

SPEAKER 1: The ability to look at and use inhaled liposomal suspension amikacin. It opens up some interesting questions or prospective questions. One is, does this provide an opportunity that is better for us and our patients than we've historically had with the IV amikacin preparation alone, and is this a better advantage for our patients? We don't have comparison data in a head to head randomized fashion, to look at and analyze the question carefully. Is this better than, the same as, or worse than, IV amikacin? What we can certainly say is, the side effect profile in the studies that the two performed so far and published show a very low side effect profile for a drug that again historically, we could use for no more than typically three or four months without encountering big risk for ototoxicity or nephrotoxicity. And the study design allows us now to say, that for an initial six month period of liposomal suspension amikacin inhalation exposure, side effect profile was less and they're now continuation data up to a year that still show that the side effect profile is quite good. So we can concretely say, side effect profile is better than we would ever imagine to be able to achieve with a similar duration of IV amikacin. I don't think we'd be particularly willing to try IV amikacin for one calendar year in much of any patients.

The other issues are, I think a little bit less certain. What is the disease eradication rate if we were to imagine a comparison of inhaled liposomal amikacin suspension vs. IV amikacin? We don't have data to be able to make that statement. What we in the field, I think do have, is a continuing concern about the extent to which an inhaled agent, in this case inhaled antibiotic, might be able to successfully get into cavities for eradication. And to maybe simplify the dilemma, inhalation of agents into damaged portions of the lung including cavity is oftentimes limited and are there going to be subset patients where inhalation therapy simply won't be as effective as giving IV agents. We don't know, though it's tempting to wonder that question.

I think there is still a view that for substantial cavitary disease, we have an historic sense that IV amikacin has utility. And I think we have a continued current composite consensus view, that for substantial cavitary disease IV amikacin is likely better. I should parenthetically add, for some of those cavitary disease patients, there are surgical considerations for selective resection of cavities and thus, those clinical decisions then evolve around both antibiotic treatment strategies as well as coupled surgical approaches but those are for a rather small subset patient populations. But again, to come back to this question of the relative utilities of inhaled amikacin vs. IV amikacin, we can say for now a substantial population with refractory disease, the inhaled delivery approach is associated with an improved outcome and we in the field, I think, welcome this as an added additional agent for better management of these infected patient.