

Heat Mapping Noncompliance to Better Target the Extent of Corrective and Preventive Action Plans and Training

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1. Background

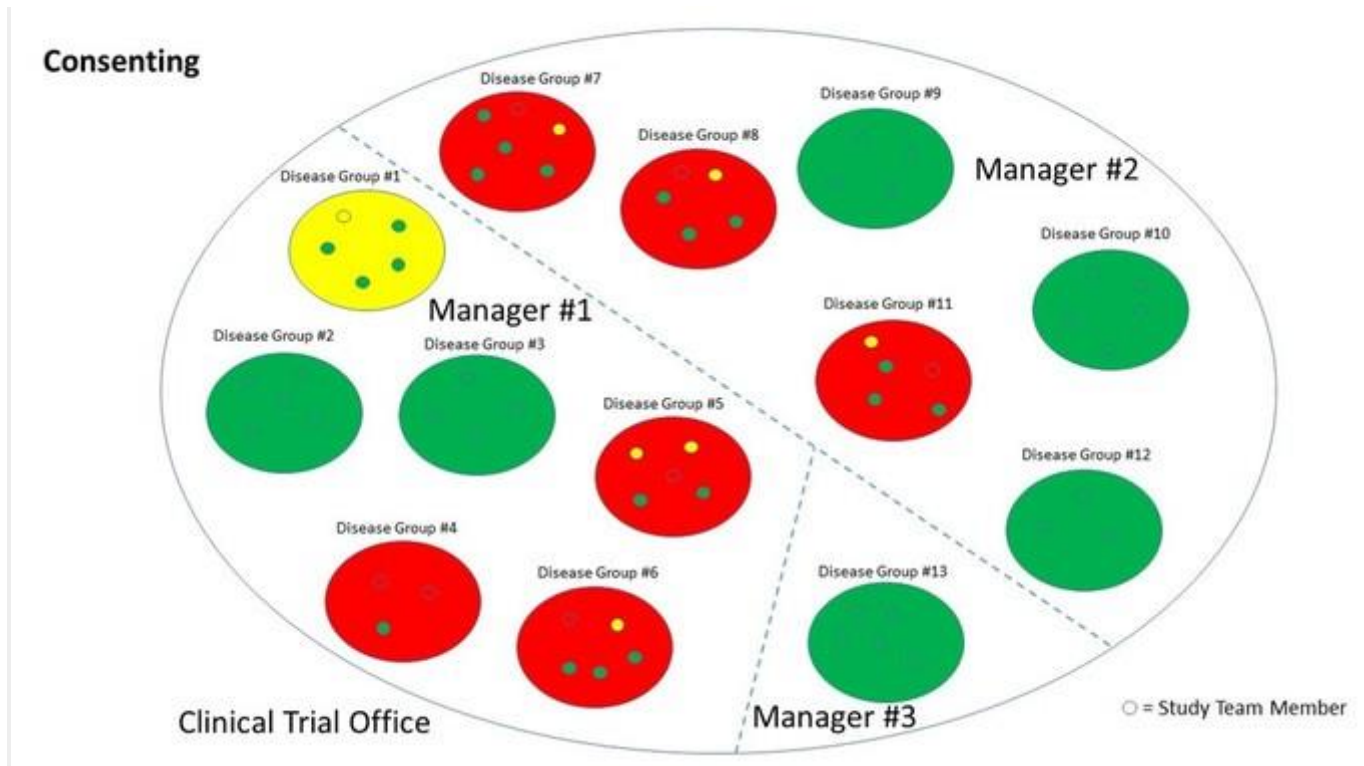
In a complex regulatory environment, where the first reaction is always to institute new procedures or office wide trainings, we needed a better way to determine the required scope of proposed corrective and preventative action plans (CAPAs). Often academic centers rely on office-wide CAPAs due to a particular instance of noncompliance getting escalated by a single stakeholder such as a principle investigator or functional group manager. However, many of these single events are not representative of the totality of the office and may not require a change in office-wide practices. Rather these less prevalent instances of noncompliance may simply require a more focused training or subgroup change in process to more easily and accurately address gaps in compliance.

2. Goals

The goal of this experiment was to find a way to better visualize the extent of noncompliance within our Clinical Protocol Office and to determine if this noncompliance was isolated to a single individual, disease group, functional group or management group, or more widespread across the office.

3. Solutions and Methods

Heat mapping can be used to determine the scope of the required CAPAs. Our heat mapping is a graphical representation of events requiring CAPAs. Colors from green to yellow to red represent the numbers of CAPAs an individual, group, or the office has submitted over the last year for a specific a category of noncompliance. Specifically, green represents no CAPAs and yellow and red represent a certain number of CAPAs with red indicating a higher number than yellow.



The categories we have explored include consenting mistakes, dosing errors, missed assessments, privacy breaches, eligibility violations, and individuals receiving prohibited medications.

4. Outcomes and Future Directions

Heat mapping enabled us to determine the extent of noncompliance in order to better target the scope of CAPAs. Not only did we observe that many events were more isolated occurrences of noncompliance that did not rise to the level of requiring office-wide corrective action, we also determined that many of the more talked about events due to stakeholder escalation were not prevalent within the office and thus did not necessarily require office-wide SOPs, trainings or procedure updates. Additionally, we determined certain subgroups were incredibly compliant on issues that plagued the majority of the office. This allowed us to better analyze what those compliant groups may be doing more successfully and what knowledge they may be able to share with other subgroups within the office.

Importantly, we learned that sometimes the more hot topic occurrences of noncompliance may not be the issues that overall are the most prevalent in the office and that by focusing on these hot topic issues we may not improve overall office compliance. Our future directions include better understanding the contributing factors that make some groups more successfully compliant within different categories and to work with those subgroups to spread their knowledge with other subgroups within the office.