- As discussed on the conference call, please revise the supporting statement to clarify what AHRQ means by "the public release of the tools." Please also clarify that the results of this study are not intended for a report to Congress but are, rather, formative findings that will be used to guide a fuller study for which OMB clearance will be sought in the future. Please make all revisions as track changes.

These modest changes have been made and are attached. Track changes was used. Changes were required only in Part A

- Supporting Statement Part A, page 5: please explain what the regulatory compliance issues are.

Compliance refers to HIPPA and section 508. Section 508 is the regulation requiring IT applications to be accessible to persons with disabilities

- Page 9: what does "Section 508" refer to, and what is its relevance to this ICR?

It would be desirable that the tool be accessible to persons with disabilities

- Page 10: "In phase I we found that participants preferred paper tools because ti facilitated the collection of data from electronic medical records." Does this mean that the software is not capable of extracting the relevant information for the participants directly from the EMR? Are there plans to improve the tool to enable this, especially as more and more providers move towards EMRs?

A software tool to extract data directly from an EMR would be preferable. However, the practical concern here was the level of effort required for the software tool in the context of this pilot, especially the necessity of developing and using a paper and pencil and electronic tool simultaneously. Given the nature of this pilot and its emphasis on validation, this expenditure seemed unwise.

Long term, a software tool to extract data from EMR would be preferred. In fact, as mentioned in the supporting statement we have an ongoing collaboration with the Department of Veterans' Affairs related to the PSI and the VA is using an EMR to collect PSI related data. However, given the evolving IT standards and the heterogeneity of EMR systems in our volunteer participating hospitals the development of a software tool with the capability to extract data directly from the EMR would be resource and time intensive. The full study with OMB clearance could include conceptual design and preliminary testing of such an application with further development supported under AHRQ's HIT portfolio in support of national goals for interoperability.

- Page 11: Please explain how this study will "identify explicit processes of care associated with the adverse events that will provide a basis for quality improvement activity."

The medical record data abstraction tools include questions about processes of care or patient risk factors that potentially increase the risk of experiencing an adverse event. For example, in the Postoperative Metabolic and Physiologic Derangement Tool question 4. 6 asks whether the patient received a beta blocker (beta-adrenergic blocking agents, beta-adrenergic antagonists, or beta antagonists) within 24-hours of the adverse event, question 4.8 asks for information describing the patient's nutritional intake in the 24-hours prior to diagnosis of the event, and question 4.9 asks for information on the type and amount of IV fluid solution did the patient receive in the 24-hours prior to diagnosis. All of the questions related to a patient's subsequent risk of experiencing a diabetes-related adverse event. The pilot study will identify which of these processes seem to be potentially contributing factors for patients that experienced the adverse event, and would suggest quality improvement activities that either supports modification of these processes or the implementation of standards of care to monitor patients with these contributing factors for the potential onset of these events. The pilot study will inform which of these factors warrant further study and the inclusion in the full study for OMB clearance of "case-control" type of studies where the sampling design supports analyses of whether patients with these factors are more likely to experience an adverse event.