

**THE JOINT COMMISSION TELECONFERENCE  
ANTICOAGULANT MEDICATION ERRORS  
SEPTEMBER 24, 2008**

**CATHY BARRY-IPEMA:** Hello and welcome to The Joint Commission news conference about anti-coagulant medication errors. Two Joint Commission health care safety experts are joined by experts from US Pharmacopeia to discuss why these medication errors occur and steps that health care organizations can take to reduce the occurrence of these devastating mistakes.

With us is Dr. Mark Chassin, president of The Joint Commission, Dr. Peter Angood, vice president and chief patient safety officer; and Diane Cousins, vice president for the Center for the Advancement of Patient Safety at US Pharmacopeia, and they will all offer brief remarks. Then we will take your questions.

Before we get started, I want to remind you that a complete press kit, which includes the *Sentinel Event Alert* on preventing anti-coagulant medication errors, bios for our three speakers, and other related information is available on The Joint Commission website at [www.jointcommission.org](http://www.jointcommission.org).

Now I'd like to introduce Dr. Mark Chassin.

**DR. MARK CHASSIN:** Good morning or good afternoon depending on where you're located. Thank you very much for joining us today to discuss a problem that continues to challenge health care organizations and caregivers and has caught the attention of the public. Blood thinners, the informal name for anti-coagulation medications, have caused serious harm in a variety of incidents over the years and including very recently, they cause harm to babies and adults in very different settings across the country. These medications, when used appropriately and safely, are life-saving and they prevent very serious conditions like stroke and other problems that are indeed beneficial to patients.

But the reason that they are so difficult when it comes to medication errors is that the difference between an appropriate and life saving dose and an excessive dose or insufficient dose is very, very narrow. A little bit too much can cause severe bleeding. A little bit too little can fail to prevent the clotting problem that the medication was intended for. They have been widely known and widely used for years, but they are subject to medication errors through a very, very broad array of different reasons, including confusing labeling and packaging, monitoring processes that break down, miscommunication and misinformation and misadministration.

Medication management across a number of different areas is one of the most complicated and complex in terms of systems in health care and these medications are subject to all of the problems that all medication systems are plagued with, but cause more serious harm when those problems arise. This problem is so damaging that in addition to the section in The Joint Commission standards manual that requires hospitals and other organizations to be able to manage high risk and high alert medications, The Joint Commission in 2008 created a separate standard called the National Patient Safety Goal to highlight the very important attention that these medications must attract at all health care organizations. This *Sentinel Event Alert* builds on that National Patient Safety Goal by identifying the underlying factors that lead to adverse events related to medication errors with anti-coagulants and providing recommended strategies to reduce the risk of error and the risk of harm.

And I want to emphasize that The Joint Commission's *Sentinel Event Alerts* come from a long experience going back more than a decade with organizations who report voluntarily adverse events to us and ask for our help in working through the assessment analysis that leads them to understand what the causes of the adverse events are and what corrective action plans might be most effective and that sentinel event database, that experience with helping organizations work through the solutions, leads to our *Sentinel Event Alert* program that shares that learning very broadly across the delivery system.

These are very important and as I said often life saving drugs but we need to be even more careful with them than they are with many other medications. And it's important that we stop relying on the idea that if only everyone in medication delivery process tried harder, that we could all perform perfectly; that doctors, nurses, pharmacists and other caregivers can eliminate every single error by just trying harder. That's not going to happen. And instead we need to learn from other organizations outside of health care that do have very, very highly reliable and safe practices and safe processes. The way in which those organizations secure the safety of their processes is by creating systems that anticipate, look for and then trap the small errors that people make every day before they result in harm.

The first step that every health care organization and hospital that uses anti-coagulants should take is an in-depth assessment of the risks based on how we know these processes fail, look at the risks in their own organization that go along with using the anti-coagulants, and then they can use their experiences, their own data along with the guidance that we and other organizations have provided to create the systems and processes that will prevent mistakes from ever getting close to reaching patients and doing harm. Health care organizations also need to use evidence-based practices that have been proven to be successful to get their systems and processes of care for patients who are taking anti-coagulants to a much higher level of safety.

As an added resource, there's a lot of work in these areas coming from the Institute for Safe Medication Practices, the Institute for Health Care Improvement, UK's National Patient Safety Agency, the Agency for Health Care Research and Quality. We'll be hearing from Diane Cousins from US Pharmacopeia and there is lots of good information and best practices, much of which is summarized or referenced in this *Sentinel Event Alert*.

Dr. Angood will talk about the specific strategies contained in the *Alert*, but the most important point that I want to emphasize is that with this *Alert* The Joint Commission is again publicly committing itself to further raising the awareness of this problem and to serve as a

catalyst and a conduit for positive and sustainable change. Patients have the right to expect that they will receive safe care all the time and that if a mistake happens, they expect efforts to correct problems will occur and make sure that it's not repeated.

So now let me turn this over to Dr. Angood.

**DR. PETER ANGOOD:** Thank you Dr. Chassin. Well, yes, indeed anti-coagulants are notoriously tricky drugs to manage, but they are not the only types of drugs that are difficult to manage. The Institute of Medicine reports that on average there's about 1.5 million adverse drug events on an annual basis—400,000 of those are within hospitals and this creates billions of dollars of increased economic strain on our health care system.

Within these adverse drug events, the top three are anti-coagulants, opiates and insulin and within the anti-coagulants is Heparin, low molecular weight Heparin and Warfarin. There is also evidence that this is a big problem in other countries well beyond the United States.

So how do we fix this problem? It's a very complicated set of issues as Dr. Chassin was highlighting, but important early in first steps are to follow The Joint Commission's standards and the National Patient Safety Goals that have been highlighted. Our medication management standards are very much focused on efficient and high quality approaches to managing medications overall and we have a very specific set of standards within that chapter regarding high risk medications, of which anti-coagulants are. Our patient safety goal on the management of anti-coagulants as well as our medication reconciliation goal are also a part of this overall strategy to better manage medications.

What specifically are we suggesting in the *Alert*? Well first off, patients should be screened for the appropriateness of receiving anti-coagulant drugs because these are very difficult drugs to manage and they should be evaluated for any contraindications and the possibility of adverse drug interactions. Health care organizations should standardize the way anti-coagulants are prescribed, delivered to the bedside and administered; i.e., improve the

processes of care. Facilities also need to communicate the laboratory values associated or are monitoring and managing these types of medications and should set dose limits on anti-coagulants where the dosing may be outside of the usual and expected ranges and unless there's a specific physician order that says, yes that's an okay dose, those drugs should not be administered.

The caregivers also need to help educate the patients and their families regarding the issues around these medications, the potential for complications, the drug interactions, and a variety of other issues. And that should occur before a patient leaves an organization's care.

Special attention also needs to be specifically paid to the babies and the children who may receive anti-coagulants. A lot of the recent media profiling has been on this patient population, but these problems occur across the spectrum of ages that are particularly problematic in the younger.

The Joint Commission is also asking for organizations to consider computerized physician order entry and the use of bar-coding technology to facilitate and improve safety in managing these types of medications.

And then finally, the quality improvement processes, data monitoring, engagement of leadership in organizations, and the development of strong policies and processes to help improve the systems around managing these patients are important.

There's a variety of other strategies outlined in the *Alert* and we'll be happy to answer further questions around those. But as these other strategies are considered, it's important to understand that there are numerous factors that contribute to anti-coagulation medication problems and errors, inconsistency of naming, labeling and packaging was mentioned by Dr. Chassin. That's a very broad issue, but it clearly creates ongoing problems. When we look at our compliance within our medication management standards, the issues of storage of the medications and the legibility of written orders and the transcription of those orders are two of the problematic areas that persist.

These drugs have narrow therapeutic ranges. Caregivers need to have current approaches, make sure their dosing and administrative practices are contemporary and appropriate for the patient populations. Failure to do so creates harm.

And then finally, a very important message in all of this is just to reiterate this *Alert* really brings attention to the issues of medication errors, specifically the anti-coagulation errors and these errors are preventable. We owe it to our patients, we owe it to ourselves as caregivers and to our professions that we need to prevent medication errors and we need to increase patient safety overall.

So we hope that organizations will review this *Alert* critically and I would like to now turn over the remainder of this presentation to Diane Cousins, who is a vice president at United States Pharmacopeia and the Center for Advancement of Patient Safety.

**DIANE COUSINS:** USP appreciates this opportunity to participate in this briefing on this very important topic of errors and anti-coagulants and just by way of background, if you're not familiar with USP, we are a non-profit organization that sets legally enforceable standards for drugs in the United States. Since 1991, USP has also operated medication errors reporting programs, so USP's Med-Mark, which is referenced in the *Alert* is an anonymous database for subscribing hospitals and health systems to track and trend their medication errors in a standardized fashion. In the 10 years since Med-Mark's inception, nearly 900 of the nation's hospitals, which is roughly about 16 percent have reported a million and one half medication errors, making the database the largest of its kind.

Given that under-reporting of errors is widely recognized, then these numbers become even more daunting in our quest to determine the frequency of medication errors in health care.

Med-Mark captures about 40 elements that describe a medication error, and I'm just briefly going to describe a few of those to you today and reveal the findings of an analysis of anti-coagulants. And these few areas will involve the severity of errors, where these errors are

occurring, the level of staff that makes the initial errors as well as the types, causes and contributing factors.

In the last seven years, and this includes the calendar year of 2007, about 70,000 medication errors involved the therapeutic class of anti-coagulants and nearly 3 percent of these cases or roughly 2,000 reports involve harmful outcomes. Twenty-six of these cases were fatal. USP's analysis of anti-coagulant errors has consistently identified Heparin, Warfarin, and Enoxaparin in the top 10 most frequently reported drugs, and more troublesome, in the top 10 drugs involved in harmful to fatal outcomes. In fact, twice as harmful relative to Med-Mark's overall. So in other words, 1.5 percent of all medication errors in Med-Mark's were harmful as compared to 3 percent of the anti-coagulant errors are harmful.

So it's for this reason that we consider anti-coagulants to be high alert drugs, meaning that when an anti-coagulant error does occur, it's more likely to result in harm.

Med-Mark's data shows that the elderly may be particularly vulnerable. Of 14 deaths reported in calendar year '06 in Med-Mark's overall, four of those deaths involved Heparin, Warfarin and Enoxaparin and all four involved elderly patients. And cases involving the elderly show that they're taking multiple medications so there's a chance for interaction that increases. They're usually sicker, that is they're often co-morbid conditions. They're more frail, so they're less able to recover from an adverse event. And finally the coordination of care may involve multiple physicians, thus increased chances for communication errors.

So where are these errors occurring and who's involved in them? Well, the cases show that errors occur at every phase of the medication is processed—from ordering, transcribing or documenting, dispensing, administering, and monitoring. And they happen in just about every unit in the hospital and we track over 30 different locations, from emergency departments to the ICU to general patient care units. Nurses, pharmacists, physicians and their ancillary and support staff are all involved in these initial errors, so no one is immune. And these facts

explain the need for the broad reaching systems-based risk reduction strategies provided by The Joint Commission in this *Alert*.

Overall, the most frequent type of error and one that's very preventable are omissions, which include failure to administer a single dose but also failure to initiate a course of therapy when ordered, failure to resume therapy, for example after surgery. And these omissions are followed most frequently by wrong dose of anti-coagulants, such as might be the case in a calculation error where a misplaced decimal point could result in a 10-fold overdose. Or a miscalculation or inaccurate documentation of a patient's weight resulting in the wrong dose. In fact, in one case it was inaccurate reporting of a patient's weight as 130 KG rather than 130 LB that resulted in a fatal overdose over several days. So in other words, in summary, patients are likely to receive no anti-coagulant at all or when given, the wrong amount may be given based on reported cases.

More than 60 causes of error can be tracked by Med-Mark's hospitals and errors are often multi-causal. Among the 10 most frequent causes include poor communications, knowledge deficits of the health care practitioners involved, monitoring that's inadequate or absent, inaccurate computer entry, including CPOE and performance deficits. And performance deficits are cases where the inexperienced individuals with the requisite training and education to perform a task are erring nonetheless.

And you might ask, well why would that happen? Well, in addition to types and causes, hospitals also track contributing factors and these give us a sense of the situational, organizational and environmental conditions that could influence the likelihood of an error occurring. So for anti-coagulants, leading factors include distractions, workload increases and inexperienced staff. And this last factor, inexperienced staff contributed to an elderly patient's demise due to an incorrect dose of Heparin. The case noted that the error was made by an inexperienced staff member who was temporarily assigned to the unit.

Now while these are only highlights that I presented today, I assure you that what we do know about these errors is sufficient to drive the action that The Joint Commission is proposing today and we commend them for this action. Thank you.

**QUESTION:** As a nursing publication, I would like to find out what specifically nurses should be concentrating on in this; what they most need to be aware of and concerned about?

**DIANE COUSINS:** I think one of the first things they need to do is be familiar with the drugs that they're managing. Of course this goes beyond anti-coagulants, but because these are high alert drugs, they need to be particularly familiar with them. They ought to understand what the proper dosing is. They ought to stay up to date on different dosing regimens. They should be aware of what these products look like and the various strengths that are available. I think that kind of knowledge about the product will help them in safer handling of the drugs.

**DR. MARK CHASSIN:** I think it's extremely important that all nurses recognize how potentially dangerous these drugs are, particularly for nurses in hospitals, the use of intravenous Heparin, the fact that it is produced and packaged in different dilutions, different strengths, particularly with respect to the way those dosages are then translated into IV solutions that are infused at particular rates. If there isn't an automated way to make those calculations to be really, absolutely sure you've got the right calculation for the dose that's ordered, to be familiar with the usual ranges for different kinds of patients so that you can perhaps intercept and order if it's inappropriate by knowing that the usual range for this kind of patient is this number, but the number I've been given is a lot higher than that or a lot lower.

And then, lastly, I'd point out another one of the ways in which these medications can cause catastrophe, which is also within the purview of nurses to avoid, one of these medications, Heparin, can cause patients to become highly allergic to the medication and for

those patients who've experienced a reaction called Heparin induced thrombocytopenia, getting the drug again can be lethal and has been lethal. So it is incredibly important for nurses who are administering Heparin to be absolutely certain that the patients that they're administering the drug to do not have this Heparin allergy. That again is a common nursing practice, but in this particular circumstance, uncommon as it is, even the smallest dose of this drug in that setting can cause a lethal reaction.

**DR. PETER ANGOOD:** I'll make one other additional set of comments, focusing in primarily on the patient safety goals. The patient safety goal #3 around anti-coagulation is in its one year phase-in during 2008, so nurses should be aware that their organizations at this stage should be in a test pilot's process at the minimum and need to be geared up and ready to have full implementation by January 1. I think it's important that the front line nursing staff are aware of that patient safety goal, what the different elements of performance are within it, and if they're not seeing or aware of activity within their organizations they can and should be asking for clarification regarding this, because the goal sets up very good criteria of how to better support and manage these patients overall.

**QUESTION:** I was wondering what kind of role you see technology playing in helping prevent these errors and helping comply with the National Patient Safety Goals?

**DR. PETER ANGOOD:** First and foremost, technology has strong potential to help us with all of the processes of care, but we should not slip into relying on technology to be the solutions for our different issues. It's very important that organizations look at the underlying systems and processes they have in place before they overlay technology overall. Computerized provider order entry or CPOE, yes it's certainly a valuable adjunct to care, but it does have the potential of perpetuating or propagating errors once they are put into those system. So again, caution

about the use of technology. The bar-coding technology can help with the storing, the stocking and the management of the medications as they move through an organization where they are kept and stored, and so that is an important capability as well.

The other types of technologies out there, we could spend the rest of our time today talking about, but the importance is not to rely on the technology, but to utilize it as an adjunct for safe processes of care.

**DR. MARK CHASSIN:** I guess I would just add a general point as well that unfortunately for errors and harm caused by errors for this class of medication, there is no single answer to prevention. And that's why the *Alert* goes into some detail on risk assessment, strategies, identifying the causes of errors that have been studied and reported in other organizations and identifying all of the parameters of a safe medication administration system that need to be in place in order to maximally protect patients.

**DIANE COUSINS:** I might add two things. Over these last few years, as we've seen computerization implemented more and more, we've actually seen it rise closer and closer to the top as a cause of error and we document two types of computerizations, one just general computer entry that might be done at admission or done at a pharmacy and also computerized prescriber order entry. For the years 2001-2006, computer entry actually was sixth in the ranking of the top 10 causes. What we see when we look more closely at these kinds of errors in general are things like looking at how these systems are designed to prevent errors, for example, in drug selection or the selection of drug strength that is clear for the prescriber, the particular drug that they're choosing from a list of drugs on a computer screen that they're dosing when it's built into the computerization that the prescriber can rely upon if there's a mis-entry.

We also find that there's a lack of integration of systems. So while there are computerized systems at admission or the computerized system in the pharmacy it may not be completely integrated with the physician order entry systems. So I think that the initial design of these systems is important, what they do or do not do are important features for health care practitioners who are going to use these to really understand how best they can be designed and integrated with existing systems.

**QUESTION:** The way I understand the anti-coagulation patient safety goals are primarily looking at treatment doses of those anti-coagulants, Heparin, low molecular weight Heparin and Warfarin, and I was wondering what the expectations were this year around prophylactic doses of these drugs and what is planned for the future as far as patient safety goals and prophylactics. I've heard different things about risk stratification and things like that.

**DR. PETER ANGOOD:** If you've not had a chance to review the most recent version of the National Patient Safety Goal 3, we have put in a few clarifications in the language and added a couple of notations about this type of issue.

The goal is primarily focused on Heparin, low molecular weight Heparin and Warfarin, because of the issues that you've heard earlier and the types of patients is focused on those who are receiving therapeutic ranges of anti-coagulation or who are on long-term prophylaxis where their laboratory values are going to be abnormal. So an atrial fibrillation case that's on Warfarin long term would be an example of that.

The idea is that if those patients who are at most risk over time who will be exposed to the potential for complications and that's the applicability of the goal for that patient population. What it's not applicable for are those cases that are in for some short-term prophylactic strategies where their laboratory values may well not even move out of the normal range. A short-term stay for a patient undergoing surgery that's going to get subcutaneous Heparin twice

a day is not the type of patient that needs to be under this goal. That's far too burdensome and not very valuable in terms of improving the processes.

Parenthetically, however, if there are some patients, and we have known examples of orthopedic patients who get fully anti-coagulated as “pari-operative” prophylaxis then those patients are at risk because their laboratories are going to be into therapeutic ranges. They will be at risk for complications and so those types of patients should be managed under this patient safety goal.

And, again, I would encourage you to look at the most current version of the goal. Hopefully, it'll help clarify that further for you.

**CATHY BARRY-IPEMA:** Thank you. I'd like to thank all of our speakers today and I would also like to thank all of you who have joined us. And members of the press, if you do have additional questions, please feel free to call our media relations unit at 630-792-5175. Thank you and have a great day.