

CATEGORY 10 – Outcome-Based Quality Monitoring (OBQM) REPORTS

Q1. Please clarify whether a start of care and a discharge assessment have to be within the time frame for the OBQM case mix report -- I thought that only the discharge or transfer assessment needed to be in the time frame.

A1. There are two forms of the case mix report -- one that accompanies the OBQM report and the other that accompanies the Outcome-based Quality Improvement (OBQI) report. Each case mix report includes the same patients whose outcomes are represented in the respective report. For the OBQM report, the episodes are required to have only a transfer or discharge within the specified period. For the OBQI report, the episodes are required to have both a start (SOC or ROC) and an end (transfer or discharge) within the specified period. Agencies should obtain the case mix report that corresponds to the specific report they are examining, as there may be slight differences.

Q2. Why is the term 'episode' used two different ways?

A2. As you identified, the term 'episode' is indeed used two different ways for the Medicare patient -- which is why it is important to clarify exactly what is being referenced when the term is used. The Medicare PPS patient has a 'payment episode' of 60-day increments, while this same patient also has a 'care episode/outcome episode' that begins with a SOC/ROC and ends with a transfer/discharge. Patients of all other payer sources have the same 'care episode/outcome episode,' but they do not have the same payment episode as the Medicare PPS patients do.

Q3. How would you calculate an increase in the number of pressure ulcers?

A3. This measure is calculated in the Adverse Event report. To calculate your own measure, please use the Technical Documentation of Case-Mix and Adverse Event Measures found on the OASIS web site at: <http://www.cms.hhs.gov/oasis/obqm.asp>.

Q4. Will Windows XP with Internet Explorer 6.0 work with the CASPER system?

A4. Internet Explorer versions 5.0, 5.5, and 6.0 have been tested and are currently being used with the CASPER Reporting application. Verify that Java Virtual Machine (JVM) is installed and enabled on your PC, and that Active X controls are also enabled. These components must be present to correctly view the reports.

Q5. Now that OBQI reports are available, when will the OBQM reports no longer be available?

A5. The OBQM reports are still and will continue to be available, but are now accessed the same way as the OBQI reports via the CASPER Reporting application. If you have a bookmark in your browser to the old OBQM application (before 2002), you should update that to coincide with the new link available from your OASIS State Welcome page.

Q6. Can we get a written procedure on how to retrieve OBQI/OBQM reports, or is that on the web site?

A6. A manual entitled *Accessing OBQI and OBQM Reports* is available at <http://www.cms.hhs.gov/oasis/obqi.asp> (scroll down to the heading, "Outcome-Based Quality Improvement Implementation Manual). Click on the link, "Download the OBQI manual zip file for the crosswalk" at #1 to get the entire *OBQI Implementation Manual* (the last section, "Accessing OBQI and OBQM Reports," provides instructions for downloading the reports). (The instructions for accessing the reports included in the OBQI Manual replaced the earlier instructions found in the OBQM manual in February 2002.) We recommend that you also download the *Supplement to the OBQI Manual* from the same page.

Q7. The OBQM QI process differs from the follow-up and monitoring of the OBQI system processes. Will HHAs be expected to apply all steps of the OBQI system to the OBQM adverse outcome events as part of their overall QI program?

A7. There are some differences in the quality improvement approaches suggested for use with the OBQM reports compared to the OBQI reports, but these differences are primarily 'cosmetic' rather than conceptual. Because the types of outcomes contained in the two reports are different, the QI processes also are slightly different. For example, all the outcomes reported on the OBQM report represent an adverse event for the patients noted -- therefore all these outcomes need to be investigated to determine whether quality of care issues are present. In contrast, for the OBQI report, you have some specific criteria to apply for selecting target outcome(s), which then is the focus of your QI activities. Both processes are patient care focused and involve review of the care provided to specific patients, the development of improvement plans, sharing of pertinent areas for improvement with agency staff, and ongoing monitoring to be sure that new/revised approaches to care delivery are occurring. Both also look to the subsequent reports for information on the success of your improvement efforts.

Q8. One of the disclaimers on the reports says that it is to be used by the home health agency and not to be shared. Can you clarify what can be shared and with whom and by whom? Which reports can be shared without infringing on patients' confidentiality rights?

A8. The risk-adjusted and descriptive outcome, adverse event, and patient tally reports are produced for the internal use of the Medicare-certified HHA and for use by the State survey agency for the defined purpose of improving the quality of care in the agency. These reports do not meet the privacy requirements required for public use. CMS has developed the publicly reported outcomes for that purpose. Reports with patient identifiable information (such as the information contained in the adverse event and patient tally reports) MUST be protected against release to the public.

Q9. How often will the OBQM reports be available - can I get a quarterly Adverse Event Report?

A9. It is possible to get monthly Adverse Event Reports; however, we recommend that reports be run no more frequently than quarterly. The first time you get this report you should you get it for the whole year. This is the default selection that will be made for you unless you make another selection. It is very important to have a picture of the pattern of adverse events over an entire year and also have a large enough sample of patients to conduct an investigation. After you have reviewed the Adverse Event Report

that represents an entire year, it is then appropriate to select the report for a quarterly review.

Q10. What is the recommended time period for reviewing the first OBQM reports and then subsequent reports?

A10. When the agency begins to review its Case Mix and Adverse Event Outcome Reports, we recommend that you review them using a one-year period. There will be more events in a full year's report and it is more efficient to initially look at a full year of data. Once you have done your first investigation(s) and put some improvement plans into effect, you can review them more frequently. We recommend that a quarterly report would be appropriate for monitoring your progress. As time goes by, you may find that the occurrence of some events is so low in your agency (depending on agency size) that you may choose to access the reports for a longer period, like a six-month time frame.

Q11. Should I investigate only the Adverse Events that are marked as statistically significant on my Adverse Event Report?

A11. No, not at all. The definition of an adverse event is a 'marker for a potential problem in care.' Over time you should look at all the Adverse Events on your report. It is important to prioritize your investigations based on the events of most clinical relevance to your agency. In contrast to the risk-adjusted Outcome-Based Quality Improvement Reports coming later, all adverse events in your report should be investigated. For additional information on prioritizing the adverse event outcomes for investigation, refer to Section 4 of the OBQM manual, 'Quality Monitoring Using Case Mix and Adverse Event Outcome Reports,' which can be found at: <http://www.cms.hhs.gov/oasis/obqm.asp>.

Q12. Which report is more important to investigate, the Case Mix Report or the Adverse Event Outcome Report?

A12. The Case Mix Report provides a picture (a snapshot) of what your agency's patients look like at the beginning of a care episode. It is useful for many decisions that require knowledge of your patients' characteristics, some of which are listed in Section 2 of the OBQM manual, 'Quality Monitoring Using Case Mix and Adverse Event Outcome Reports.' While the Case Mix Report is useful for your agency, it does not typically require 'investigation.' On the other hand, the Adverse Event Outcome Report is important for your agency to investigate, since these events serve as markers for potential problems in care provision. The Case Mix Report can assist you in prioritizing specific adverse event outcomes to investigate. For additional information on prioritizing the adverse event outcomes for investigation, refer to Section 4 of the manual, which can be found at: <http://www.cms.hhs.gov/oasis/obqm.asp>.

Q13. On the OBQM Report, what percentage of change in improvement can I expect after changing clinical practice?

A13. It is impossible to predict with any certainty the degree of improvement that can be expected for a given home health agency. A number of factors may affect patient outcomes, including patient characteristics, family and environmental factors, natural progression of disease/disability, and aspects of clinical practice. In addition, smaller agencies may experience greater variation in adverse event outcome incidence for

purely statistical reasons. Your goal should be to achieve a downward trend in adverse events, but we are unable to provide guidance as to the amount of improvement you can expect.

Q14. How quickly will the OBQM data be available to show response to the Quality Improvement process?

A14. Aggregated adverse event and case mix statistics are updated monthly. Because of the time allowed for home health agencies to encode and submit OASIS data, there will be a lag of at least two months between the time an episode of care ends and the inclusion of that episode in a report. We recommend a minimum of three months of data be included in a report for quality monitoring purposes. Therefore, it will require at least five to six months before a discernable response can be observed.

Q15. On the OBQM reports, why are adverse events considered significant only when they exceed a norm? Shouldn't zero adverse events be a goal? In my view, those that exceed the norm may be the highest priority cases but not the only ones that cause concern. Comment please.

A15. You are correct in stating that all adverse events should be cause for concern. As stated in the OBQM manual 'Quality Monitoring Using Case Mix and Adverse Event Outcome Reports,' page 4.1, all adverse event outcomes are worthy of investigation, and the comparison of your agency's incidence to the national norm should be used primarily for the purpose of prioritizing cases for investigation. Your goal should be to reduce the incidence of all adverse events, to the extent it is possible to influence them through the care you provide. The manual is available at <http://www.cms.hhs.gov/oasis/obqm.asp>.

Q16. On the OBQM reports, what constitutes the 'reference group' - is it a random sample or stratified in some way?

A16. The reference group is technically not a sample. It is based on 100% of OASIS data submitted by home health providers that are subject to Medicare conditions of participation (CoPs). The following criteria apply: OASIS assessments that fail to meet data specifications (due to missing or invalid data) are excluded; only Medicare or Medicaid patients are included; user-specified date range criteria are applied to the reference group data as well as to the home health agency's selected episodes of care.

Q17. In the Patient Listing on the OBQM report, what is the sort within each category?

A17. There are no explicit sorting criteria applied. The order in which episodes will be listed is determined by the order in which they appear on the database.

Q18. Where is the data for the Adverse Event Outcome report retrieved?

A18. The data for both the Case Mix Report and the Adverse Event Outcome Report are derived from the OASIS national repository. Aggregate statistics by agency are calculated monthly.

Q19. Can we get a Regional or State reference sample on the OBQM reports to help with benchmarking?

A19. Not at this time. Currently, only national benchmark data are available. We hope to enhance the report in the future with State, Regional and other benchmarks.

Q20. How can I possibly have time to do adverse event outcome investigations in my agency with everything else I'm doing?

A20. Effective use of time is important to every home health agency. Every agency currently is required by the Medicare CoPs to monitor the quality of care it provides. It is very possible to integrate the investigations of the OBQM reports into your current activities and make the investigations a true part of your agency quality-monitoring program. In Section 4: Using Reports from the Outcome-Based Quality Monitoring Process of the manual, *Quality Monitoring Using Case Mix and Adverse Event Outcome Reports*, which is available at <http://www.cms.hhs.gov/oasis/obqm.asp>, tips are offered on how to involve your staff in investigating these reports. Using a chart audit tool is recommended as an approach. For example, a chart audit tool can be developed for use (and reuse) by a number of staff in your agency's current quarterly record review processes. It is very possible to integrate this process into an agency's current quality-monitoring program. The agency, thus, is evaluating care on a quarterly basis, not simply examining whether the clinical record is complete, forms signed appropriately, etc.

Q21. Unless information is taken from a recertification and significant change assessment, the Adverse Events Outcome Report will not reflect a true picture of incidents that need further investigation. For example, a patient develops a urinary tract infection during a certification period and is re-certified and not discharged. The follow-up assessment is used for recertification purposes. The information is not included and the total percentages will be inaccurate. Will this change in the future?

A21. In December 2002, the OASIS data collection requirements were changed in response to industry requests. Those changes eliminated all OASIS items at the follow-up time points (RFA 4 and 5) **except** the payment items. The payment items do not provide enough information to incorporate the data from RFA 4 & 5 assessments into the Adverse Event reports.

Q22. Is there a place I could look up the definition of substantial decline in three or more activities of daily living?

A22. Yes, the definition of Substantial Decline in Three or More Activities of Daily Living is provided on page 5 of the appendix, 'Guidelines for Reviewing Case Mix and Adverse Outcome Reports,' found in the manual, *Quality Monitoring Using Case Mix and Adverse Event Outcome Reports*. The manual is found at <http://www.cms.hhs.gov/oasis/obqm.asp>. In short, the scale points to a decline of two or more levels in three or more activities of daily living categories (grooming, toileting, bathing, transferring, and ambulation/locomotion) in patients who are not terminal. Patients who could not have declined by two or more points in three activities of daily living are excluded from this computation. Note that the definitions of all adverse event outcomes are found in this same appendix.

Q23. Are the Adverse Event Reports case-mix adjusted?

A23. No, they are not. Because the events in the Adverse Event Report occur very infrequently, it is extremely difficult to risk adjust with a similar population. Many of these events started out as potential outcomes to be included in the regular risk-adjusted outcome report, but they occurred so infrequently that they could not be adequately risk adjusted. However, risk adjustment research is continuing and may result in our ability to risk adjust these events.

Q24. A higher current mean versus reference mean in many areas can be used as one of the tools in measuring quality of care provided by an HHA. In the Integumentary Status, for instance, 'Stage 2-4 ulcers present' and 'Stage 3-4 ulcers present' are two of the categories. Since we are not supposed to downstage decubitus ulcers, how does a finding of this clinical information on a Start of Care or a Resumption of Care reflect on agency practice?

A24. The items you identify are found on the Case Mix Report. Please refer to the definition of the Case Mix Report as a 'snapshot of what a home health agency's patients look like at the beginning of a care episode' (page 2.1 of the manual *Quality Monitoring Using Case Mix and Adverse Event Outcome Reports*, which is available at <http://cms.hhs.gov/oasis/obqm.asp>). The Case Mix Report merely describes your agency's patients -- it does not make any statements about the quality of the care you provide. The current means compared to the reference means on that report simply indicate where your agency's patients differ from the total home health patient sample during the report period requested. The Adverse Event Outcome Report and the Risk-Adjusted Outcome Report should be used to evaluate the quality of your agency's care. Reverse staging (down staging) pressure ulcers is NOT appropriate clinical practice, as noted in the Item-by-Item Tips for the OASIS items (Attachment B to Chapter 8 of the *OASIS User's Manual*) available at <http://cms.hhs.gov/oasis/usermanu.asp>.

Q25. The Adverse Event Outcome Report and Patient Listing, contains identifying information about the patient (name, birth date). The only OASIS data that we send to CMS containing identifiers are the patients being billed to Medicare or Medicaid for home health services. The other OASIS data for the patients whose home care billing is other than Medicare or Medicaid are transmitted with masked identifiers. Are we to assume that the Adverse Event Outcome Report, the Patient Listing, and the Case Mix Report contain only those patients for whom Medicare or Medicaid has been billed?

A25. At the present time, the Adverse Event Outcome Report, the Patient Listing, and the Case Mix Report are a picture of only your agency's Medicare or Medicaid patients since these are the only patients for whom you are required to transmit OASIS data to the State.

Q26. How do you derive the statistical significance in the Case Mix and Adverse Event Reports?

A26. In both reports, statistical significance is based on standard tests for differences between proportions, or in the case of scale values, differences in means. They are explained briefly in the appendix entitled, 'Guidelines for Reviewing Case Mix and

Adverse Outcome Reports' (found in the manual, *Quality Monitoring Using Case Mix and Adverse Event Outcome Reports*, which is available at <http://www.cms.hhs.gov/oasis/obqm.asp>) on pages 2 and 6. The actual statistical tests used are: Chi square or Fisher's exact test for differences in proportions, and the T test or Mann-Whitney test for differences in means.

Q27. Where does information about unexpected deaths on the Adverse Event Outcome Report come from?

A27. The definition of Unexpected Death is included in the appendix entitled, 'Guidelines for Reviewing Case Mix and Adverse Outcome Reports' found in the manual, *Quality Monitoring Using Case Mix and Adverse Event Outcome Reports*, which is located at <http://www.cms.hhs.gov/oasis/obqm.asp>. It is defined as a discharge due to death (reason for assessment = 8), combined with a life expectancy at start/resumption of care greater than six months (M0280 = 0).

Q28. Can a corporate office get a password to access all of its HHAs' OBQM reports?

A28. If an agency uses its corporate office to submit OASIS data, the corporate office must have the required password and ID to submit the OASIS data. In this case, the corporate office would be able to retrieve the OBQM report for each agency by using the required individual agency password and ID. Beyond that, there is no access for a national corporate office to access all the reports at one time. If an individual agency manages its own OASIS data transmission process, then only that HHA can retrieve the OBQM reports.

Q29. Do we use the same log-on and password to get our OBQM and OBQI reports that we use to submit OASIS data to the State?

A29. Yes. For HHAs, the login and password you currently have for submitting OASIS data to the State is the same as you will use to request OBQM and OBQI reports. State surveyors and CMS Regional and Central Office staff need to request a login and password from CMS Central Office. The password and login will be sent by secure means to the approved user by the State OASIS Automation Coordinator.

Q30. Can I request more than one outcome report at a time?

A30. Yes, multiple reports can be requested in the same submission by simply checking multiple check boxes that precede the report. When you request multiple reports, they will all display in the 2-column or the 3-column format.

Q31. What is a Plug-In and why do I need it to view OBQM or OBQI reports?

A31. A Plug-In is a program that allows your Internet browser, i.e., Netscape or Internet Explorer, to do things that it normally couldn't do. In this case, it allows you to view the OBQM or OBQI reports that you request. If you have been accessing HHA web reports so far, you have already installed the Plug-In and don't need to download it again.

Q32. Could you explain the default dates for the OBQM reports again?

A32. The two-column report defaults to a twelve-month period ending two months prior to the current month. Example: Suppose you request a report in July 2002. If you backed up two months (June - May) the current default end date would be April 2002 and your current begin date would be May 2001. The three-column report works the same way except it defaults to a 3-month period instead of a twelve-month period. Each report's default setting is to a 2-column report with the default date period being one year. As it was pointed out earlier, the HHA should first use the default period to request reports to give them an entire year's worth of data.

Q33. Why must you log off and come back later to view your OBQM and OBQI reports once you've selected them?

A33. Your OBQM and OBQI reports won't be available immediately. We don't know how long it will take for the report to complete its run so we suggest that you log off and come back at a later time to retrieve it.

Q34. Please review the printing instructions for printing the OBQM and OBQI reports.

A34. A 'Printing Instructions' button is located in the lower left hand corner of the OBQM and OBQI request and response page. In order to print the report simply right click on your mouse anywhere on the report and select 'print' from the drop-down box.

Q35. Will surveyors have access and use the Adverse Event Outcome patient listing report for HHA survey?

A35. Yes, the State survey agency will have access to the OBQM/I reports in the pre-survey process to target their on-site investigations. The surveyors, who have been authorized to use the OASIS State system, will have an individual password that will allow them to access an agency's reports directly in a confidential and secure manner.

Q36. Now that we have Adverse Event Reports, will utilization review no longer be required?

A36. The advent of the OBQM reports does not eliminate the requirement for the HHA to evaluate its program as stated in 42 CFR 484.52. The OBQM reports could be incorporated into the HHA's process for administrative and clinical record review as part of the required agency evaluation required under the conditions of participation at 42 CFR 484.52.

Q37. With the new outcome-based focus to the survey, what current requirements are patient oriented?

A37. Many sections of the conditions of participation (CoPs) are focused on the patient. The comprehensive assessment is certainly a critical CoP that is focused on the patient and is important to planning adequate care. The Plan of Care (POC) condition outlines key elements that are expected to be included in planning care for the patient. The Coordination of Care standard is also outcome oriented. Surveyors investigate how the agency coordinates care and how staff assignments are made to take care of the patient. Surveyors look at compliance with the coordination of patient services standard at 42 CFR 484.14(g), to see if staff communication supports the objectives outlined in

the POC. For example, they will assess how the physical therapist communicates with the nurse, how the nurse communicates with the home health aide, thereby evaluating if HHA staff all know what's happening with the patient and are following the POC. The drug regimen review is also patient focused and is another critical standard. It is required as part of the patient comprehensive assessment and is a crucial step toward providing patient care and improving outcomes of care.

Q38. I am curious about whether the surveyors consider the fact that, when patients were discharged from the agency, the goal was to educate the primary caregiver or family member to continue the care. Say the patient was discharged to the community still requiring wound care and toileting assistance. The goal may not have been for the wound to be healed or the person to not need toileting assistance. These things--termed adverse events--when the goal may have been to discharge the person from the agency to the care of the primary care giver.

A38. It is important for agencies and surveyors to fully understand the definition of each Adverse Event Outcome. (These definitions can be found on page 5 of the appendix, 'Guidelines for Reviewing Case Mix and Adverse Event Outcome Reports,' found in the manual, *Quality Monitoring Using Case Mix and Adverse Event Outcome Reports*, which is available at <http://www.cms.hhs.gov/oasis/obqm.asp>). For example, the Adverse Event Outcome of Discharged to the Community Needing Wound Care or Medication Assistance indicates that the patient was discharged to the community without paid or resident assistance, while confused or nonresponsive, and while unable to take medications without assistance, or with either a Stage 3 or 4 pressure ulcer or a non-healing surgical wound. Such patients will not have a primary caregiver identified on the discharge assessment. Extenuating circumstances MAY have been present, however, which is why the surveyors will not look at the Adverse Events Report and the Case Mix Report in a vacuum. They will be looking at what's happening to that patient, what's happening with the plan of care, the comprehensive assessment, what the goals were, and what the agency was trying to accomplish. They will look at the total picture of what is happening to that patient. Surveyors also assess whether the HHA investigated the reason(s) why a patient was identified on the adverse event report and whether it was related to care practices or omissions in care planning and delivery.

Q39. What is the regulatory basis for an agency's use of the OBQM Reports?

A39. Since the beginning of the home health benefit, agencies have been required to conduct an annual evaluation of their total program, including patient services. Agencies are also required to conduct quarterly clinical record reviews to evaluate the care provided under the agency's policies. The conditions of participation (CoPs) require an agency to have policies and procedures to promote patient care that is appropriate, adequate, effective and efficient. With the availability of OBQM reports, which are based on OASIS data submitted to the State as required by regulation, we would expect agencies to integrate these reports into their evaluation and patient care review programs. We expect HHAs to incorporate a review and investigation of these reports into their evaluation program and to include them as part of their quarterly record review.

Q40. Could you tell us who in the State survey agency will be involved with the OBQM reports?

A40. Initially, it will be the OASIS Education and Automation Coordinators, as well as the home health surveyors. The OASIS Coordinators will continue to work directly with the home health agencies to help them access and review the reports. In addition, the OASIS Coordinators will expand their current OASIS support and training to State surveyors to include assistance with accessing and interpreting the OBQM reports.

Q41. Will the surveyor look at an agency's OBQM reports before they arrive at the agency for the survey?

A41. Yes. We revised the State Operations Manual in August 2001 to include instructions to surveyors to review these reports as a part of their pre-survey preparation at the State agency. This will help surveyors because it will give them a preliminary picture of the agency's case mix, as well as some idea of what's been happening during a recent time period. For example, surveyors can now know before they arrive at a particular agency how many Medicare and Medicaid patients the agency has who are receiving skilled services and what percentage of the patients are elderly, live alone, have diabetes or open wounds or have had a fracture. This will help them determine their sample selection for record review and home visits. They can also use some of the information to identify areas they want to focus on while they are conducting the survey before they go to the agency. Refer to **S&C-03-13** memo at <http://www.cms.hhs.gov/medicaid/survey-cert/sc0313.pdf> for details on the enhanced survey process.

Q42. Can you give an example of how the surveyor may use the Case Mix Report as part of the survey process?

A42. Surveyors will review the Case Mix Report before they arrive at the agency for the survey. This review will give the surveyor a quick sense or 'snapshot' of the type of Medicare and Medicaid skilled patients this agency admits and what they will likely find when they are on site. We recommend surveyors review the Case Mix Report as described in the OBQM Manual that is available at <http://www.cms.hhs.gov/oasis/obqm.asp>. Surveyors should review the report, identify any significant results, and note report highlights. Focusing on report highlights will allow the surveyor to begin to identify potential clinical groups of patients that could be included in their record review and home visit samples and will help identify focus areas to be investigated on site. For example, in the Case Mix Report for Faircare, the sample in the OBQM manual, the surveyor would likely note that, compared to the nation, Faircare has a higher percentage of patients with pressure ulcers and a much larger percentage of stage 3-4 pressure ulcers. In addition, a larger percentage of Faircare's patients have urinary catheters and UTIs, and their most frequently occurring acute conditions are open wounds and cardiac conditions. Based upon the report highlights, the surveyor would likely include patients with pressure sores, urinary catheters, and wounds in their record review or home visit samples. The surveyor could also plan to interview agency staff about their comprehensive assessment process and care protocols. Refer to **S&C-03-13** memo at <http://www.cms.hhs.gov/medicaid/survey-cert/sc0313.pdf> for details on the enhanced survey process.

Q43. During the survey what will the State survey agencies do with the OBQM reports the agency has run?

A43. Surveyors will be interested in looking at both how the agency reacts to its reports and what it does in response to its reports. We expect agencies to use the information in the reports to improve outcomes for their patients. For example, surveyors will look at the Adverse Event Report and may ask about any investigation the agency has done on the reasons or possible explanations for any of the documented adverse events. They will also want to discuss how the agency prioritized any investigation to improve the care delivered to patients. Surveyors will also be interested in the agency's review of their practices, policies, and procedures. They will be looking to see if the HHA's policies and procedures may have played a role in any way in contributing to a negative outcome. The main thing they will want to understand is how the agency uses the information as a part of their overall agency evaluation to improve care and to address any systemic issues that may be present to prevent similar adverse situations from occurring in the future.

Q44. Will the surveyors use the information in these reports to give the agency an automatic deficiency?

A44. We understand there is some concern about automatic deficiencies. Surveyors will not look at the Adverse Event or Case Mix Report in a vacuum. At this time, CMS has not given any direction to surveyors to take a certain action based upon a single value contained in one of these reports. Rather, surveyors will take a look at the reports and review them in light of all information they gather during the survey. The reports were primarily designed for the agency to use and to help the agency improve outcomes for their patients. Use of these reports by the surveyor is secondary to this focus.

Q45. Will HHAs be cited if more than 2% of their patient episodes are in any of the 13 adverse event categories?

A45. CMS currently does not have any thresholds in place to enforce an automatic deficiency citation based on the reports. Our expectation is, of course, that agencies will investigate any adverse events to determine if quality of care is an issue--but we don't have any thresholds in place at this time. We do say that agencies should prioritize those adverse events that are higher than the national reference group, but they should not ignore ANY of the adverse event outcomes. They should investigate all adverse events, even if the incidence is lower than the national average.

Q46. Can you elaborate on the statement that surveyors will not use the OBQM reports in a vacuum?

A46. The overall purpose for conducting a survey is to assess the agency's compliance with the Medicare conditions of participation (CoPs). Surveyors do this by gathering information in a variety of ways: talking to staff, reviewing records and plans of care, understanding how the agency collects OASIS information and assesses patients, talking to patients and family members, and then evaluating their findings. One of the many things the surveyor will want to know is if the care provided to any patients identified in the Adverse Event Report was due to any non-compliance with the CoPs on the part of the agency. If there was non-compliance on the part of the agency, the agency will be expected to correct the deficiency; if no non-compliance is found, there isn't a problem.

Q47. What are some examples of some adverse events and actions the surveyor may take as part the survey investigation?

A47. In the adverse event called, 'Emergent Care for Wound Infections/Deteriorating Wound Status,' surveyors can review the patient's comprehensive assessment and plan of care to see if the emergent care was appropriate, because not all emergent care will be seen as a negative. A patient with a wound that is deteriorating with no apparent response from the clinician is a very different scenario from the patient who receives prompt attention from the clinician that ultimately results in appropriate emergent care. The surveyor will also investigate if any additional action on the part of the agency could have prevented an emergency room visit or prevented the wound from deteriorating. For example, surveyors may review the agency's clinical notes to see how it evaluated the patient during the visits and determine if the agency notified the physician promptly of any changes that suggested a need to alter the plan of care. This relates to the plan of care requirements. In the adverse event called, 'Emergent Care for Injury Caused by Fall or Accident at Home', surveyors may review the comprehensive assessment to see if any identified safety hazards were discussed with the patient and review if the plan of care included any safety measures necessary to protect against injury, as required by the plan of care condition. Surveyors will also review the patient's condition, diagnosis, medications and plan of care to identify whether the agency used the comprehensive assessment to make sound care planning decisions appropriate to the patient's needs. Any number of factors can contribute to the risk of a patient falling: the patient may be confused or forgetful, might be dizzy or weak, might have low blood sugar, might abuse drugs or alcohol, or he/she might be non-compliant with a piece of equipment. If these risk factors were present, we would expect the agency to identify them and plan appropriate interventions.

Q48. Is the requirement to review and investigate the OBQM reports a new burden on agencies?

A48. Agencies have been required to review clinical data and evaluate their program in order to improve patient care and outcomes as part of the conditions of participation (CoPs) for over 35 years. We expect that many agencies already generate quality-monitoring reports that may look very similar to the OBQM reports.

Q49. Must HHAs write an official report of the quarterly review and develop an action plan based on the OBQM Reports?

A49. Agencies currently have a requirement to complete an overall evaluation of the agency's total program and to complete a quarterly clinical record review. We expect HHAs to begin to download the OBQM reports from the State OASIS server, and to start using the reports to begin improving care to the patients of the agency. The HHA is expected to incorporate this information into the quarterly record review. Keep in mind that the reports only include Medicare and Medicaid patients, so the agency needs to incorporate all patients the agency has accepted for care into their quarterly record review and evaluate their care also.

Q50. How will surveyors review information about the annual evaluation requirement if it's not part of the standard survey?

A50. Reviewing the information about the evaluation of the agency's total program is not part of the standard survey; however, evaluation of the agency's program is part of the Medicare conditions of participation (CoPs) and we would expect Medicare-approved agencies to maintain compliance with all of the CoPs at all times.

Q51. When will HHAs be required to incorporate the OBQM reports into their agency evaluation programs?

A51. OBQM reports have been available since February 2001. We expect agencies to incorporate the reports into their annual evaluation and quarterly record review. These reports contain valuable information to assist the HHA in improving the care they deliver to patients.

Q52. Are the OBQM reports in compliance with the Health Insurance Portability and Accountability Act (HIPAA) regulations?

A52. HIPAA regulations required HHA compliance by October 2003. OASIS and associated reports (i.e., case mix, adverse event and risk-adjusted outcome reports) are HIPAA compliant as applicable.