These were average times. There was certainly in some facilities in the hands of some nurses shorter times, and the published times that have been done by the developers of the 2.0 with highly trained Gold Standard nurses, the best average time is about 90.

So you may be one of those highly trained Gold Standard type nurses who can do it in that average of 90 minutes. But these were average times, so certainly there were some that were quicker and there were some that were longer.

And that's just what the facility - they had sheets to record their start time and their stop time as they worked on the different sections of the tool. Those times - they did not sum those times. Those times were data entered and then measured analytically to come up with what the average and total were.

(Mary Weidner): Okay, but I'm saying that I probably complete the whole process in less than an hour and 12 minutes.

Debra Saliba: Yes, I understand that. And again, as I say, in the hands of a very highly trained Gold Standard nurse, studies have shown that you can get to an average of about 90 minutes, which is still 30 minutes more time than the average on our tool with pretty new users.

But what we were reporting to you today were the average times that were recorded in comparable patients in our sample between - in actual facility use between the 2.0 and the 3.0. Thank you.

(Mary Weidner): All right.

Natalie Highsmith: Okay, next question from the phone, please.

Operator: Your next question comes from (Cindy Briggs). Your line is open. Ms. (Briggs), your line is open.

(Cindy Briggs): Can I please get the Web site again repeated a little slower so we can view the Power Point?

Natalie Highsmith: Okay, the Open Door Forum Web site is www.cms.hhs.gov/opendoorforums -- with an s -- and when you get to that page, you'll see on the left-hand side a link for special open door forums. You click on that and you'll see a download section and then you'll see the four links for today's special open door. All four of them will say Tuesday, January 24.

The second link is the Power Point. The third link is the Word version of the Power Point and the fourth link is the timeline.

(Cindy Briggs): Thank you.

Natalie Highsmith: You're welcome.

Okay, we have a question here in Baltimore. Thank you.

(Amy Hasselcris): My name is (Amy Hasselcris) and I'm here from the American Speech Language Hearing Association, and I wanted to start out first of all by just noting that there's obvious effort that was put into this revision and I do appreciate the opportunity to comment.

First of all, I'm pleased to see some - the addition of some specific items related to swallowing disorder, signs and symptoms, and I'm very appreciative to see that in there.

Also, the addition of an item in Section B about whether or not the resident has a hearing aid and uses it, I think it's a good piece to include in there.

I do - wanted to comment on a couple of concerns on what some information that was shared today, however. When I was listening, I was noting that for both the cognitive and pain sections described in some detail how the previous 2.0 observation format was less reliable and had some problems for the staff to complete. Yet at the same time you indicated that for those residents who have significant communication disorders that the observation format would be used in those cases.

The concern here is that in the absence of a better alternative, these patients may be disadvantaged because of having to be possibly scored in a less reliable manner. And so I would just urge CMS to investigate this a bit further and certainly we would be happy to help out in any way that we could if that's needed. Thank you.

Debra Saliba: Thank you. I think to clarify a little bit about the items, we did revise the observation items for pain so that we now have observable checklist of pain that actually come from some validated tools that are out there to help observe pain behaviors in cognitively impaired older adults.

And it is a very big challenge, but what we're hoping is that by focus - you know, getting these interviews that are so efficient, the pain interview took an average of about three minutes to complete, then the staff can be focusing their times on doing these observations better.

For the cognitive items, the observation actually doesn't do that badly. I mean, the correlation between the observational items and the cognitive items and the Gold Standard measures is not bad. It's sort of the one section in 2.0 that's not - that doesn't behave really badly.

But the challenge again is that it just - staff are just not as comfortable with it. And so again, we're limiting the number of patients that they have - the residents that they have to do that with. And we're - also the other reason for doing the more structured cognitive interview is that it improves the detection of the delirium.

So we do face that quandary with the less communicative and patients that are harder to do the assessment with, so I totally appreciate your concerns about that. And we've tried to introduce the best assessment that we can for the cognitively impaired, but it really has been an ongoing challenge to do that.

Robert Connolly: Deb, do you want to mention the use of the amplifier and how that helped a number of patients?

Debra Saliba: Okay. One of the things in the instruction manual that you'll see and in the training materials that we've provided to CMS that we'll make available to you as this rolls out was that we encourage people to make sure the residents could hear them before starting the interview process.

So, one of the things that you saw on this video that was playing when you came in was someone using - just putting on these little earphones and then speaking into a microphone. These are commercially available products that you can order for under \$50 that really enhance the ability to hear with your residents.

And we had several interesting stories from the field about the affects that these alone had. One of our nurses who was a little skeptical initially about interviewing cognitively impaired adults went to a nursing home and said, "Please let me interview one of your cognitively impaired adults." And they said, "Well, go see Ms. (Jones) who's down there in Room 10. She is totally out of it. She never gets anything."

So they go down to see Ms. (Jones) and they put the hearing amplifier on her and she sort of perks up but then she goes flat again. So when they're about to leave the room, they try a few questions, they don't get much of a response. So when they're about to leave the room, they check the hearing device on themselves, and they realize the batteries are dead.

So they head back out to the nurses' station. They ask for a set of batteries. They put them back in the headpiece and they go back to Mrs. (Jones). They put the hearing amplifiers on her and she perks up. She starts interacting with them. She's responding to questions, pointing to answers on a queue card that they have.

So it really - one of the things that we say is, so here is this woman, she's been in the nursing home for a year and had been felt to be cognitively impaired by the staff who were doing the observation types of things with her. And it was only when our staff went in and tried to do a structured process and tried to make sure that she could actually hear them that they understood that that was the fundamental issue for this resident.

So you'll see in the instructions again and in the training materials that we have, the encouragement to try out these - or some type of way of making sure

that they can hear you before you start assuming that their inability to respond to you is because of a lack of cognitive ability.

Now that's a caveat that's in the 2.0. I mean when you look at the 2.0, and in the RAPS it tells you if they're cognitively - if they come across as cognitively impaired, think about hearing as an issue.

But what we're doing is getting structured protocols for when you go in assess their ability to hear before you start asking the questions.

Natalie Highsmith: Okay, a question here in Baltimore.

(Leshawn): Yes, My name is (Leshawn). I'm from Genesis Healthcare, and I have a question about the look-back periods. I noticed that the first revision to the second revision there was some changes in the look-back period, as well as the former section T where you were allowed to project rehab minutes. I noticed that that was also not there.

And I just wanted to know what part of the evaluation process determined that that was eliminated, as well as the changes in the look-back period.

Debra Saliba: Section T is being evaluated by the STRIVE study, and so you'll hear more about that from them.

The look-back periods, basically what we did when we met with our validation panel, we identified a five-day look-back for the clinical items as being valid with facts to give you a good snapshot of what was going on with that resident's current clinical state and clinical needs.

We were trying to have consistent look-back periods across the whole tool so we tried them out also with therapy section and with the ancillary section. When we tried to do - we did a cross-walking activity and we found that that made too big of a change in that particular section.

So in our case we couldn't go back and recalibrate, you know, or do anything other than what we did in our study, so we just recommended going back to the 2.0 time window for those particular items.

Part of what our commitment in the beginning was is that we weren't going to voice any untested items on the field. And so if the 3.0 item didn't work better than the 2.0 item, we were going to go with the 2.0 item. In that case, at least in our analyses, decreasing those time windows affected the ability to really crosswalk the tool.

Robert Connolly: And I'd just to add that CMS is awaiting the STRIVE study and is really evaluating all and we're not prepared to talk about look-back today, either. It's really something that we want to look at carefully.

Natalie Highsmith: Okay, we'll take another question from the phones, please.

Operator: Your next question comes from (Yvonne Atkinson). Your line is open.

(Yvonne Atkinson): Hi. My question is on Section M, Skin Conditions. M6 states the colors of the different of either the slough or eschar. You used brown in both of those definitions, but then further down below, also in M8, 3 again where it says sloughs, it's only described as yellow or white. The other colors which you stated above seem to have gone away and then you took tan from above and added it in number 4 where it says necrotic tissue.

So these are kind of contradicting each other. I was wondering if these areas would be cleared up.

Debra Saliba: Yes, actually we had a conference call just this past week working with NPUAP, WOCN representatives, other content experts in the pressure ulcer measurement to try to align, not only this tool, but others with sort of the evolving language for pressure ulcers.

They've made a recommendation in terms of changing the unstageable ulcers definition. They've also recommended that we not keep the extra data item in the tools, so we may be deleting that particular item. So there is some effort to sort of make these definitions consistent with NPUAP recommended language just to clear up any possible confusion that might happen in the field.

The definitions that you see for MH are taken right out of the PUSH tool, so that's where they came from, but as you know, it sounds like you're very interested in this area. It's evolving right now in terms of the language and definitions and labels.

So again, we don't want to put in any untested items, so we're not adding like totally new categories, but to clean up the language and make it more consistent with more recent recommendations from NPUAP that came out after our field study. We will go ahead and make those minor modifications to the language.

(Yvonne Atkinson): Okay, thank you.

Debra Saliba: Thanks.

Natalie Highsmith: The next question from the phone - sorry, Bob, did you want to comment?

Robert Connolly: I just wanted to add that CMS is looking across its tools to, as Deb said, look at definitions and align them so it's not just the MDS. The MDS has advised the care tool and we're now working with other components through NPUAP and others to look at it so we can be as consistent across setting.

Natalie Highsmith: Okay, next question from the phones please.

Operator: Your next question comes from (Karen Vankamp). Your line is open, ma'am.

(Karen Vankamp): Hello. I'm calling from Jackson County Medicare Care Facility and my question is regarding the Section M, also. It's a little bit confusing when it says staging ulcers report based on highest stage of existing ulcer and it's worse, but not reverse. So are you trying to say, don't reverse and if you first note it as a Stage 3 that you can continue to document as a healing 3.

Debra Saliba: Exactly.

(Karen Vankamp): And therefore you're not reversing.

Debra Saliba: Yes, exactly.

(Karen Vankamp): But would you - if it worsens, are you going to call it a 4 then?

Debra Saliba: Yes. If it worsens to a higher stage, then you put that as its stage.

(Karen Vankamp): Okay, so don't reverse. Go forward.

Debra Saliba: And that's why - sorry, yeah. So that's why there's the worsening in the healed section, as well, because we realize that it makes, to some extent,

knowing sort of the change over time a little more difficult to track, so we put those items in there to help a little bit.

But yes, this is a very, very strong recommendation, as you know, from pressure wound care and pressure ulcer experts throughout the country.

And it really aligns the 3.0 with what most facilities are doing already in their charting so that it saves us from having, you know, people charting one thing in order to do what's considered standard of care for tracking their pressure ulcers and then doing something different in the MDS.

So it will take I think a little bit of a transition and you're at a bit of a disadvantage because you don't have our training tapes and you don't have our instruction manual which we haven't finalized because we're still finalizing these items, but when you get those, hopefully it will make it a little bit clearer about the reverse staging issues because I realize it will be a little bit of a transition for some folks.

(Karen Vankamp): Okay, now if I have noted one at a Stage 3 at first, it worsens, so I'm going to stage it at a 4 and that's maybe, you know, when I do the 60 day MDS, it's improved again, am I going to call that Stage 3 then?

Debra Saliba: Once it's a 4 - no, once it's a 4, it's a 4. It's just a healing 4.

(Karen Vankamp): A healing 4 so call it whatever it got - whatever it's worse than it ever got.

Debra Saliba: Exactly.

(Karen Vankamp): Okay.

Debra Saliba: You got it.

(Karen Vankamp): Okay. Thank you.

Debra Saliba: Okay. I'll bring you to the next training so you can help other people understand this.

(Karen Vankamp): Okay, thanks.

Debra Saliba: Okay.

Natalie Highsmith: Okay, are there any questions here in Baltimore? Okay, if not, we'll go ahead and go to the phone.

Operator: Your next question comes from (Jay Trumbo). Your line is open, sir.

(Jay Trumbo): Thank you. Interested to know about the Gold Standard you keep referencing that. I'm assuming that's the baseline standard or expectations, but how is that developed and a little bit more information on that.

Debra Saliba: Well I use Gold Standard in two different ways. One I use Gold Standard to refer to our highly trained research nurses. So we got very credentialed nurses to be - two Gold Standard nurses for each state that were highly credentialed and had filled out at least - they were either ANCC credentials or had filled out at least 100 MDSs and had experience with MDS.

Then we brought them and did very intense training with them at our research offices in Santa Monica, and they were to serve as part of the - you know, sort of the ideal kind of assessor. And if they couldn't make the items work, we knew there was no hope that the item would work.

So that's one way I use the term Gold Standard.

In other instances where I used it is where I was using a criterion measure. So the specific criterion measure used varies by the item. So for the cognitive items, the criterion measure was something called the 3 MS which is basically the MMSE but expanded. It's a more sensitive and specific scoring scale than the MMSE that is longer and is used more and can be used better in research settings.

And basically for Gold Standard measures, what we're doing is picking those things that, you know, they're really a better most accurate measure of the condition that can be done within the confines of our research study, but they're way too long or complicated to be asking the field to do.

So in the 3 MS case, it's scored from 0 to 100. It includes a lot of items like pentagon drawings that are similar to the MMSE, but it also includes things like animal naming and things like that.

For the mood items, the PHQ-9 we used a Gold Standard criterion known as the (MSAD). It's been validated as a semi-structured approach to assessing mood disorder in older adults. The University of Pennsylvania has used that as a Gold Standard measure and published its performance criteria.

For the cognitively impaired people for mood, we use the Cornell Scale, which is also a validated scale. For behavior, we use the CMAI which is a validated way of assessing Gold Standard type measure for assessing for the presence and severity of behavior. And then we use the NPI to look at the psychosis type items.

Does that help? Is that what you needed?

(Jay Trumbo): It is. Is there a list of those somewhere that we...

Debra Saliba: I think they're on the slides. If not, they're in the write-ups that are on the Web site, as well, when we summarized the VA data.

(Jay Trumbo): That's great.

Debra Saliba: We can check and be sure, but I'm pretty sure it's in the supporting materials.

Robert Connolly: Yeah, if you go to the cms.hhs.gov Web site and type in MDS 3.0, on our Web site, there's a detailed list because most of this work was done through the help of the VA with the four centers that Deb talked about helped us define which protocol to use that was the Gold Standard. And we are truly indebted to them, but it's on our Web site.

(Jay Trumbo): Thanks.

Natalie Highsmith: Okay, next question from the phones, please.

Operator: Your next question comes from (Wanda Spedal). Your line is open.

(Wanda Spedal): Yes, I have a question on the average age you keep referring to that you got most of your information from VA hospitals. And I am wondering the age of the people because most of our residents are like between 80 and 90 and their memory - they would have a difficult time remembering five days past line on their pain.

Debra Saliba: Yeah, thank you for asking. We actually did our pilot testing in the VA, but we didn't rely on that to make these recommendations. We then took the items that we were able to refine and test very carefully in VA populations which incidentally in the nursing homes tend to be a little bit older and have more cognitive - more psychological impairments than what we see in our community nursing home populations. They also seem to have a higher burden of comorbid medical conditions. So there are some differences between VA populations and community populations that we're very aware of.

So the data that I presented today on validity, reliability, nurse satisfaction, ability of the residents to complete the data was entirely based on the community sample. There were no VA patients in that sample that I presented today. Now, we saw the same trends in the VA as we're seeing in the community, but I did not present the VA data specifically because I knew this would be a community audience today and because of concerns about the potential differences between populations.

The - but that said, if a resident can't recall something, they can't recall it. If they can't answer it, they can't answer it. It doesn't matter whether they're a man or a woman, if they can't do it, they can't do it. And we don't have any reason to believe that, you know, the veteran - that a male is going to be less able or more able to recall their pain than a female at a five-day interview, and our VA sample did include men and women.

The - and again, you have to look at the information that's there. We found that even the cognitively impaired patients, the detection rate for pain with interview was higher than the detection rate with observation.

And when we look at the accuracy of the five-day look-back and three-day look-back, it was - we didn't find people reporting that they had pain who had not actually had it.

Robert Connolly: And I'd just like to add that we made - we're very clear that our samples are different but I want you to know that the VA uses the MDS for their patient care planning and they're very, very interested and involved so that their research helped us to do our research in our population but the data is not next, it's separate and what we're reporting on today is just our community sample case.

Operator: Your next question comes from (Ann Deekman). Your line is open.

(Ann Deekman): Hi this is (Ann) from Emmanuel Nursing Home in Richfield, Minnesota. I first want to say that I am really excited to hear that the pressure ulcer area that we can now note the presence of an ulcer on admission, but some of us here were also wondering as far as UTIs or other infections if there will be a section to code or to differentiate between a nosocomial versus an infection that was present on admission, also.

Debra Saliba: No, not in the current 3.0. I mean, in all cases we're facing this sort of balance between having a tool that is long enough to meet essential program functions but parsimonious enough that it doesn't become a burden and difficult to collect.

So there's certainly a lot of different pieces of information that we could ask for but - and that would be very helpful and important to note, but we didn't do it because of the tradeoff between trying to - and there were some items we might would have taken off the form except that they were needed for other program functions.

So there was sort of this fine line that we were trying to balance between being able to maintain important program functions that CMS needs to keep going and having a parsimonious and efficient tool that does what does really well or as well as we can given that it's a form and then - and still try and make it a useful instrument.

(Ann Deekman): Thank you. And I know you're not prepared to talk about the quality indicators at this point, but if that section was not changed, I hope that you'll take that into consideration when computing the new quality indicator, quality measure form or however that's going to work. Thank you.

Debra Saliba: Thank you.

Robert Connolly: We're definitely aware of that.

Natalie Highsmith: Okay, we have a question here in Baltimore.

(Leshawn): This is (Leshawn) again from Genesis Healthcare. I just have a question about the present on admission. I noticed that the wound and the fall with injury was something new that they're looking at that.

Does CMS know or do they have any plans on implementing any of that present on admission that they're doing in the hospitals in the nursing home setting?

Debra Saliba: I'm sorry I don't understand what you're asking.

(Leshawn): Well, the information that you're collecting about present on admission, can you just tell me a little bit about that?

Debra Saliba: Okay, this was included at the request, really, of a lot of providers felt this was very important to be able to document. So for Stage 2, 3 and 4 ulcers, we asked of the pressure ulcers listed in that particular section, how many were first noted at that stage within 48 hours of admission and not acquired in the facility.

And we do in the instructions try to make sure that that's not something that, you know, the resident had it, they got discharged to the hospital and they came back with the same one, that that's not considered a present on admission ulcer, but it was an attempt to really try to help with the, you know, concerns that providers had that a lot of patients - residents were showing up with pressure ulcers and the 3 or a 4 is not going to away by their next assessment. So they really wanted to be able to document the present.

Is that what you needed information on? Okay.

Natalie Highsmith: Okay, we have a question in Baltimore.

(Judy Simpson): I have a comment. I'm (Judy Simpson) from the American Music Therapy Association, and I wanted to thank CMS and all the people involved for the multiple opportunities to provide input and feedback on this document as it's been going through revisions, and to thank you for the inclusion of music therapy under the O4 therapy section.

Although we're a separate discipline from recreational therapy, we really appreciate being on the form because it's going to give music therapists in those nursing homes an opportunity to accurately reflect their services, so thank you.

Debra Saliba: You're welcome.

Natalie Highsmith: Okay. Question from the phone line?

Operator: Your next question comes from (Kelly McLaughlin). Your line is open.

(Kelly McLaughlin): Hi, I work some form at Knightsbridge in Columbus, Ohio, and I heard you say that the different - some of the different pilots were given the opportunity to train members of the interdisciplinary team such as Social Services and Dietary to complete their respective applicable sections of the new 3.0.

But was there a reason why, say, social workers and dieticians or diet techs were choosing not to participate in the pilots, because I would really like to see some more piloting and see what their opinion of the 3.0 is.

Debra Saliba: Yeah, well they're sort of listening, I mean, certainly with the PHQ-9, for example, I mean, who fills out what section of the MDS 2.0 sort of varies from facility to facility. So that was one of our challenges in sort of setting up a training plan was that, you know, who would be trained.

The other was just the feasibility of trying to bring in from 71 facilities all the members of the interdisciplinary team to actually train them.

There is a little bit of a learning curve and so we didn't want people just to do one or two but, you know, to be actually doing more than a few to fill it out and to just towards the training.

I will say that in our pilot studies we had the social workers - let me just say it this way, instead of confusing our pilots to reference. The PHQ-9 oftentimes

some of the mood items are administered by social workers - the cognitive items are administered by social workers, depending on the facility.

And we actually, the PHQ-9 has been tested with case managers, social workers, nurses, in other settings. Basically, multiple members of the interdisciplinary team have used it to screen for mood disorders. In addition, it's been translated and validated in multiple languages.

The cognitive items, again, we - in our pilot testing we had actually a social worker that did the pilot testing activities for the cognitive items and they worked just fine. I mean, because they are a structured performance measure, people can - you know, it can be handed off to a clinician to do and it doesn't require a highly trained person in that particular content area in order to complete them.

For the dietician section, was there a particularly large change there that worried you that you felt that...

(Kelly McLaughlin): No, it's not there was a big change in those sections, I just thought it would be interesting to have those particular members of the IDT look at the 3.0 and I heard you say that social workers were participating with the cognitive piece and some of the mood piece. I just thought it was interesting that in the slides it was referring to nurse satisfaction more...

Debra Saliba: Yes, because that's, you know, who we in the survey. You're totally right. Yeah, and it would be very interesting to do more work to figure out, to understand better how interdisciplinary teams function across facilities and how they split up the MDS and function and their care planning, maybe, so as a researcher, too, I would love to see it.

The - and I will say - and any sections that we revised, we had input from content experts in that particular area and from that particular discipline. So they weren't revised in a vacuum.

(Kelly McLaughlin): Okay, thank you.

Debra Saliba: Thanks.

Natalie Highsmith: Okay, next question from the phones, please.

Operator: Your next question comes from (Elisa Spencer). Your line is open.

(Elisa Spencer): Hi. This is (Elisa) from (unintelligible) Nursing Home in Honolulu, Hawaii.
Can you hear me?

Natalie Highsmith: Yes, we can.

(Elisa Spencer): Okay. Thank you. For Section A10, you know, the (unintelligible) submission and state requirement submission, right now it is automatic and just depending on the software that we use, but what will happen with 3.0 and what are your requirements for those (unintelligible) requirements?

Debra Saliba: I think Bob earlier referred to the fact that we probably weren't going to be talking about submission requirements right now or different types of record submission requirements, and so I would like to just suggest you send that - a written comment in and we'll read it and look at it carefully. Thank you.

(Elisa Spencer): Thanks so much - oh, someone has a question. Okay. The other question I have is, you know, according to your form right now the 2.0 that we use has

like (CPS) items and just (plain) over items and even triggers for your RAPS, would the new 3.0 have that also?

Debra Saliba: I'm sorry. For some reason, it broke up a little. Did anybody hear?

(Elisa Spencer): The current 2.0 forms that we use have (CPS) items highlighted and even triggers that would help us with (unintelligible) our RAPS. With the 3.0...

Debra Saliba: Okay. I'm sorry. I understand you now. Yes, we will be recommending RAPS triggers to CMS.

(Elisa Spencer): How about (CPS) items?

Debra Saliba: Oh, I see what you're asking. Thank you, someone in the audience is telling me what you're asking, so that's why I'm silent here.

I think, you know, additional labels on the form come from some of the people that print out the form so it varies depending on who you buy your forms from. So...

(Elisa Spencer): Oh, okay. So it's not going to be part of the 3.0?

Debra Saliba: Well, I mean you could purchase your forms from somebody that adds that information onto your form for you if that's important to do. I mean that's my understanding about how those things are on there now.

(Elisa Spencer): Oh, okay.

Debra Saliba: Okay.

(Elisa Spencer): All right. Thank you.

Debra Saliba: Sure.

Natalie Highsmith: Okay, next question from the phones, please.

Operator: Your next question comes from (Rodonna Early). Your line is open, ma'am.

(Rodonna Early): Hi, my question -- excuse me -- also concerns the RAPS and I didn't know if you were prepared to discuss that today.

Robert Connolly: No, we would prefer that you send - but you can - my boss just told me it would be good for you to talk. Go ahead and give us your question and we'll see if we can answer it.

(Rodonna Early): My boss doesn't tell me that - no, I'm teasing. Anyway, I know there's been some talk about updating RAPS including a pain RAP, that sort of thing. I was just wondering if there was an intent to do that when you roll out the new 3.0; include some of those ones that have just been talked about before.

Can you hear me?

Debra Saliba: Yeah, sorry. I'm trying to get my microphone on. I just wanted to hear your question to make sure that it was, you know, something that we could or could not answer just to try to understand.

I guess at this time we wanted to let people know that we really - we don't have any announcements or any information to share right now with our plans, but as you obviously are aware, we have been investigating and we've heard requests about pain RAP, so it's certainly a topic that we're very

interested in, but at this time, I don't have any specific announcements that I can make publicly.

(Rodonna Early): Thank you.

Natalie Highsmith: Okay, we have a question here in Baltimore.

(Amy): Hi, (Amy) from the American Speech Language Hearing Association again. Question is a follow up from my previous comment. I noticed in the section on hearing, vision and communication that the modes of communication item was eliminated from 2.0 to 3.0.

I was wondering, you had mentioned earlier about amplifiers and things being in the instructions and I haven't seen in the instructions whether - the modes of communication was whether the person uses the communication board or writes their answer or anything like that.

Is that somehow captured?

Debra Saliba: No. You know, the feedback that we got from providers was that really wasn't helping them do a better job of screening for those needed the modes of communication and that it wasn't necessary for program functions to keep it on the form. That was really just an additional documentation requirement that wasn't changing care.

You know, we did - so that's why you don't see it there because it wasn't necessary for program. It wasn't improving the rates of use of the important communication devices or helping people do a better job of targeting the communication devices to need and so we felt that it really wasn't - the MDS 3.0 wasn't where that belonged.

(Amy): Okay, thank you.

Natalie Highsmith: Okay, next question from the phone.

Operator: Your next question comes from (Nancy Pearce). Your line is open.

(Nancy Pearce): Thank you. My question is about the mood section with self-report. How can you accurately assess a resident - two types of residents; the first one who under-reports their mood symptoms for whatever reason, maybe they don't want to be labeled as depressed or anxious and then the second resident is the one who over reports their symptoms.

Debra Saliba: Yeah, I think that's an issue whether, you know, you're observing or using a structured survey. I can say that this structured survey has been tested in literally hundreds of thousands of patients and that it does a very good job of matching a Gold Standard clinician psychiatrist assessment of someone's mood.

And that - and it did so in our sample. I mean we found that the underreporting - you know, basically the prevalences that we found were higher than what were showing up with the observational items in 2.0. Could there still have been some patients that underreported? Possibly.

But when we look at it on the population level, the prevalences would tell us that that wasn't a significant problem and we picked up much - many more cases by going directly to and talking to the resident than we did with the observational approach to assessing mood.

The over-reporter, let just say, this is not a diagnosis of mood disorder or depression. It is a screening tool. And you know, it gives you a score and a categorization of the score that you can report to a mental health provider or to the primary care provider for that patient and then the assessment still needs to be made whether that person really has depression; clinical depression or not and whether their treatment should be initiated.

So you're not being asked based on just this interview to actually, you know, start someone on a medication or to initiate therapy. It requires, you know, a clinical confirmation of the items. Does that help?

(Nancy Pearce): It does, thank you.

Debra Saliba: Okay.

Natalie Highsmith: Next question from the phones.

Operator: The next question comes from (Nadine Edelman). Your line is open, ma'am.

(Nadine Edelman): Hi. My name is (Nadine Edelman) and I work in a SNF located in a hosp (unintelligible). My question is about Section 01, Special Treatments. Regarding my patients, they have multiple complex issues. I'm surprised that you haven't put better delineations for the IV meds with the chemotherapy with the radiation. We get very complex people that require a lot of care planning in that area.

I'm very surprised that there's no more additional questions there?

Debra Saliba: Yeah, could you send your question in to the Web site? The STRIVE team is looking at treatments and therapies and we can - they'll take a look at questions that you send about Section O.

(Nadine Edelman): Great, thank you.

Debra Saliba: Thank you.

Natalie Highsmith: Next question from the phones, please.

Operator: Your next question comes from (Roxanne Nelson). Your line is open, ma'am.

(Roxanne Nelson): Hi. I just wanted to tell you that we appreciate the attention from the Continued Care Leadership Coalition that you have put related to seeking residents' voice and the need to reduce the time to complete the MDS, so we really appreciate that.

Just wanted to know if there were any deadlines we should be thinking about in terms of providing comments - additional comments to what you presented today and in particular any timeline goals for developing training materials.

Robert Connolly: This is Bob Connolly. Yeah, we would like to hear your feedback, so mds30comments@cms.hhs.gov would be helpful. And you can send them in at any time. As I said before, we're formulating a training plan so ideas for training or what some of the challenges might be or we've asked before for recommendations of people who want to work on multi-disciplinary committees. So if you want to send us information, we're open to that.

And in terms of, you know, particular items you see that we'll need to focus on more, that would - we'd find that useful.

(Roxanne Nelson): Okay. That's great. Thank you very much.

Natalie Highsmith: Next question from the phones.

Operator: Your next question comes from (Theresa Fulweler). Your line is open.

(Joel Vanam): Yeah, this is (Joel Vanam) listening in with (Theresa Fulweler) here in Christian Care Center of Johnson City in Tennessee, and I just want to echo appreciate the efforts to reduce the time from those of us who think 112 is even a conservative figure for completing that - 112 minutes.

Also, I guess the question that was just asked, maybe I didn't quite hear the full answer, is there a timeline - in the timeline I didn't see, first of all, if there was any particular timeline for issuing training manuals and so forth. And then also, I wanted to know has there been any movement or - coinciding with this tool now in the pack; demonstration tool that's being worked on at this time?

Debra Saliba: I can answer the pack and then I'll turn the timeline over to Bob. So the - you're talking about the care tool that's being test.

(Joel Vanam): Yes.

Debra Saliba: And basically, I participated as a consultant to the care projects and they made every effort to have persons familiar with OASIS, persons familiar with IRF, persons familiar with the MDS process involved in their efforts to come up with a tool that they're currently testing in the demonstration project.

Several of the new ideas that you see in MDS 3.0 are actually included in the care demonstration project because they were able to benefit. Again, they were the kind of items that people were sort of waiting to use but they didn't know if nursing home residents could use them.

So once we were able to document that they could be used in this population then they knew they could incorporate them into a tool that looked across settings. But that's not to say that everything that's in the care tool is in the MDS 3.0, but it's still, you know, being tested and I don't know what will ultimately be recommended at this point.

Robert Connolly: Let me take a first shot at your timeline. We're interested in comments, but as I said in the beginning, we've completed this phase of the research and we don't have any Deb Salibas to continue this, so we will evaluate the comments and what you're bringing in to us and it may ultimately be used in later versions of MDS 3.0 versus this one.

But we would like to hear from you and we would like to have your feedback as you're seeing it, because as good as RAND is and as good as all our tests, we're not really practicing in your nursing home in your state with your Medicaid with your survey agency, with whatever.

So we appreciate the feedback but we're not - like the Town Hall meeting was give us your feedback and we'll integrate it into the new MDS 3.0. We're now reporting out what we think is the strongest findings that we have and are planning to move forward with them with any information you give us we'll look at, but what we'll do with it, we'll have to evaluate each one, one by one.

(Joel Vanam): Thank you.

Natalie Highsmith: Okay, next question from the phone.

Operator: Your next question comes from (Dan Vost). Your line is open, sir.

(Lois): This is (Lois). I'm sitting in with (Dan) and my question has already been answered. Thank you.

Operator: Your next question comes from (Debbie Labarren). Your line is open.

Your next question comes from (Lowell Feen). Your line is open.

(Lowell Feen): Yeah, I just have a question. How would you code deep tissue of injury, because according to the NPUAP, if you had been meeting with them, that there are now six stages and we're not seeing DTI on it.

Debra Saliba: Yes, you're right, DTI is not on this form. Basically when we went to the field, the recommendation to code DTI was not there. And again, our commitment to the field is that we're not going to give you items that we haven't tested in this form, and so we, at this point, aren't including DTI on the form.

What we would like to do is to include something in our instruction manual and we've asked for input from the organizations about language that we can put in, guidance that we can put into the instructions to help people as the field is evolving.

And as Bob has referred to, I mean, all these fields evolve and improve and, you know, in a few years, there may well be an opportunity to retest some of these items for inclusion.

But our decision, our commitment from the get-go was that, you know, it would only be items that really had been thoroughly evaluated and tested, being used in this form, not, you know, in, you know, individual separate research studies that got put into the form and that if an item didn't improve performance, we'd go back to the 2.0 version of it.

(Lowell Feen): Okay, thank you. I have one more question. With regards to the time management of completion, did you have like an average time, an average coordinator, a nurse completed, let's say, in the initial admission quarterly PPS or annual?

Debra Saliba: So all of our MDS 3.0 forms were full assessments. The 2.0 forms about half of the samples were admission assessments and the other half were either annuals or quarterly.

(Lowell Feen): What was the average time of completion for the MDS 3.0?

Debra Saliba: The average time was 61 minutes.

(Lowell Feen): Sixty-one minutes, okay.

Debra Saliba: And again, you know, this was with nurses that were just learning it, so...

(Lowell Feen): Learning, yeah, that's true. Okay.

Debra Saliba: We had sort of thought that actually we were going to be doing good if we sort of broke even with the 2.0 time. So we were very pleased that the times were better and hope that as facilities are able to retool to it, get their documentations set up for it, their pre-population set up for it, that you'll see

even more efficiency gains or as we start - as it moves, some of them will be quarterly and stuff, so...

(Lowell Feen): Okay, that is including RAPS? Does that include RAPS? Hello?

Debra Saliba: No. Neither estimate included RAPS.

(Lowell Feen): Okay. All right. Thank you so much.

Debra Saliba: Sure.

Natalie Highsmith: Okay, next question from the phone.

Operator: Your next question comes from (Joan Shorn). Your line is open.

(Joan Shorn): Thank you. We are a long-term care facility where the majority of our patients are either confused or with dementia. And so we're wanting to know will - in the case of a confused or a demented resident, will the MDS 2.0 be available to complete instead of the 3.0?

Debra Saliba: No, again, what we ask that you do - we went into this thinking that we were going to identify an absolute clear cognitive cut point below which we would say to you, don't interview this resident because if they have a score below this point, they're not going to be able to answer your questions.

What we found was that if you sat down, set up an environment where the resident could see you, talked clearly, made sure they could hear you, but even patients with diagnoses of dementia, even with patients with cognitive impairment, even some with severe cognitive impairment could answer these questions.

People with cognitive impairment can tell you how they feel. They can answer questions about their feelings, about pain. Are there some residents who can't answer these questions? Yes. And so what we tell you is that if they're not capable, if they're rarely or never understood, so we tie it off with an MDS item, if they need a language interpreter who's not present, or if you start to try the item with them, so they can make themselves understood, they don't need a language interpreter but you decide to try - so you should then try the item with them.

If they give you non-sensible answers that have absolutely nothing to do with what you're asking to three items, you don't have to finish the interview. You're done. You can then move on to doing the observational item.

For some of the sections like cognition, the observational item is your old 2.0 item. For other sections we've improved the observational item. It's still - it doesn't require an interview, it's observational, but it's based on newer science about how to do observations. And again, they worked when staff used them.

(Joan Shorn): Okay, thank you.

Debra Saliba: Okay.

Natalie Highsmith: Okay, (Rebecca), we'll take our final question from the phone.

Operator: Your next question comes from (Rhonda McKinley). Your line is open, ma'am.

(Rhonda McKinley): Hi, this is (Rhonda McKinley) and I'm calling from CB Home. Our question was just about the form. And I don't know if you know this yet, I see that there's questions that are only answered on admission or on follow-up assessments. Are there going to be other forms like a quarterly form or a short form PPS or are we going to have to use this 26-page form for all assessments?

Debra Saliba: Again, the form is 26 pages - the answer is yes. The plan is obviously to have the quarterlies and the PPS records for people. This is the full assessment, so we're getting you all the items that are there.

But again, let me emphasize that it's 26 pages because we didn't (squinch) down the font. We left white space. We put in logical page breaks. We could get it down to the same exact same number of pages that your 2.0 form is. But what we found was that this was easier for people to use when they go out and start trying to answer the items and it actually made it a little - and we've put some definitions on the form.

The other reason why it's the number of pages that it is is again, because we have these two options for a lot of sections. So for mood, mood now takes - we've got twice as much space for mood because we've got the interview version of mood or the staff version of mood. You're not going to be completing both on the same resident, but in terms of pages, it's there and accounted for.

So - and let me say, too, that we actually cut some items after the field trial. So those time estimates are based on the uncut version of the form, but we did cut some items because, again, they didn't work and we took them out.

(Rhonda McKinley): Okay, thank you.

Natalie Highsmith: Okay. We'll go ahead and end the call now. Any closing remarks?

Robert Connolly: We just thank each of you for your interest and we are very excited about the MDS 3.0. Deb and I are very proud and many of you have seen it through all its five years and I think it's really something that's hopefully going to be useful to each of you in your work. Thank you.

Debra Saliba: And before we go, I just wanted to thank everyone that I've picked up the phone and called and asked for help with a particular section or to give us feedback has been so generous in terms of helping us and really wanting to make this a better tool.

I have been just really amazed at the commitment to quality and the commitment to really trying to do a better job of taking care of residents and doing a better job of assessment.

So I just want to thank the field for all of the help that they've given us in getting this project done. So thank you.

Natalie Highsmith: Great. Thank you all, again, for joining us. (Rebecca) can you tell us how many people joined us on the phone?

Operator: Two thousand, seven hundred and sixty-eight.

Natalie Highsmith: Okay, wonderful. Everyone, please remember that the Web - I'm sorry, that the email address is mds30comments -- with an s -- @cms.hhs.gov for the folks that we did not get a chance to hear from today.

Thank you.

Operator: This concludes today's conference call. You may now disconnect.

END