How do you determine which *adverse events* are *problems that are unanticipated*?

The following Venn diagram summarizes the general relationship between adverse events and problems that are unanticipated:

The diagram illustrates three key points:

- The vast majority of adverse events occurring in human subjects are not unanticipated problems (area A).
- A small proportion of adverse events are unanticipated problems (area B).
- Unanticipated problems include other incidents, experiences, and outcomes that are not adverse events (area C).

(Taken from [www.hhs.gov/ohrp/policy](http://www.hhs.gov/ohrp/policy))