be entering patients that have a higher risk of mortality, which I would think would be a good representation of patients with VAP, such that the development program of the two trials together would be collectively giving us something on the order of 120-160 deaths which would provide substantial insight about the relative effects of current therapies and new therapies on mortality.

DR. TOWNSEND: Thank you. Dr. Bennett?

DR. BENNETT: I want to return to Susan Rehm=s idea that ventilator-associated pneumonia is very difficult to study and very difficult to define. I am looking here at a 29-page article that just came out in the Journal of Antimicrobial Therapy, and it is on guidelines for the management of hospital-acquired pneumonia. They have 14 people here discussing how to diagnose hospital-acquired pneumonia, including VAP. And the only grade A recommendations about VAP were things that they don't trust. They say do not use endotracheal aspirates; do not use quantitative cultures of BAL. What they don't say is what to use. So, we may not have reached a point where we have design entry criteria for VAP that will have broad enough consensus so we can actually do a study and enroll patients.

DR. TOWNSEND: Thank you very much. Any other comments? Questions? Anybody have any comments about the question about enriching the population for Pseudomonas? Dr. Leggett?

DR. LEGGETT: Just that I wouldn't limit it to Pseudomonas because next year it is going to be Acinetobacter again or something.

DR. TOWNSEND: Thank you. We will move on to (b). Describe the appropriate diagnostic criteria for nosocomial pneumonia and VAP, clinical, radiologic, and microbiologic.

Dr. Bennett just made a comment on the VAP part of that. We may not have such things. Any other comments? No one wants to stick their neck out on this one. Dr. Ohl?

DR. OHL: Nothing helpful, I would just suggest that wherever possible I try to use some objective measures even if they are not perfect or potentially validated, rather than using subjective aspects because it creates more noise. And, at least objective data can more easily be looked back on to see what it is. You know, the CPIS score is basically about as good as we have.

DR. TOWNSEND: Dr. Stoller?

DR. STOLLER: I certainly don't offer an answer but

I think that this question really frames an issue that has been kind of squirreling around this discussion, which is the classic difference between effectiveness and efficacy. You know, I think that some kind of rigorous definition, albeit arbitrary, whether it is, you know, non-bronchoscopic BAL data or something, would certainly answer or get closer to the efficacy issue, while recognizing that that may not deal with the patient that Dr. Ohl sees in his ICU as we see in ours who have infiltrates and fever and may not be ventilator-associated pneumonia.

So, I think given the arbitrariness of this definition and the impossibility of having an all-inclusive, rigorous decision, I think the guidance that should come from the agency around this should grapple with do we want an efficacy definition or an effectiveness definition that really has generalizability, and I would argue for an efficacy definition even at the risk of recognizing that we all see patients for whom we scratch our heads, saying is this VAP or not in demonstrating the efficacy of new drugs in that regard.

DR. TOWNSEND: Thank you. Dr. Edwards, do you have comments?

DR. EDWARDS: So, I am lagging behind a little bit and I am still thinking about Dr. Fleming's comment regarding enriching for death in a patient population. So, if I could just go back a step, I would be a little bit interested in hearing Dr. Rex comments as to what that might do to either increase or decrease the complexity of enrollment.

DR. REX: I suppose there is a sense in which it makes it easier if you are not trying to exclude people at high risk of dying in the short term. But the interpretive challenge is a real one. What does it mean to enroll somebody? You could, for example, take out the exclusion criteria, "it looks like they are about to die in the next 36 hours." I mean, you could imagine doing a study where you didn't have that exclusion; sign up anybody. By the very definition, those folks are not in good shape. And, we have all seen them. We know exactly what they look like. And, what does that mean in that setting?

The point of doing a trial like this is to actually ask a real question in patients who can respond. We did a trial a few years ago where we compared two therapies for candidemia. We did an exploratory analysis

where we looked at response of the two arms by APACHE score loosely. What we observed was that the people who had low APACHE scores, well, they did well no matter what you did for them, and the people who had high APACHE scores, they didn't do well no matter what you did for them. But in between these curves are together at the top and the bottom but then they separate in between. You have this space in between where the APACHEs are survivable, I guess would be a way to say it. You get an APACHE of 35 and you are quite close to dead, and an APACHE of 2 you and are looking really very good.

So, it is that in between group that actually gives you the truest measure. So, I guess, you know, it is interesting that Tom said it that way. Yes, it would give you more events but would I be any smarter as a consequence of having done it or would I have just actually added on to the bottom where they are not going to get better no matter what I do?

So, I am a little torn on that one. I think here the question is how do I identify syndrome and a point in its evolution that is meaningful enough to clinicians so that the words we write down say, well, yes, this matches

more or less what you are going to do. That is my answer on the mortality question, yes, you can do it but it might have other consequences that you need to think about carefully.

Is that going in the right direction to answer your question?

DR. EDWARDS: In part. One of the issues that I have some concern about is that in our changing culture, which is getting risk avoidant in a clinical milieu, randomizing patients into an experimental drug protocol who are about to die may vary in its complexity from institution to institution. There are, I am sure, settings where it is much more difficult to do that. A patient who is about to die gets proposed to go on an experimental drug protocol. There may be settings where that doesn't add complexity but I just have a feeling it adds significantly to the complexity of enrolling patients in general. So, I am just sort of trying to get a sense for the practicality of enriching for increased mortality.

DR. TOWNSEND: Dr. Fleming?

DR. FLEMING: It is certainly a very good discussion. It is a very important point. If you think that a patient is so severely ill that what you would do

wouldn't impact that course, including offering antibiotics, then they wouldn't be a good candidate for the trial. In the extensive literature review that we did leading up to the CAP advisory committee and the manuscript that we had written and what I see in what has been done by the FDA in the NP setting, there are some very impressive effects that we see in patients that have very high mortality risk. Antibiotics work very effectively and provide major benefits in patients that have really high mortality risk.

If we think that is the case, if you are looking at a patient that you think is very likely to benefit with a high risk of mortality, we should be entering those patients. I suspect you would be treating those patients with a new antibiotic if it were found favorable in a clinical trial for marketing approval. Therefore, what better place than in a clinical trial to understand what its true benefit to risk is across the spectrum of patients that you are likely to be treating in clinical practice?

So, antibiotics have an impressive effect in high risk settings, and the benefit from the clinical research perspective is to get a generalizable answer to understand that effect in a high risk setting and a low risk setting,

and it does reduce the size of the trial to be able to understand effects on mortality.

DR. TOWNSEND: Any other comments? Dr. Brantly?

DR. BRANTLY: So, I would like to hear comments from my pulmonary colleagues as well. Typically, when we see early VAP it is because somebody has made a huge mistake. The patient has not been elevated; they are not getting cord suctioning, and that kind of stuff. I think it is a different story than when we see VAP late, which is a much more common thing that we will see because you just can=t keep a patient elevated 24 hours a day.

DR. OHL: I would just add though that potentially with the exception of trauma and a lot of trauma patients early VAP reflects the trauma and the microbiology at the time of it.

DR. TOWNSEND: Thank you. Other comments? Dr. Rex?

DR. REX: I want to pick up back on the theme about diagnostic rules and what makes VAP and what makes HAP. I think it is important to recognize that there isn't a perfect set of guidance. There probably never will be actually. We might spend the next 20 years trying to come

up with a perfect set of rules.

I have had the realization recently where somebody was talking about approaches to prophylactic therapy for something and the rules they were going to use to identify the patients who need prophylaxis. And, I realized that there have been 15 studies that got 15 different results, and maybe what that really meant was that everybody's ICU is a little bit different and the rule was never going to be universal. So, there may never be as well a perfect rule here.

I think the rule that gets used needs to be one that is practical. And, practical means that pretty much anybody reasonably can do it and identify the keys to it, and it needs to make some clinical sense. And, you have to look at the factors that have been used classically for HAP and VAP, the things that you see in the U.S. trials, the support with the CPIS score. That encapsulates clinical thinking and it is hard for me to imagine how we are really going to do a lot better than that. There is always going to be a bit of a blur around the edges.

But the indication on the label has to match something that I can then do at the bedside. So, that is

the other part of this, that you need to identify people who have been studied so the FDA labeling says when you see this thing, you too can recognize these patients and know that the drug works in this setting. So, it has to be sort of at that level of simplicity and clarity.

I have to say, you know, given all this debate, and I love the fact that Jack Bennett pulled out that paper that says, you know, we don't know, well, that is nice for a guideline group to say but, of course, as developers we really have to have a set of rules, and I think practical and pragmatic sways the day here. There is a fair bit of experience with it. And, if you look at the things that go into the CPIS score, isn't that what you do at the bedside? That is the strength of it.

DR. TOWNSEND: Dr. Bennett?

DR. BENNETT: If you do a Google search for whatever, for CPIS, you will find more papers saying how bad it is rather than how good it is. So, people try to correlate the score with other outcomes, such as autopsy results or whatever. That is why people don't agree on should they have 10, should they have 12, should they have microbiology, gram stains, because it doesn't work very

well. You can't validate it. So, when we say, well, we know how to do this; we will use the CPIS. Do we? I am not so sure.

DR. TOWNSEND: Thank you. I think we will move on unless there are any other comments on that. Next, discuss whether non-inferiority studies are appropriate for this indication. Dr. Hilton?

DR. HILTON: I have a lot of comments but I think I will just piecemeal them out as the discussion goes on. But the first one is that I want to throw out two alternative study designs for consideration.

So, today we have been talking about a controlled versus an experimental head-to-head comparison. Early on in the dayB-it was actually CC-10, that slideB-they talked about the need for a multi-drug regimen. So, you know, I became convinced that maybe a combination cocktail was what is needed in this setting as opposed to a single drug. So, then I was pretty surprised that the discussion went towards DORI alone.

Anyway, one of my alternative study design ideas is DORI versus DORI plus the other treatments that ought to be in this cocktail. If we went with that approach I would

view that as a non-inferiority trial, with the question being is the stand-alone experimental arm as good as or not too inferior to the cocktail arm.

But another possibility that I think is probably a better one is to have those background cocktail drugs in one arm and then the background cocktail drugs plus DORI, or whatever experimental drug, and then to ask what the added benefit of DORI is. That could either be run as a superiority trial or even as a non-inferiority trial if you thought that it might be just a tiny bit worse but it might be better. You know, it could be one of these trials where actually the answer could go in either direction. Food for thought.

DR. TOWNSEND: Thank you. Any other ideas? Dr. Fleming?

DR. FLEMING: So, discuss whether NI studies would be appropriate, if I could somewhat lump in the second question as well as to what the proper endpoints would be because that influences at least my answer to whether they are appropriate, I do think we could do non-inferiority trials in this setting. At this point in time the endpoint that I am persuaded would be an appropriate measure for non-

inferiority is mortality, specifically 10-14-day mortality, assuming that the study was conducted according to high standards for quality of study conduct so that you would have sensitivity to differences that are real. And, we have already talked about those specifics.

I would like to be in a circumstance where we could expand this to being able to do non-inferiority trials with a lot of other endpoints. But we don't have the anchor. We haven't established the effective antibiotics on many other clinical endpoints, and by clinical endpoints I mean endpoints that unequivocally reflect tangible benefit to patients and endpoints that directly represent how a patient survives, feels or functions.

Here clinical response is a composite endpoint that puts together some components that are clinical endpoint components, some of which are signs. We have talked a lot about this, that many of these signs are signs that clinicians appropriately use in guiding clinical practice, or measures that are used to assess prognosis or diagnose disease.

It is important to understand that biomarkers have many different purposes, and they may be effective for some

but not for others. So, clinical signs could be very effective for diagnosing disease, for assessing prognosis, for managing a patient and determining when to alter therapies.

However, to be used as the endpoint in a trial is what is more treacherous. It doesn't follow necessarily that effect on one of those biomarkers reliably predicts an effect on clinical endpoints.

So, I would prefer that we would be using, if not mortality, other measures that clearly are clinical efficacy measures. So, time to resolution of symptoms, resolution of cough, shortness of breath, pain, fever, malaise, reduction in the composite endpoint of death complications, where complications could be ARDS, meningitis, endocarditis, or reducing time on the ventilator, or time in the ICU, or hospitalization time, although those would definitely need to be in blinded trials. In fact, most of these symptom measures would be if not blinded trials, would require blinded adjudication.

Once we have shown superiority, and it would need to be superiority on those measures, once we have shown superiority on those measures it would set the stage for

using those measures in future studies as non-inferiority endpoints. So, we can build the collection of measures that we do, in fact, use for non-inferiority as we have established the effects of antibiotics on those measures beyond just being able to show the effects on survival.

So, I think there is an array of studies that we could do that would allow us to determine whether or not we are superior on measures that unequivocally reflect tangible benefit to patients or whether we are non-inferior on survival. In fact, we could be doing non-inferiority trials on survival where secondary measures could be determining whether we have superiority on some of these other key tangible measures which would give us a broader sense, true sense of benefit to risk and would increase our ability over time to have a larger array of endpoints where we could justify non-inferiority.

DR. TOWNSEND: Any other comments? Dr. Dowell?

DR. DOWELL: Yes, I also think non-inferiority studies could be appropriate. I also think clinical cure could be an appropriate outcome, but would suggest that you require blinding, that the investigators are blinded. I think that is feasible and I think it removes so many of the

potential biases that we have been troubled with today that everybody would be better of if that decision were made. Then, the people conducting the trials just have to figure out how to ensure that people are blinded.

DR. TOWNSEND: I think we will move on to (d). Oh, Dr. Rex?

DR. REX: I just want to test an idea real quick. We have talked about the sizing of studies with a mortality endpoint. We haven't talked about whether we are doing it on the CE population or the cMITT population. If you are on the MITT, or the cMITT, roughly speaking you have to double it if you want to do it on the CE population if you get a 50 percent evaluable rate. I am rounding that, and I realize you might get 40 percent or 60 percent evaluable so let's call it 50 percent for now and just say simply you have to double it.

So, that would mean that with a 15 percent mortality rate and a 10 percent margin, if everybody is evaluable you need 550 people. That is the MITT crowd roughly. I have rounded it a bit. And, you have to double that in order to have the CE population also be powered.

I wanted to ask for opinions about powering it

just for the MITT population which, from a developer standpoint, might allow me to do two trials of that size. You know, do them independently and so, in effect, meet that criteria and at the end of the day I have 1,000. Or, do I have to do two 1,000-patient trials? Again, recognize I have rounded the numbers a little bit. So, just opinions on that as a theme, please.

DR. TOWNSEND: Dr. Fleming?

DR. FLEMING: It is a good point. My sense about this was ITT and it kind of leads into the fifth question here, which was describing the right primary analysis population or co-primary analysis population.

To put things into context, I served on the cardiorenal advisory committee several years ago for a four-year term and my predecessor, in reviewing the PRECISION trial that had 16,000 patients that excluded 16 of those 16,000, called it fatally flawed because 16 patients weren't assessed for the endpoint out of 16,000.

I am not quite that rigid. However, it does give some context as to the level of the difference in the perception across disease areas as to how close you have to come to maintaining a true ITT. ITT doesn't mean randomize

everybody and then follow those that are convenient. It means follow everybody who is randomized for outcome. That is what ITT is. It is only the ITT analysis that truly allows you to preserve the integrity of randomization.

Now, if we are excluding people in a non-inferiority trial because they don't have the condition, they don't have the bugs, they don't have pneumonia, there is a considerable justification and that is based on information that could be gathered. It may not be known until after randomization but it is based on samples prior to randomization. That is much less problematic.

What is problematic is when you have large numbers of exclusions because of irregularities and quality of study conduct. So, when question 5 is stating what is the right primary analysis population, or co-primary analysis population, my answer to that isn't it is the MITT or it is the CE or it is the microbiologic. It is let's conduct trials with sufficiently high quality that the difference between those populations is not very substantial. Then all of the analyses have integrity, instead of none of the analyses having integrity.

So, what I would hope is that we could strive

toward achieving as high level study conduct as possible, and my sense, John, is that for mortality, just as was done by the sponsor here, you are essentially including everybody, or at least everybody who had the recognized condition that the study was intended to address.

DR. REX: And I think that would a fair place that you would wind up. You are going to lose some in the CE. I just can't see how you are going to keep that from occurring. People are going to die early and that is going to make it harder to evaluate. There are going to be concomitant meds and some of that is going to occur, but you can work to minimize the risk of it.

DR. TOWNSEND: Dr. Dowell?

DR. DOWELL: I was just going to say, and I want to check this with others, I don't think making mortality the endpoint solves the problem of the bias of noise in a non-inferiority trial design. I mean, I think mortality is a nice, clean endpoint. You know, you are either dead or you are not, which is great. But if you make mortality the endpoint you still could enroll lots of patients, as John is saying, who are going to die anyway and bias your non-inferiority trial towards the null, towards concluding non-

inferiority when the two are the same anyway.

So, the one step of making mortality your endpoint does not get the FDA and the committee off the hook of if non-inferiority is the design, then the burden of ensuring the high quality of the conduct of the study is still there. Is that right?

DR. FLEMING: If you have a strong sense that a patient has such a severe condition that whatever you do doesn't matter, then sure, including those kinds of patients will bias you toward no difference. So, yes, in your clinical judgment if someone has such an extreme condition that it doesn't matter the nature of the antibiotic you are using, it doesn't affect their outcome, you don't want those patients.

But there is a very large fraction of patients who are very ill, very severe, where antibiotics have a major benefit and entering those patients would be very important.

But coming back to the population that would be used in the analysis, if you are able to identify patients who don't have the intended condition based on baseline information not including those in the analysis makes sense. However, if you conduct a study in such a way that there

are major irregularities post randomization, no analysis fixed that type of irregularity.

So, the goal should be to achieve the highest quality study conduct as possible, with the plan that you would use all of those patients in the mortality analysis. By that, I mean all the patients who have the identified condition.

DR. TOWNSEND: Let's move on.

DR. BRANTLY: Sorry, I do have one other comment. One of the things I would like to make a proposal for as other outcome variables that might be useful is the fact that pneumonia is an infiltrating process, and one of our best ways for assessing the size of a pneumonia is actually by CT scan. It is pretty obvious whether you have one or outcome, instead of with a chest x-ray as well. Perhaps using low-dose CT scan to quantify the size, whether it is growing or not, may be a very useful, you know, method of documenting whether you basically have efficacy in an antibiotic in this particular category. I think it should be explored as a possible way to go.

DR. TOWNSEND: Thank you We will move on to (d). Describe the appropriate primary endpoint for clinical

efficacy trials for this indication, such as mortality, clinical outcome or other endpoints. Dr. Hilton?

DR. HILTON: Well, if the flip side of cure is failure you could measure time to failure and you would reduce the 21 percent that dropped out of DORI-10 because they didn't have an assessment within a certain window. It just seems like a very simple change that would help a lot.

DR. TOWNSEND: Any other comments? Dr. Leggett?

DR. LEGGETT: Just remember to factor in the fact that you have to make sure you randomize equally to Pneumococcus which has a 10 percent mortality in the first 24 hours no matter what you do. So, you don't want to make them all on one side of the DORI group in 09 who maybe had a lot of mortality because they got more pneumococci.

DR. TOWNSEND: Other comments? Dr. Rex?

DR. REX: So, I want to test my understanding because I think what I have heard is that there is a general sense that mortality isB-with the 10 percent margin and when the overall mortality is in the range we are seeing here, 15-odd percent is not a bad place to be. That is an endpoint for which there is reasonable support and you could get reasonably comfortable with. And, I could power a study

for that.

Now, if I did that, and I am going to come back again to my-Bwell, actually I should make sure that I am saying it correctly in a way that doesn't set off any alarms anywhere so let me pause on that one. Eighty-five percent mortality, 10 percent margin, yes, you are comfortable?

DR. FLEMING: No.

DR. REX: You are not?

DR. FLEMING: The FDA, in considering essentially the scenarios that the doripenem study had, 10-15 percent, we are looking at a 6 percent margin and it is the 6 percent margin that gave the sample size that you and I both independently derived to be about 1.5 times the size of what was presented for doripenem.

DR. REX: What, 85 percent? That is right, 15 percent mortality, 6 percent margin. That is 1,500 patients required--

DR. FLEMING: Yes.

DR. REX: In the MITT population. Right.

DR. FLEMING: In a population that would probably be what you would call MITT, yes.

DR. REX: Okay, 1,500 patients and that is one

trial?

DR. FLEMING: Yes, one trial for mortality at that level, yes. It could be an aggregation of two studies, each of which would be roughly half that size that could be looking at other endpoints as well.

DR. REX: You know, that is the thing I think we need to have the bigger debate on because I think that is pushing it in terms of practicality for the future. Because then we have to think about what you are going to want to know about the clinical response. It should be well powered, I guess, for a clinical response--

DR. FLEMING: And you just gave that argument about ten minutes ago, that it would be well powered if you had 750 people in each of two sub-studies with clinical response, as it would be powered for a number of other measures that I would call more true clinical efficacy endpoints.

DR. REX: You know, that is all in one study and you are comfortable with that.

DR. FLEMING: It is a compromise. It is what I call SOE1, strength of evidence of one study to rule out that level of excess mortality from a single trial, but you

have to walk before you can run. Given that this is increasing by about a factor of 1.5 the total sample size that people would have versus what they would have had with the doripenem program, it is an important advance over what we currently have.

In other clinical settings it may well be required to have two such studies, but I think it is a reasonable middle ground here to propose one such study if it is vigorously establishing non-inferiority on mortality.

DR. REX: And that 6 percent figure, we come to that through a series of meditations that involved taking the upper and lower bounds of 95 percent confidence intervalsB-why 95 percent?B-we then attempt to retain 50 percent of the interior of that effect. Why 50 percent?

You have cooked it down about as far as it can possibly go, and it just feels to me like, basically, if that is what we walk away with, if that is the conclusion that that is what you need to do, that is a pretty negative story. And, you know, why 6 percent? If it backed off even to 7.5 percent? You know, we get to that 6 via the 12, via, you know, the logic and the logic is very soft. And, if you go all the way back to what we have really observed, which

is that there is a big effect of appropriate antibiotics, I guess that is the thing that has really bothered me--

DR. FLEMING: But therein lies the reason that you shouldn't be so much more generous because when you have major benefit--why is it that there is such a compelling argument that you correctly made that we are not going to do placebo-controlled trials if placebo means depriving people of standard access to antibiotics. It is because we know antibiotics provide such a major benefit. But not all antibiotics are the same, and it is important to ensure that patients have an informed judgment as to whether or not the alternative options they are being provided are preserving at least half of what it is that standard of care provides.

It is actually pushing the envelop toward a lower level of rigor than what you might see across many of the disease settings. Just preserving half the effect, just having a single trial, allowing, in essence, for the acknowledgment that if there is a 10 percent mortality you are willing for it to be as much as 50 percent higher. It can't be 60 percent higher.

Where did that number come from? It came from an in-depth analysis that the agency did here and it also

aligns with two in-depth analyses that were done in the CAP setting, one by IDSA and one by Fleming and Powers, and they all come up with a very similar answer, which is in the vicinity of ruling out a 67 percent increase could be justified as an appropriate middle ground to preserving an important benefit that antibiotics provide.

So, there are many sources of information leading to this perspective. But also, as my colleagues were saying, just from a clinical common sense perspective how much excess mortality are you going to allow? If you have an intervention that provides major benefit on clinical complications or other aspects of the safety profile one might grant a little more leniency on that margin. On the other hand, if the opposite is true more rigor on that margin should be appropriate.

But this standard across disease areas is actually relatively lenient compared to what you would be expecting in many other settings, particularly when you have a classic example of interventions, antibiotics, that provide major benefit on mortality.

DR. REX: And the benefit exceeds 30 percent and we are down here fighting around a margin of around 6.

DR. FLEMING: The benefit in the context of historical use of antibiotics may have exceeded 30 percent in various settings. To argue that in the context of supportive care, as we have been designing these trials as we should be designing these trials, to argue that if you took piperacillin out of the cocktail given in DORI-09 that mortality would have been 30 percent higher, no, it wouldn't have.

DR. REX: But, wait, in the Luna 2006 recent data set, prospective observational cohort, as I said earlier, the APACHE scores for those who received inappropriate treatment, they weren't higher. They weren't one point lower. Those people were pretty dissimilar and we are not talking about data from 1902; we are talking about data from a few years.

Dr. Fleming: The 6 percent absolute margin is granting the FDA the full level of benefit that their analysis presumed, even though there were obvious biases that exist when you characterize the treated patients as those who got adequate therapy and the controls that didn't. By the way, that type of analysis wasn't done in the CAP analyses.

So, this proposal is already granting considerable flexibility, recognizing that there is a balance here between what we rigorously need to understand scientifically and what we can practically achieve.

DR. TOWNSEND: This is an important discussion but I don't think we have time to get it settled now. Dr. Bennett, you had a comment?

DR. BENNETT: I had a question for Dr. Cox. Can you recall a randomized inpatient trial of an antimicrobial agent that enrolled 1,500 patient? I couldn't think of any.

DR. COX: Not off the top of my head. Most of the studies have been smaller studies, typically on the order like, you know, 300 per arm or somewhere thereabouts. So, that is what we have seen in the past.

DR. BENNETT: That fits my recollection which makes me wonder if we are postulating something that no one has ever done. That doesn't mean no one will ever do it but the fact that they have never done it doesn't suggest we should be optimistic.

DR. FLEMING: But the discussion here today was we have two trials put before us that each provide about 550 patients. If they each provided 775 patients you would have

what we are talking about. And it is true that across disease areas there has been an evolving recognition that trials may need to be larger than they have been in the past. And, the decision was made by the metabolic advisory committee two weeks ago in the diabetes setting that there are essentially few, if any, large-scale, long-term clinical endpoint studies of diabetic agents and now there needs to be routine conduct of those studies even in settings where there aren't signals in advance for cardiovascular risk and those studies will be well larger than a totality of 1,500 patients.

So, this comes back to the discussion with Dr. Rex. It really would be ideal to have much more than just a 50 percent increase than what we currently have. But a 50 percent increase of a total of two trials, each of which has 750 patients would provide us greatly enhanced understanding about effects on mortality as well as other measures.

DR. TOWNSEND: If you make it brief, Dr. Edwards?

DR. EDWARDS: Again, I would like to make the point I made before about the desirability of a workshop over this issue. I would also like to raise a note of caution about modeling antibiotic studies after diabetic studies and

cardiovascular studies. I think that is a completely different discipline than the issues with the antibiotics.

DR. TOWNSEND: Well taken. Thank you. I think in the interest of time we will move on unless anybody else has any other significant points to make on this one.

Describe the appropriate primary analysis population or a co-primary analysis population. We have had some discussion already about that but any other comments to make? Dr. Hilton?

DR. HILTON: So, as you know, I am a bit bothered by the exclusions, dropping from the ITT to the per protocol populations. As I look at the list in slide CC-58, it seems that insufficient study drug could be eliminated as a reason and replaced with a compliance analysis if we did an ITT analysis. Negative lower respiratory tract culture for only resistant pathogen could be stratification factors instead of reasons for elimination. The TOC event missing could be solved by a time to failure outcome. And, confounding antibiotic therapy could be eliminated by a cocktail arm or a cocktail control in both arms.

So, I just think that there are much better study populations than this CE that was presented and ITT is the

way I would recommend that we go.

DR. TOWNSEND: Thank you. Any other comments on that?

[No response]

Describe the indications for concomitant antibacterial agents in NP and VAP, and discuss how the treatment effect of study drug will be determined in patients administered combination antibacterial therapy. Dr. Calhoun?

DR. CALHOUN: So, the issue here is that as physicians, even running a study, we are obligated to do the right thing by our patients. So, completely eliminating physician judgment, even to the extent of eliminating a patient from a trial because they believe it is not in the patient's best interest or the subject's best interest to remain in a trial, it is essential.

The flaw in the trials that we talked about today was that the investigators weren't blinded and, therefore, there was the potential and, in fact, probably some actualization of bias there. So, I think the lesson to learn is that these trials really need to be blinded so that the physician who is caring a subject/patient can, in fact,

discharge that responsibility appropriately without damaging the credibility or the integrity of the trial.

DR. TOWNSEND: Thank you. Comments? Dr. Fleming?

DR. FLEMING: My sense or at least my understanding of the area here is that there is a lot of uncertainty as to what the actual true benefit is with two drugs rather than one, for example, and if, in fact, that is the widespread view then the addition of additional therapies does add to some complications in trying to interpret a non-inferiority trial. If you want to do a non-inferiority trial it makes it more difficult to set up a margin.

However, I am not opposed to a view that would say, well, we need to. We need to provide this added supportive care. We need to have combination. In that scenario though what you are really saying when you take that view is that the added intervention does have important additional benefit on the outcomes of interest, which means you can't do a non-inferiority margin justification without it being based on the context where you are giving that added supportive care.

If there is a widely held view though that two versus one isn't yet resolved, then randomized trials with

add-on, along the lines of one of the designs Joan was talking about, does allow you to do a valid superiority assessment in an ethical way. So, if there is uncertainty about whether two beats one, studying B added to A against A alone gives you a straightforward superiority opportunity for assessing the role of B.

DR. TOWNSEND: Dr. Ohl?

DR. OHL: Yes, there is really going to be no way to get around this. The empiric therapy up front, because of resistance issues, is going to have to use more than one agent unless the ideal agent is discovered that does it all.

But one of the problems I think in the data that we saw today is not necessarily that more than one drug was used empirically up front but was the failure to de-escalate. There really were a lot of de-escalation opportunities. Most of us in clinical practice try to do that. And, in any trial that includes multiple agents up front can include, you know, fairly rigorous de-escalation criteria that would, hopefully, remove some of the effect.

The other thing that we have to kind of keep in mind is that some of this sorts itself out on its own. You know, the vancomycin really doesn't mean a hill of beans to

me when assessing the efficacy when three-quarters of your patients or half you patients have gram-negative pneumonia, whereas for the MRSA population it may be significant. So, we are talking about trials that are becoming larger and you may be able to look at some subset aspects microbiologically in order to factor that out.

Then, the second thing is that the drugs most of us use as a second agent are aminoglycosides which may not have all that much impact in nosocomial pneumonia or ventilator-associated pneumonia. We really don't know that answer. So, some of this doesn't concern me quite as much. But de-escalation should be part of it in future trials.

DR. TOWNSEND: Any other comments?

[No response]

The last question, describe the role of switch to oral medication, and discuss how the treatment effect of study drug will be determined if oral switch is permitted.

I think Dr. Fleming already addressed the possibility of using an endpoint of the clinical condition at the time that oral switch is performed to try to address that issue. Any other comments? Dr. Leggett and then Dr. Stoller.

DR. LEGGETT: I would opt for a shorter time frame when we do this evaluation. More recent trials have all looked at 5-7 days of therapy and found that to be just as good as 2 weeks. In the original nosocomial pneumonia ciprofloxacin studies they looked at daily cultures and found that there was nothing left by 5 days if it was going to work. So, I mean, I think that we need to get on board sooner and maybe, you know, do things as weird as cultures every day and see when things to away and they don't, for instance, and I think that mopping up with oral, if you do it after 3-5 days really is who cares?

DR. TOWNSEND: Dr. Stoller?

DR. STOLLER: I agree with that. I recognize at the same time that trials I think should allow switch to oral but I think doing so requires potentially one of three strategies. One is evaluating, as Dr. Fleming has said, the time of switch. Another is evaluating, although it is a signal-noise challenge, time to stability to switch. The other is to make the switch highly protocolized and not at physician discretion.

I think it is important to preserve the possibility for patient length of stay and morbidity of

remaining in the hospital, which has to do with all kinds of other things, to allow a switch to oral therapy and perhaps effecting earlier discharge is possible, although obviously the ICU patients may not be quite so amenable to those benefits. But I think you have to pick one of those three strategies, either evaluate at time to switch; a protocol that is rigorous and not subject to physician discretion; or time to switch.

DR. TOWNSEND: Dr. Fleming?

DR. FLEMING: I would tweak what it is that I have been stated to support. What I would support, for example on mortality, is a mortality assessment that would be in 10-14 days.

I am a little concerned with an analysis that would just purely be analyzing when you switch because you have differential periods of follow-up and informative censoring can occur.

I am interested in understanding the evidence that would suggest we really need to switch or, at least to put it this way, if the primary endpoint was mortality at day 10-14, wouldn't it be reasonable to not introduce oral therapy until after that? What is the evidence that you

even get added benefit from oral therapy?

So, what I would prefer more ideally would be to maintain the original assigned therapy through a time period of 10-14 days unless somebody has scientific evidence. Now, what we heard is my understanding as well, look, even less could be as good as more. What is the evidence that indicates that if you are on IV and you are treating to resolution that the switch to oral provides added benefit?

DR. TOWNSEND: Dr. Ohl?

DR. OHL: The answer to that is if you basically say somebody is going to have to be in-house for your full 7-14 days of IV therapy when they don't need it, good luck keeping them in the trial. They will walk on you.

The second aspect is that you could potentially do it with follow-on home IV therapy but it is complicated, a bit expensive and carries with it the added burden of a line and the morbidity with that.

Thirdly, unless the sponsor is paying for all elements of hospitalization it is very unlikely that the inpatient facility is going to--

DR. FLEMING: So, enlighten me, how often does it happen that a patient is ready to walk and it is your

judgment that if they don't switch to oral therapy it will be really to their disadvantage, and there is evidence to indicate that?

DR. OHL: The evidence would be-Bwell, the clearest evidence would be in-line related complications which is measurable and a fact of life and de-lining is important. So, I would take the course that, yes, you would need to include an oral therapy switch option.

DR. FLEMING: But even there, what you are indicating that makes sense to me is that there are certain clinical conditions that would dictate that, even if not proven tp be important, could likely be important. But that is different from having widespread oral switching.

In any event, I am all for having patients having access to what caregivers believe is best available standard of care. Under that scenario, if we do non-inferiority we are presuming that that added supportive care could be doing something and we have to define our margins in that context.

It is an advantage in having an endpoint like 10-14-day mortality though because it becomes less confounded by these other longer-term aspects.

DR. TOWNSEND: Any other comments?

DR. LAESSIG: I think we are quite pleased with the discussion this afternoon, and recognize that it required a lot of time and effort from everyone. We really appreciate it.

DR. TOWNSEND: All right, thanks very much for everybody=s attention and we are adjourned.

[Whereupon, at 5:05 p.m., the proceedings were adjourned]

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