



Pharmacy

Specialty Pharmacy Adverse Event Reporting

An analytic retrospective pretest-posttest design with interventions, used to evaluate the time taken to document drug adverse events at Banner Health Specialty Pharmacy, as well as identifying the top five medications that lead to adverse events to help increase medication awareness.

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Key Points

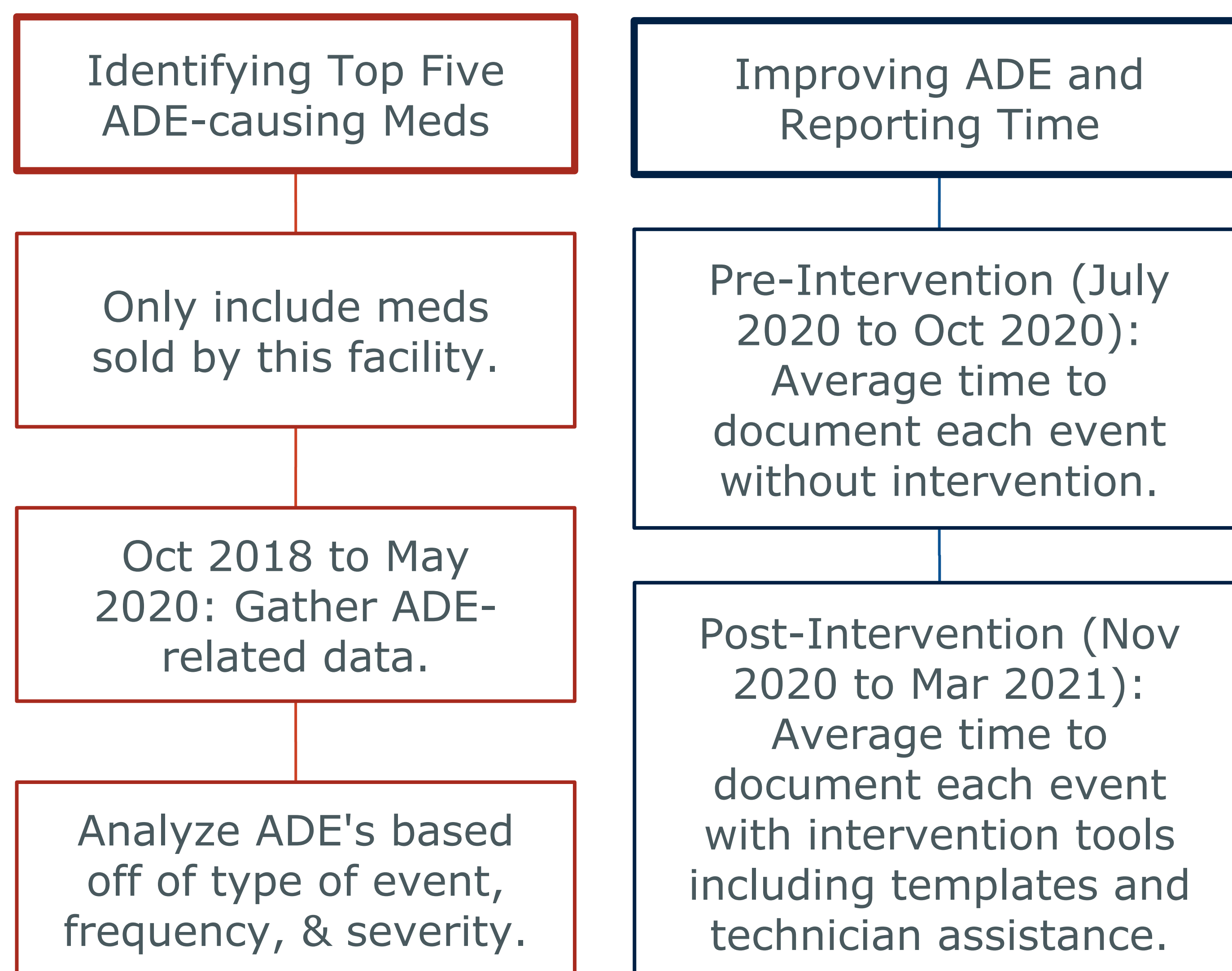
- Specialty pharmacies document adverse drug events (ADE's) and counsel patients on ADE's to mitigate patient risk and improve health outcomes.
- Documentation templates and technician utilization are strategies that can be used to decrease the documentation time of ADE's at Banner Specialty Pharmacy-Chandler and make the process more efficient.
- The top five medications that cause ADE's at Banner Specialty Pharmacy may highlight side effects that require more counseling by Pharmacists.

Introduction

Specialty Pharmacies can use ADE reporting systems to improve med safety and patient monitoring, and identify new drug information and potential risks^{1,2}; therefore, the goal is to make this reporting more efficient and make med use safer.

Purpose: First, to improve the average time taken to document ADE's before and after new strategies are implemented. Second, to highlight important drug information for future and existing patients by documenting and analyzing the severity and frequency of ADE's among the top five specialty medications that cause the ADE's.

Methods



Results

Table 1: Average Time to Document Adverse Events

	Pre-intervention (Jul 2020 - Oct 2020)	Post-intervention ^c (Nov 2020 - Mar 2021)	P-value ^d
Number of ADE's (N) ^a	33	31	
Time to document ADE's (min/event) ^b ($\bar{x} \pm SD$)	12.22 \pm 0.83	10.00 \pm 2.68	0.032

^a Total number of med related ADE's for pre and post interventions.
^b Total average time calculated for pre and post intervention periods.
^c Intervention began November 11, 2020 and ended March 1st, 2021.
^d The p-value is for a student's paired t-test.

Table 2: Top Five Meds at Banner Health Specialty Pharmacy that cause the most Adverse Events

Medication (N events) ^a	Adverse Reaction Type: N events (severity ^b N)	
Humira (18 events)	Skin allergic reaction: 6 (mod 1; mild 5) Other; neurologic: 4 (mild 4) Infection: 3 (mod 1; mild 1; unknown ^c 1)	GI symptom: 2(mod 1; mild 1) SOB: 1 (mild 1) Hematologic, leukemia: 1 (mild 1) Facial swelling: 1 (mild 1)
Enbrel (13 events)	Neurologic: 3 (mild 1; unknown 2) Injection site reaction: 3 (mild 2; unknown 1) Musculoskeletal: 2 (mild 2) Infection; cellulitis: 1 (mild 1)	Cardiac, peripheral edema, SOB: 1 (mild 1) GI symptom: 1 (mod 1) Skin allergic reaction: 1 (unknown 1) Anaphylaxis: 1 (mild 1)
Capecitabine (9 events)	Skin allergic reaction: 3 (mild 3) GI symptom: 3 (mod 2; mild 1)	Hepatic: 1 (mild 1) Low ANC: 1 (mod 1) Flu-like symptoms: 1 (mild 1)
Imbruvica (5 events)	GI symptom: 1 (mod 1) Cardiac: 1 (mod 1) Musculoskeletal: 1 (mild 1)	Hematologic, anemia: 1 (mild 1) Respiratory, neurologic, cardiac: 1 (mild 1)
Sutent (5 events)	GI symptom: 2 (mild 2) Infection: 1 (mod 1)	Cardiac, hypotension: 1 (mild 1) Musculoskeletal: 1 (mild 1)

No significant difference in severity between meds (*p-value* = 0.843)

^a Top 5 meds identified to cause the most ADE's at Banner Health Specialty Pharmacy (170 total ADE's identified).
^b Severity classes: mild (med discontinuation), mod/moderate (close monitoring), severe (hospitalization), death, and other. Data based on what was selected in the ADE reporting system when the event was documented.
^c Severity classified 'unknown' due to unspecified severity documented in the data.

Discussion

The total average documentation time for the pre-intervention period was 12.22 min per event (SD=0.83), while the total average documentation time for the post-intervention period was significantly faster at 10.00 min per event (SD=2.68) (*p-value*=0.032). This showed a clinically significant decrease in documentation time of 2 minutes after the intervention was made. Humira, Enbrel, Capecitabine, Imbruvica and Sutent were identified at the top 5 medications to cause ADE's, and no significant difference was noted in severity between groups (*p-value*=0.843).

Implications: Given the decrease in documentation time, current intervention tools and templates can now be altered to try and decrease this time by a larger amount. Future studies may want to investigate decreasing the number of ADE's before and after the intervention along with documentation time. For the top five medications that cause ADE's, the goal was to use the data to alter counseling points for these medications. It is with hope that this data is used as an informational tool to guide more quality improvement projects in the future.

Limitations: Inability to fully identify template/email use by all pharmacists and technicians, sample size of adverse events used was rather small, and discrepancies that were found in the severity data when pulled from the database (i.e., "unknown" severity).

Conclusion

Pharmacist documentation templates and pharmacy technician utilization strategies may decrease the time to documentation of ADE's at a Banner Specialty Pharmacy. Lack of complete controls for some variables leaves room for altered correlation between the intervention and a decrease in time, but this can be investigated in future studies. Information about the top five ADE-causing meds at this Banner Specialty Pharmacy should only be used as a tool to highlight counseling points. Hopefully, it can be used as insight or a baseline for future quality improvement projects in specialty pharmacy settings.

References

- Patient safety and adverse event reporting: Creating alignment between specialty pharmacy and manufacturer. (2014, July 1). Retrieved from <https://www.pharmacist.com/article/patient-safety-and-adverse-event-reporting-creating-alignment-between-specialty-pharmacy>
- Morimoto, T. (2004). Adverse drug events and medication errors: detection and classification methods. *Quality and Safety in Health Care*, 13(4), 306-314. doi: 10.1136/qshc.2004.010611