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

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Abstract

In a complex regulatory environment, where the first reaction is always to institute new procedures or office-wide trainings, we need a better way to determine the required scope of proposed corrective and preventive 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 (PI) 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.

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 was more widespread across the office.

Introduction

Heath mapping can be used to determine the scope of the required CAPAs. Our heat mapping is a graphical representation of events requiring CAPAs. Color from green to red represent the numbers of CAPAs an individual, group, or the office have submitted over the last year for a specific category of noncompliance. The categories we have explored include consenting mistakes, dosing errors, missed assessment, privacy breaches, eligibility violations, and individuals receiving prohibited medications.

Schematic Representations of different trends that we looked for:

Isolated to an individual:

Isolated to a disease group:

Isolated to a particular manager's staff:

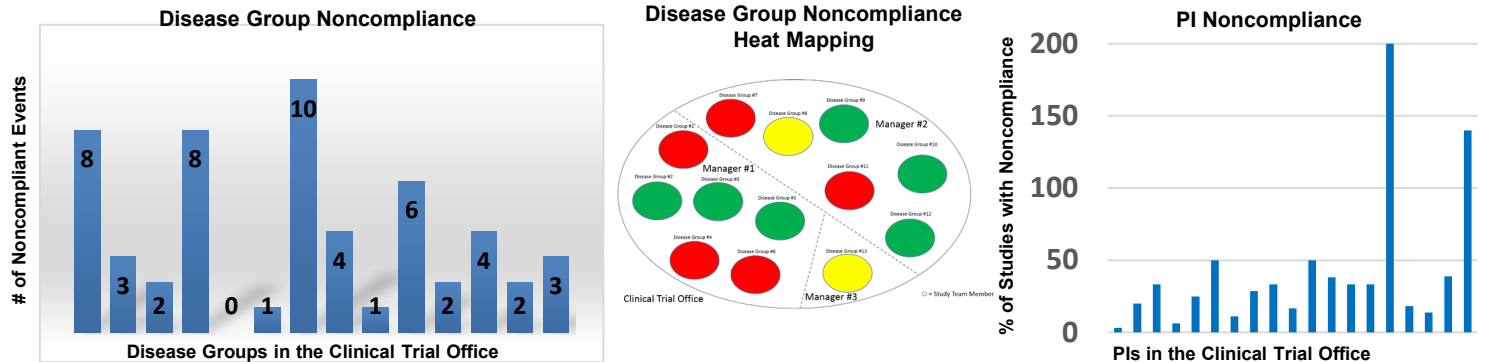*Widespread throughout the office:*

Results

Figure 1: Heat Mapping Helps Disease Group Leader Visualize Noncompliance

Disease group leaders often question how their team is operating in comparison to other teams in the office. By providing them a visual comparison, the disease group leader can better understand where their team may need improvement and where their team is succeeding.
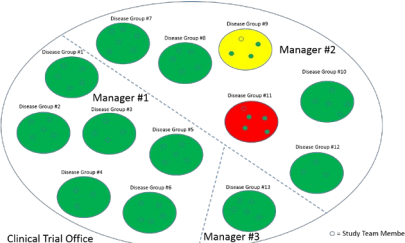
Figure 2: Heat Mapping Helps CTO Leaders Direct CAPAs and Training for Noncompliance

Noncompliance Related to Treatment:

Noncompliance Related to Prohibited Meds:

Noncompliance Related to Consenting:

Noncompliance Related to HIPAA Violations:
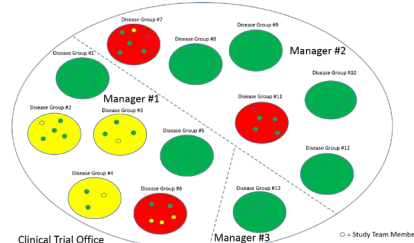
Heat mapping allowed us to see that noncompliant events surrounding releasing subjects for continued treatment and maintaining consent properly throughout the study were prevalent issues across multiple disease groups. As a result, these events required office-wide corrective actions and trainings.

When examining noncompliance involving giving subjects a prohibited medication, heat mapping allowed us to see that multiple individuals in a limited number of disease groups were responsible for the events. As a result, more directed training and corrective actions could be focused on the unique aspects of these disease groups.

Interestingly, 2 events of noncompliance surrounding HIPAA regulations were hot topics for the office. They were escalated and the PI involved wanted large scale corrective action. However, when examining HIPAA noncompliance via heat mapping we determined that they were isolated events limited to a single individual and did not require broad scale action.

Conclusions

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.