Division of Oncology

Data Talks:
Using Non-Compliance Tracking to Improve Patient Safety

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Background

Reportable non-compliances (also known as major deviations) are defined as *changes in research made without prior IRB approval that have the potential to negatively impact the rights, safety, or welfare of a participant*. Since 2012, non-compliance tracking has been managed by various teams without standardized guidelines or terminology.

This resulted in:

- variation in user interpretation of non-compliance categories, leading to unreliable data and inconsistent tracking (i.e. similar non-compliances were categorized differently)
- creation of new categories for each uncommon non-compliance, resulting in 18 different "types" of non-compliances

Additionally, while the reportable non-compliances were reviewed monthly by management, aggregate data was not analyzed for trends, leading to missed opportunities to prevent future non-compliances (e.g. by establishing re-education plans). To improve the quality of our data and better inform our leadership, we needed to investigate areas for improvement.

Goals

Methods and Outcomes

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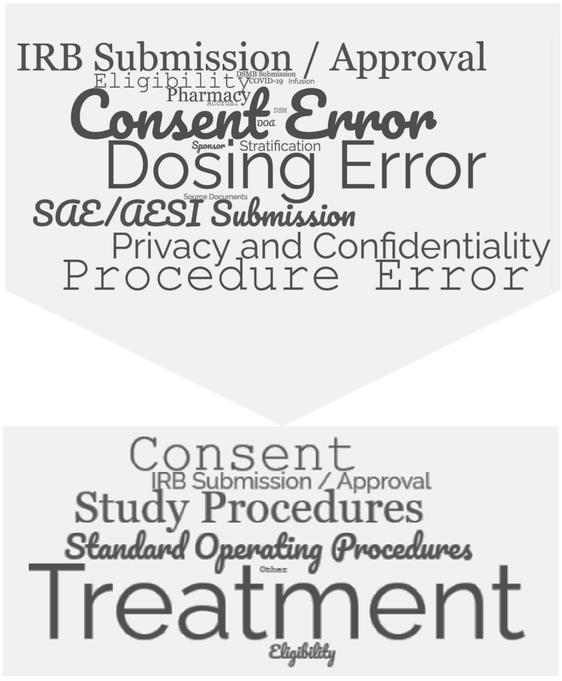
Standardize: terminology to eliminate redundant and mislabeled non-compliances	We simplified the possible non-compliance types to 7 categories.
Create: method to improve consistent categorization	We now have a reference key with examples to ensure all users categorize in a consistent manner.
Re-categorize: historical data to increase sample set for analysis	We updated data from 2015-2021 with the new standardized terminology.
Develop: plan for continued aggregate data review	We will analyze and present data to management on a quarterly basis.
Present: data analysis and trends to stakeholders	We reviewed historical (2015-2021) and quarter 1 data with management in April 2022.

Standardize Outcome Illustrated



Create Outcome Illustrated

Type	Sub-type	Examples
Treatment	Dosing hold/reduction/ discontinuation error	Two patients were given incorrect dose reductions when resuming treatment after a dose hold. Patient treated beyond progression without medical monitor's approval.
	Infusion administration error	Patient's infusion was restarted at the original infusion rate after an immune-related reaction rather than 50% of the original rate, as mandated per protocol.
	Prescription or dispensing error	Patient was dispensed expired study medication. Study drug was mixed with 50 ml 0.9% Sodium Chloride instead of 100 ml.
	Prohibited meds administered	Two patients took medications known to prolong QT interval, contrary to protocol requirements.

Lessons Learned & Future Directions

We learned the importance of clear guidelines and consistent execution, especially when it comes to shared tools. We expect improved tracking will lead to improved data, which will better inform our priorities for re-education, staffing, standard operating procedures, and protocol development.

We will continue to track non-compliances using the new category system and reference key. Quarterly presentation of aggregate data will serve to better inform our leaders and more quickly identify trends in non-compliances.

The 2022 Q1 analysis has already been presented, with managers utilizing the insights learned to set goals for Q2. We have partnered with our Division's Education & Training Team to target areas needing re-education, starting with an upcoming staff presentation on the types and frequency of non-compliances occurring across all teams.

In conclusion, by collecting, analyzing, and communicating clear and consistent data on errors made, our leaders and collaborators can use the knowledge gained to create meaningful tools and training aimed at improving patient safety and clinical trial data.