

Objection Handling Baseline HAI Study

Objection

“You don’t have a before / after baseline HAI study for DiskCover.”

Example Conversation

Clinician: You don't have a before/after baseline HAI study for DiskCover.

Rep: A controlled, ethics-clean HAI trial would be cost-prohibitive and ethically complex. Instead, we act on strong evidence: stethoscopes accumulate and transfer pathogens, and a barrier at the contact point prevents that transfer.

Clinician: We still need confidence to move forward.

Rep: Let's do this pragmatically implement DiskCover, track local compliance and incident trends with your IP team, and we'll review together at 30 and 90 days.

Rep: Multiple peer-reviewed studies document stethoscope contamination and transfer; we can provide those studies and citations for your committee, and summarize the key findings for quick review.

Objection 4:

- “You do not have a study comparing baseline HAI rates before and after use of The DiskCover System”

Refutation:

The challenge here is one of costs. The perfect study could easily be proposed, but it would be an extremely **difficult and expensive** (~\$10 million budget) endeavor.

A lesser funded study may propose obtaining baseline HAI rates, then recording HAI rates after implementation of The DiskCover System in the same environment for a period and seeing if HAI rates are affected. However, the results of such a study would be **inconclusive** unless all other variables affecting HAI rates other than the stethoscope, such as preventing visitors, keeping food sterile, ensuring all equipment is clean, etc., are removed.

Finally, a study that proposes tests to see if a disk cover protected diaphragm transmits infection from a known infected patient to another patient would be **unethical**. Patients would have to sign a consent form that they may knowingly be subjected to dangerous pathogens. Whether they sign it or not, the entire idea of the study is unfeasible.

In lieu of such a difficult and expensive baseline HAI rate comparison study, the mounting clinical evidence that cements the stethoscope as a dangerous vector, as well as the efficacy of aseptic barriers for stethoscope diaphragms, are provided together. Such articles can be accessed on The DiskCover System Clinical Library website at <https://diskcover.com/clinical-library/>.

