## All you need to know about mock inspections

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Mock inspections are a great way to prepare for real-life inspections from regulatory agencies such as CAP and JCAHO. But where do you start? And most importantly, what should you look for?

Lou Ann Wyer, Clinical Specialist, POCT at the Virginiabased Sentara Laboratory Services and Theresa Kulik, Point-of-care Coordinator at Advocate Health Care Hospitals in northern Illinois tell you everything you should know about mock inspections.

acutecaretesting.org: Why are mock inspections so important?

**Lou Ann Wyer:** It is important to get the site prepared for inspection.

With a mock inspection you can identify some deficiencies you may have before the actual inspection takes place. My facility is both CAP and JACHO inspected. For JCAHO, we do periodic performance reviews, and that complements our CAP program in some ways. But when we do a mock inspection for CAP,

we go over the specific CAP standards, which are the point-of-care checklist and the general checklist for us. During our weekly visits to our units, we check the QC logs and check for overall unit compliance.

However, it can be very helpful to get feedback from staff, and the interaction with them is usually better achieved when done through a mock inspection. Plus, it takes away some of the anxiety normally associated with inspections.

Theresa Kulik: I agree with Lou Ann.

In addition to finding deficiencies, when doing a mock inspection you may also find some strong points. It is always important to provide positive feedback whenever possible, along with addressing the negatives. Doing well during a mock inspection can ease anxieties and build confidence levels for when the real inspection comes. It is also a good way for the point-of-care coordinator to get a feel for how *"inspection-ready"* their program is, and it can reveal the areas that need additional assistance. No one likes non-compliant surprises, but it is better for you to discover these deficiencies than your regulatory surveyor.

acutecaretesting.org: Once you decide to make a mock inspection in your facility, where do you start?

**Theresa Kulik:** I start by reviewing the regulatory agency's standards, which for me is JCAHO. The standards serve as guidelines, telling you what practices must be in place and what you will be held accountable for.

The next step is reviewing the previous survey report, if there is one, to make sure that any past issues have been resolved. Were there areas that were cited for deficiencies? Has an action plan been implemented to resolve them?

Additionally, hopefully you have done some monitoring to make sure your action plan has been successful. You can be assured that your surveyor is going to be looking at your previous problem areas. This is definitely something you should spend some time on.

acutecaretesting.org: And based on that, you put together an agenda?

**Theresa Kulik:** Exactly. To just start walking and roaming around to your different sites may not very constructive. It is better to put together an agenda or action plan to determine where you should go. To do that, I would take a look at all the different areas where POCT is performed, what kind of testing is performed and what kind of volumes we are talking about.

When being inspected, it is usually not possible to go to every site, and the focus tends to be in areas where the testing is a little bit more complex. But you want to make sure that you touch base with all types of testing that is being done at your site. If everybody is doing glucose testing, make sure you go to a site that's doing glucose.

Volumes are important as well. If there is an area that is high-volume, you will want to look at that, but it is just

as important to touch base with an area where they do low volume, so you make sure they haven't forgotten things.

acutecaretesting.org: And how do you make sure you cover all bases?

**Theresa Kulik:** I think it is important to have a checklist of the things you want to review at each site.

When you start talking to staff at a site, you may forget things that could be critical to look at. The checklist will remind you of the important points you want to be sure to cover during your inspection. It is worth the effort to put together a checklist before you go out and start doing your survey.

acutecaretesting.org: Is this something you do alone?

**Theresa Kulik:** As a point-of-care coordinator, you are the person with the most knowledge about your POCT program, but having other individuals with different perspectives can assist in the overall assessment of your program. When putting this team together, ideally I would like to have someone from nursing, because they are the ones usually doing the testing, and maybe somebody from administration.

In my facility, that would be the Director of Clinical Excellence who oversees all the quality programs in the hospital. The Director of Clinical Excellence at my facility is very knowledgeable in the overall hospital surveying process. Funny enough, when you have hospital administrators walking around with you, it makes an impression on the staff that the hospital administrators feel point-of-care testing is important. This is often a struggle for POC coordinators who find that nursing may not consider (decentralized lab) testing as important as their nursing tasks.

The administrator's participation and support is valuable in helping to change the perception that this is not a priority. At any rate, having different perspectives is beneficial to the process. Nurse representatives and administrators can focus on things that they have expertise in, such as patient safety goals or environmental issues, which leaves the POC coordinator time to focus on lab testing priorities.

So my advice would be to try to set up a team, so you are not out there doing the mock inspection by yourself.

acutecaretesting.org: How do you go about notifying all the point-of-care site managers and any other departments that a mock survey will be taking place?

**Theresa Kulik:** I send out an e-mail to all parties, saying that in the next few weeks a mock surveyor may be visiting their units and that cooperation is expected.

It is important that these sites are notified beforehand, so they are aware that if we come to their unit they are expected to make time for us – just as if we really were the real inspectors.

If there is a code blue going on as we approach the site, we will of course respect that and come back later, but they need to know that saying they are busy will not excuse them from answering your questions. We have to have a different mindset, as our inspections from now on will be all unannounced. We have to realize that it is very possible that surveyors will visit at a very inconvenient time – the mock inspection provides us with the opportunity to learn how to cope with an unplanned surprise.

It is probably a good idea to include higher-up managers in your e-mail notifications so that it is clearly understood that the mock inspection is not an optional exercise and that findings will be shared with the hospital administration. This tends to re-emphasize the importance of the mock survey.

acutecaretesting.org: Do you also review records as part of this process?

Theresa Kulik: Absolutely. I review records such as proficiency testing to make sure documents exist and

are complete... and make sense! Especially in this day and age of unannounced inspections, you have to make sure your records are easily accessible.

One thing I would recommend that you do when reviewing the records is to ask yourself if these documents would make sense to a non-lab person. Make sure your records clearly show that your POC testing is compliant. Then, I go ahead with the actual inspection using the tracer methodology. The tracer methodology uncovers things the former survey process didn't.

Previously, the surveyor had a laboratory mindset: he or she would look at the quality control records, make sure everybody's training/competency documentation existed and so forth, but they didn't necessarily look at the postanalytical process such as patient's charts. The tracer process takes you through the whole patient testing process: preanalytical, analytical and postanalytical.

**acutecaretesting.org:** What is your focus when doing the survey?

**Theresa Kulik:** For any point-of-care program to be truly successful people need to be open to improving things. And that is one of the things the mock inspection gives you: an opportunity to see areas that can be improved; this includes things that a surveyor may not necessarily be looking at.

During your mock survey, for example, you may discover a workflow process that could use some changes to make it more efficient. However, making sure you are compliant with all of the regulatory standards would be your primary focus.

acutecaretesting.org: How do you share your mock inspection results?

**Theresa Kulik:** The results are put into a report that is sent to the management staff. I think feedback is very important, and positive feedback is just as valuable as the negative.

The negative you have to give – you just cannot be non-compliant – but positive feedback makes them feel good about themselves. It tends to make them less defensive and more open to make changes within the areas they are not so perfect in.

The report also informs them that non-compliant findings need to be addressed with action plans for improvement. I usually try to give them some suggestions of possible corrective action plans. These suggestions may include something I have seen on another unit, which is working well.

Normally, a meeting is arranged after these reports are distributed where we discuss the various options and determine what we will implement.

**acutecaretesting.org:** Lou Ann, is this any different from what you do in your facility – especially when preparing for a CAP inspection?

**Lou Ann Wyer:** We do pretty much the same thing as Theresa is describing. We send out a notice to key people in the units and we also use checklists of what should be reviewed at each site.

I'm very fortunate to have point-of-care coordinators to cover each facility, so what we do is switch roles, so that a person overseeing site A will switch over to site B and so forth, to do the mock inspection. It is a different set of eyes, and they can see if there is anything missing or if something has been overlooked. That is very helpful.

We don't have someone from administration helping us with the mock inspection, but our units are just used to seeing point-of-care coordinators out there all the time, asking questions and so forth, so that is usually not a problem.

acutecaretesting.org: You mentioned in the beginning of the interview that mock inspections help take away some of the anxiety that is normally associated with real-life inspections. Is preparing operators to answer some of the questions by an inspector a part of this effort? **Lou Ann Wyer:** It is important to make sure the staff is prepared and can answer the questions.

What we are seeing with the inspections is that instead of asking the point-of-care coordinators or the unit managers, the inspectors will ask questions directly to the staff performing the test. So each and every single person has to be comfortable explaining how they perform the test, what they do when they get a critical value, where they find their supplies, how they date them, how they do quality control, where they keep the QC logs, etc.

They need to be comfortable in answering these questions. They know what they do everyday; they just need to be confident that they have the right answers. And that's what we are trying to do: prepare them by asking some of the same questions an inspector would ask.

**Theresa Kulik:** Sometimes you will find that people will not know how to respond... they may get a little nervous. It is not that they don't understand the questions being asked or that they are not practicing proper policy, but they may not always know how to verbalize what they are doing or why.

**Lou Ann Wyer:** Right, and they may not use the same terminology. So it is important to practice the questions and expected answers with the staff. And you can do that by practicing in a mock inspection situation.

acutecaretesting.org: When doing mock inspections, what are the specific things you look for?

**Lou Ann Wyer:** If I'm going to a site to conduct a mock inspection or an actual inspection, I'm going to be looking at what kind of tests are being done in each unit to get a scope of the program. How many difference devices and technologies are they using?

Then I look at test volumes: look at high- as well as lowvolume units and again see what kind of devices are being used and how many. Are there different types of devices being used to do the same test? Are they using three different devices to do coagulation? How many glucose meters do they use? Inpatient, outpatient, OR, ED: each one of these may have different ways of operating. Does that have any effect in the way they do the testing?

acutecaretesting.org: What else do you look for?

**Lou Ann Wyer:** Testing manuals. We need to make sure we are doing what we say we are doing, and the policies and procedures need to reflect that.

However, with the new unannounced CAP inspections, some policies and procedures may be under development and revisions may be at different stages of their documentation process. For me, that is one difficult piece of an unannounced inspection. With unannounced surveys, you are not always perfect; and I hope the inspection teams will be instructed to inspect with that [different] perspective.

We are going to have proficiency surveys that are waiting for pathology signature, etc. We are invariably going to have things in process...

**Theresa Kulik:** I'm also the quality coordinator for the laboratory, so I also work with CAP. I have hopes that inspectors will see the overall picture, i.e. that your lab program has a solid foundation.

Hopefully, they will understand that at times your procedures, for example, may not always be reviewed exactly on the date it is due, but that annually reviewing does occur.

**Lou Ann Wyer:** Another thing I look for when doing mock or real inspections is proficiency-testing records.

Proficiency testing must be organized. I stress that, because I have been on inspections where proficiency surveys are presented with folders that are stuffed with papers sticking out all over the place. You spend more time trying to organize for them than actually finding what you are looking for.

So if I am going to inspect or if I am going to do a mock

inspection at my facilities, I want to make sure that all the information is not only there, but tabbed and in order, and that everybody keeps it that way.

Organization, not only with proficiency testing, but also with quality control records, procedures, etc. is key to getting through an inspection.

**Theresa Kulik:** Organization gives a positive first impression of the facility. If your documentation is well organized, it gives the impression of a program that is well run.

First impressions sets the tone and you want to begin the day in a positive light. If your facility is inspected and, for some reason, you are out of town, it will be important that your colleagues and surveyor can make sense of your documentation.

Keep your books organized and in a known location.

**Lou Ann Wyer:** Right. Another thing that goes with organization is making sure that you have someone that can cover for you, if you are not there. Someone who will know where all the records are, who is going to know your job well enough to provide inspectors with the information they need.

**acutecaretesting.org:** You mentioned quality control records. What do you look for in these records?

**Lou Ann Wyer:** If I'm doing the inspection, there are things I want to look at to assess the quality of the program.

For example, how often has QC been done over the last 6 months, acceptance studies as new lot numbers are received, method comparisons, validations for new tests, instruments... I also look at maintenance records showing that maintenance is done on the equipments as required.

Training and competency records are also important. At Sentara, we keep track of who has been trained, when they have taken their competencies, which actual tests they have taken and what their expiration dates are. We keep track of the dates they completed the competencies, whereas the results are kept in their employee's files. The nursing managers need to make sure that the filing of those records are up to date, so now it's not only a matter of making sure the lab has everything filed.

With 5,000 point-of-care operators, this task alone can be a little overwhelming.

acutecaretesting.org: How do you make sure it does not get too overwhelming?

**Lou Ann Wyer:** We have continuous checks, so all of this doesn't come all of a sudden – it is more of a continuous follow-up.

Some of our units are already using a web-based competency program that automatically keeps record of competencies. This is something we would like to do for all of our units across the different types of testing.

Ideally, we would merge all of our records, so we would have a single record for competency showing aptitudes and the respective expiration dates for them.

If we could automate all of that, it would make things a lot easier for everybody. But for an organization to purchase something like that is a big endeavor.

acutecaretesting.org: What kind of a system do you envision?

Lou Ann Wyer: I would like a system to be customizable, so we can change it according to our needs and target questions towards different issues. I would not want a standard program where operators would take the same tests every year, over and over again. We would want to update it, even though that would require additional resources. Nevertheless, I think it is an issue we need to be able to move ahead on for the future.

acutecaretesting.org: Inspections, whether mock or real-life ones, are about ensuring quality. Is

it important to have a dedicated quality program for point-of-care?

**Lou Ann Wyer:** Absolutely. The program helps you focus your efforts and that of the people you work with. And if you follow it, chances are that passing an inspection, mock or real, will be somewhat easier.

## Tips for preparing for a mock inspection

- 1. Review the regulatory agency's standards
- 2. Review the previous survey report and make sure any issues have been resolved
- 3. Organize mock survey agenda
- 4. Design a checklist of what you want to review at each site visited
- 5. Form a mock survey team of various individuals: lab, nursing and administration
- 6. Notify all POC site managers and the departments you will be visiting
- 7. Review records to make sure documents exist and are complete
- 8. Conduct mock survey using tracer methodology
- 9. Look for improvement opportunities when surveying
- 10. Provide feedback to point-of-care sites after survey
- 11. Work with areas that need action plans for improvement

## Things to look for during a mock inspection

- 1. POCT test menu
- 2. Test volumes
- 3. Equipment list
- 4. Testing locations
- 5. Complete testing manual
- 6. Proficiency survey testing results, organized
- Quality control results for each test can include: daily/monthly QC, acceptance studies, method validations, new instrument validations, method comparisons, AMR, linearities
- 8. Maintenance records
- 9. Training & competency records
- Quality Program/ Performance improvement activities