A Pharmacy Resident Research Project: ASsessment of a Strategy to improve Electronic allergy records at a Tertiary care hospital

Project Acronym or Short Study Title: ASSET

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1. Protocol Synopsis

This study is a follow-up to the REACT study which revealed that many electronic allergy records at Royal Jubilee Hospital (RJH) contain incomplete information. The purpose of ASSET is to compare the baseline results found in REACT to the completeness of electronic patient allergy records after implementing an educational intervention targeting nurses on 8N, an acute medicine ward at RJH. Completeness will be defined as the drug name plus any description of the nature of the reaction . The intervention will consist of in-services accompanied by a post-session email summary, complemented by informational posters placed on the ward. After the in-services have taken place the following outcomes on 8N will be evaluated: (1) the percentage of allergy entries that are complete, (2) the average number of documented allergies per patient, (3) percentage of reactions documented as allergies, intolerances or adverse drug reactions (ADRs), (4) the percentage of allergies entered as drug classes or a single drug, (5) the percentage of documented antibiotic allergies updated, and (6) the percentage of allergy entries inputted by nurses.

2. Background & Rationale:

It has been suggested that approximately 12.1% of medication errors resulting in ADRs are due to poor understanding of their classification into one of the following categories: allergy, intolerance or side effect (1). This lack of understanding can largely be attributed to insufficient documentation details about the reaction (2). Each ADR type may be managed differently in order to prevent a patient from experiencing further harm, but this requires enough information about the reaction to determine how

to proceed (3). For clinicians to make informed decisions to distinguish allergies from intolerances or ADRs, the nature of the reaction, timing, and dose given when the reaction occurred can provide vital information for guiding therapy (4). This information can guide monitoring parameters in instances like drug re-challenges, and can ultimately support a decision on whether or not a drug should be administered to a patient. Villamanan et. al suggest that as few as 6-10% of inpatients who report medication allergies actually have a true allergy (5). If this truly is the current situation, having more information about the "allergy" could be very helpful in discerning the type of reaction that occurred.

Allergies are immunologically-mediated, require sensitization with a primary exposure, will most likely re-occur, and can increase in severity upon drug re-exposure (e.g. anaphylaxis from penicillin) (4). Alternatively, intolerances are defined as undesired effects due to a low threshold to the normal pharmacologic action of a drug (e.g. prolonged drowsiness from zopiclone) (4). Side effects also occur in accordance with the drugs' pharmacologic properties, but are expected or familiar and tolerance can often develop (e.g. diarrhea from metformin) (4). Each of these reactions carries distinguishing features that can provide a more complete picture for clinicians, but this is lost when details do not accompany the documentation of a reaction. In some instances, a true allergy requires avoidance of an entire drug class and potentially even those that are similarly structured (4). An intolerance/sensitivity would more likely be drug-specific or mechanism-of-action-specific, requiring a different approach to management (3,4).

In a study conducted last year at the Royal Jubilee Hospital (RJH) by Kyle McWilliams et al. (REACT), it was found that roughly 46% of documented allergies had no associated description of the reaction experienced (6). REACT showed that the two main disciplines responsible for inputting allergy entries into the EHR were nurses at 53% and pharmacists at 31% (6). 94% of pharmacist-completed allergy documentation contained additional information about the reaction, likely attributed to a discipline-specific understanding about the usefulness of complete documentation. Of the entries done by nurses, only 60% of them reported the nature of the reaction, making nurses an ideal initial target group for the educational in-services (6). In addition, REACT found that opioids (excluding meperidine), followed by penicillins and then sulfa drugs are the three most commonly patient-reported drug allergies. These medications are frequently used in hospitals and having details pertaining to the reactions is very useful in making medication-related decisions.

Antibiotic-reported drug allergies are some of the most common, and it should be noted that this can impact antimicrobial stewardship (7). Narrow spectrum agents might be ruled out due to uncertainty around a reported allergy, which necessitates use of broader spectrum antimicrobials for an infection that would not otherwise require such aggressive therapy. This can result in increased antimicrobial resistance, and can ultimately lead to suboptimal patient outcomes (7). There also seems to be cost implications associated with a documented beta-lactam allergy as stated by one study done by Picard et al. They found an estimated additional cost of over $15,600 in one year incurred from the use of alternative antibiotics in only 55 patients (8). Satta et al. also found an additional cost of treatment per patient with a reported beta-lactam allergy compared to a patient without this allergy

status (9). This is significant, considering 80-90% of patients who report a beta-lactam allergy, can actually receive and tolerate the medication (9).

In order to improve allergy documentation completeness, other studies have implemented different strategies involving nurses, physicians, pharmacists, and patients. A pharmacist-driven intervention protocol where clarification orders were flagged and sent out to the attending clinical pharmacist to determine details from the patient/doctor/family for all allergies without corresponding reaction type resulted in a statistically significant increase in complete allergy documentation and a 10% reduction in blanks (10). Educational presentations highlighting the importance of accurate and thorough allergy documentation, informational posters, and presentation summaries sent over email more than doubled the percentage of reporting containing complete documentation describing the allergy (11). Other studies focused on educating patients about their allergies using brochures, standardized questionnaires, allergy cards and pharmacist consult (12,13). Overall, the main theme of each intervention is education.

The intervention ASSET will be implementing is similar to what was done by Kathawala et al.; a pharmacist-driven protocol comprised of an educational presentation, email summaries and posters (11). No other studies have identified which discipline inputs the highest proportion of allergy entries into the EHR and focused the intervention on that group. However, the educational intervention in ASSET will target nurses, as the REACT study showed them to represent the largest proportion of allergy documentors at RJH. While most interventions have shown to improve allergy reporting, the gaps in current literature include lack of follow-up to assess the longevity of the outcomes. There are little data to demonstrate if the interventions provide long-lasting improvement. Kathawala et al. and Jarernsiripornkul et al. both compared allergy completeness documentation from before to and 1 month after intervention, which is a relatively short time frame (11,13). ASSET will analyze data that are collected for one month after the intervention, and another dataset collected roughly 3 months later to assess for a lasting effect.

The primary objective of this study is to assess if the educational intervention is effective in improving completeness of allergy documentation. Completeness will be defined as the drug name plus any description of the nature of the reaction. If completeness is found to improve after the intervention, the results will help facilitate more extensive interventions and the possibility of targeting a broader range of health professionals. More thorough documentation will lessen uncertainty around whether or not to administer a medication, which will improve patient access to appropriate therapy, as well as prevent true allergen re-exposures.

3. Study Objectives(s)/Purpose:

Primary Objective:

- To determine if the percentage of allergy/sensitivity documentation containing sufficient detail to discern an absolute contraindication from a precaution improves after implementing an educational intervention strategy

Secondary Objectives: Compared before and after the educational intervention

- To determine the average number of allergies per patient
- To determine the percentage of reactions classified as intolerance, allergy or ADR
- To determine the percentage of allergies entered as drug classes or as a single drug
- To determine the percentage of allergy entries inputted by nurses on 8N
- To determine the number of documented antibiotic allergies updated or cancelled
- To assess the durability of effect from the intervention (if an effect is indeed found)

4. Study Population

Our Study Sample will include adult inpatients at the Royal Jubilee Hospital and be divided into two restropective cohorts. The nurses on 8N will also be involved in our study as they will be the recipients of our educational intervention.

"Before" Cohort (dataset from REACT study)

- 1000 randomly selected patients who were admitted to RJH from February to November 2016

"After" Cohort

- Patients admitted to 8N at RJH between Nov 6/17 to Jan 12/18 inclusive

Inclusion Criteria

- Age >18
- Admitted to 8N anytime from Nov 6/17 to Jan 12/18
- Nurses working on 8N during the period when the educational presentations are being delivered (Oct. 16-Nov. 3)

Exclusion Criteria

- Age <19
- Admitted to any ward other than 8N from Nov 6/17 to Jan 12/18
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5. Study Design & Procedures

This is a retrospective before-and-after chart review following implementation of an educational allergy documentation intervention.

"Before" Cohort (retrospective data from the REACT study):

- Pharmacy informatics (RxIT) retrieved data from the Cerner Millennium Database using tailor made reports. The original query identified patients that were admitted to RJH from February – November of 2016.

- The patient sample was randomly selected from the pool of patients identified. The number of participants in the retrospective cohort (n = 1000) was determined based on a convenience sample as opposed to a power calculation.
- For this randomly selected patient sample of 1000, pharmacy informatics generated a dataset consisting of the participants': Medical Record Number (MRN), Financial Information Number (FIN), unit, room, and bed for the encounter at the date/time that the allergy/sensitivity was documented, date the entry was documented, age, sex, substance that the allergy/sensitivity is reported against (medication), reaction classification (e.g., allergy, intolerance), nature of the reaction (e.g., rash, anaphylaxis), comments, and which health discipline recorded the allergy/sensitivity entry, and if the patient received a medication of the same class since the allergy/sensitivity was added to their EHR. See Appendix A for a sample data collection sheet. This was completed for each allergy/sensitivity entry on the patients' EHR. RxIT filtered the results for active drug allergies/sensitivities, preventing extraneous data on food or environmental allergies/sensitivities and data on allergies/sensitivities that have been cancelled from being included in data collection.
- When multiple allergies were entered for one MRN, data were merged on Microsoft Excel such that each MRN contains the above information for each allergy entry with associated dates for each entry. For patients with no documented allergy/sensitivity, the medication field said 'No known drug allergy (NKDA)'.
- Patients were de-identified by replacing their MRN, FIN, room number, and bed number with a study number. A 'key' that contains the corresponding MRN and FIN to each study number was kept in a separate document with a separate password in order to protect participant confidentiality and privacy.
- The data were cleaned, transferred into REDCap (the data collection and storage tool), and analyzed by the PI (Kyle McWilliams). Cleaning the data included tasks such as correcting spelling errors and switching medication brand names to generic drug names to ensure all data are correctly analyzed.
- Outcome data were summarized and charted with the appropriate statistical analyses
- The retrospective data from REACT will be transferred from the REACT folder in REDCap to the ASSET folder, where only the PI and co-investigators of ASSET will have access to the password-protected data.

"After" Cohort:

The comparative dataset will be pulled and handled the same way as the baseline data, but will come from the study ward (8N) only. The differences for the "after cohort" data are as follows:

- Location/Unit/Bed will be excluded from this dataset, as the intervention is happening on a single ward, so it is not necessary. See Appendix B for sample data collection sheet.
- The medication administration data that were gathered as part of the REACT study will also be excluded, as this was collected for the prospective arm of that study and is not necessary for ASSET

- The convenience sample will include all patients admitted to the study ward within the specified time periods (Nov 6/17 to Jan 12/18).
- The “after” dataset (admissions between Nov 6/17 to Jan 12/18 inclusive) will be compared to the “before” dataset from REACT.
- A subset analysis of the “after” cohort will compare the second “after” dataset (admissions between Dec 11/17 to Jan 12/18 inclusive) to the first “after” dataset (admissions between Nov 06/17 to Dec 10/17 inclusive) to assess for a lasting effect of the intervention.
- As per Island Health Allergy and Sensitivity Identification and Documentation Policy (See Appendix C), allergies should be reviewed and updated as necessary upon admission and at each transition point in care. With this, the length of stay on the ward should have no bearing on allergy documentation.

Educational intervention:

- Our educational interventions will not change the current standard of patient care, but rather describe the current policies and best practices, and reinforce the importance of thorough documentation upon admission.
- A 15 minute PowerPoint presentation given by the PI (pharmacy resident) to the nurses on 8N will be the initial part of the educational intervation. The presentation will address the general differences between an allergy, an intolerance and an adverse drug reaction. It will give examples of the type of questions that can help patients report useful information and it will briefly address why improving allergy documentation completeness is important for patient outcomes. See Appendix D
- This presentation will be given 2-3 times during the week of Oct 16 to Oct 20 and Oct 30 to Nov 6; it will occur multiple times a day during Oct 23 to 27 as this is the pharmacy resident’s project week.
- The Clinical Nurse Leader (CNL) on 8N has confirmed that a list of the ward schedule during that time period will be sent to the PI in order to email an informed consent form (ICF) to each nurse. See Appendix E
- The ICF will be sent out via email to each nurse 1 week prior to the start of the in-services. This will provide them the opportunity to reflect about their participation and contact the PI if they have any questions or concerns.
- If they do contact the PI over email, it will only be to set up a time for a private, in-person meeting to ensure confidentiality and that there are no breaches of privacy due to email correspondance.
- To ensure there are no power-over perceptions, the CNL will not attend the in-services and will therefore not be made aware of who attends or does not attend the in-services.
- The CNL will be sent a copy of the in-service PowerPoint after a signed ICF is received by the PI.
- The nurses who decide to voluntarily attend the in-serice will beprovided with two ICF forms to sign. One will be to keep for their own records, and the second will be for the PI.

- Our goal will be to reach 100% of nurses who work on this unit. If not all the nurses are able to attend, the proportion who do attend will be reported and this will be taken into consideration during the discussion of results. The ICFs will be used to determine the number of nurses who participated in the in-services.
- The PI's copy of the ICF will be scanned in to the computer and saved on the secure, audit-approved research drive that is only accessible by the primary and co-investigators.
- The PI's paper copy of the ICF will be confidentially shredded once scanned in to the computer and stored on the research drive.
- An email will be sent out after the in-service to those who attended, containing a summary of the presentation topics. All email addresses will be VIHA email addresses only and these will be Bcc'd to ensure there is no break in participant confidentiality. See Appendix F
- Posters containing the information covered in the in-services will be dispersed on the ward the day of the first in-service to serve as a reminder of the learned material. See Appendix G

Figure 1. Project Timeline

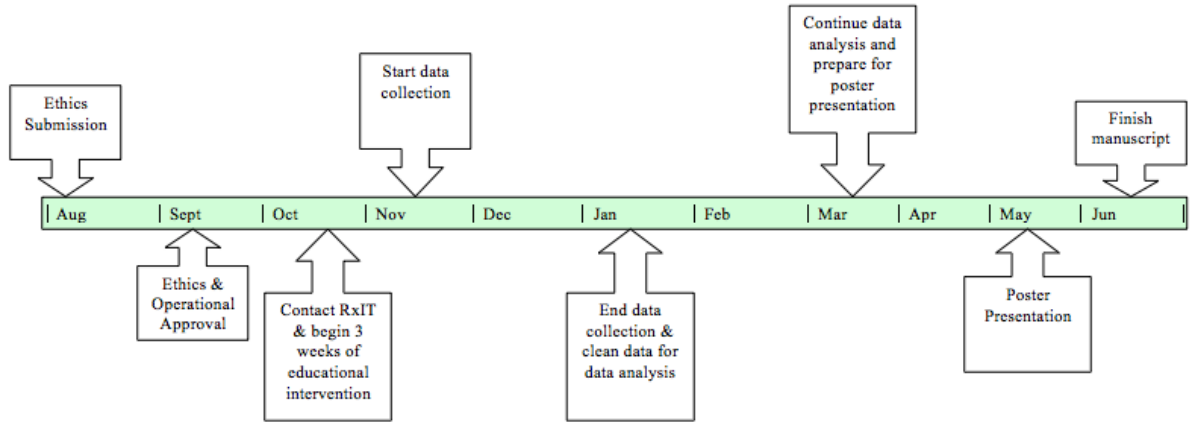
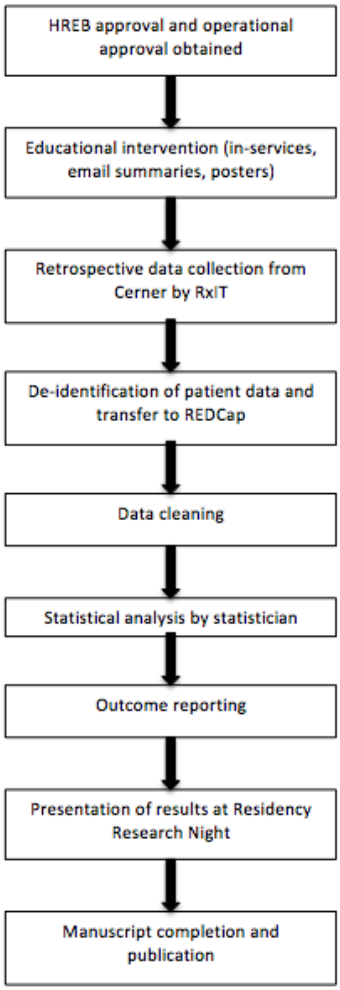


Figure 2. Flow Diagram



6. Statistical Considerations

- Sample size will be convenience based, as opposed to based on a power calculation, as the length of the study (1 year) and the actual time during which data are collected will be limited (10 weeks total for the "after" cohort).
- Victor Espinosa (Manager, Research Informatics/Statistics Vancouver Island Health Authority) has been consulted to help with data analysis, and will apply the appropriate statistical tests. He will conduct a statistical analysis of the data once it has been cleaned and transferred to REDCap by the PI, and he will perform a 95% confidence interval analysis comparing the "before" and "after" data. Incomplete/missing data would entail patient EHRs with nothing entered under allergies, and this will be recorded as such.

7. Data Collection and Data Management

- The baseline "before" dataset has already been pulled from patient electronic health records (for the REACT study), and the comparative "after" dataset will be pulled the same way, with the exception of being from a specific ward (8N).

- Allergy/sensitivity entries will be collected from the EHR for all patients admitted to 8N during the predetermined "after" data collection periods for analysis. RJH pharmacy informatics department will collect this data once ethics approval is obtained.
- We are requesting a waiver of consent for the restrospective data from the Research Ethics Board, given the minimal risk to patients and their privacy associated with our work. All personally identifying information will be removed (de-identification) and patients will be assigned a study number, the same as was done in REACT. A study key that contains the MRN corresponding to the study number will be placed in a password-protected document. Further, a requirement for patient consent would be prohibitive for conduct of our study, given our limited timeframe (1 year).
- An ICF will be distributed to the nurses on 8N and a signed copy will be collected from those who voluntarily choose to participate
- All data will be collected, processed, and stored within Island Health's secured and approved audit-able network drive. Only project members will have access to the data, and all project members are Island Health employees. Data will be contained in password-protected files, and the study list key will be kept separate from the de-identified patient list. Data will be destroyed by the PI (Alanna Janz) in accordance to Island Health Data Classification Scheme and Safeguards after being stored for 5 years. Data will be double deleted after 5 years and all ICF paper forms will be confidentially shredded by the PI after the in-services have all taken place on Nov. 3, 2017.
- De-identification will be done by the PI after the data from RxIT is received and the quality control measures have been completed. The dataset stored in REDCap will have all patient-identifying information removed and replaced with their study number.

8. Publication of Results

The PI will present the results at the BC Pharmacy Residents' Research Night in May 2018. A manuscript will be completed by the end of June 2018 to meet residency program requirements. We also intend to submit our results publication in an academic journal. Primary and co-investigators will be acknowledged according to their respective contributions.

9. References

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10. Appendices

Appendix A: Sample data collection sheet from REACT

- See attached

Appendix B: Sample data collection sheet for ASSET

- See attached

Appendix C: Island Health Allergy and Sensitivity Documentation Policy 9.1.6P

- See attached

Appendix D: Allergy Documentation PowerPoint Presentation

- See attached

Appendix F: Informed Consent Form

- See attached

Appendix F: Email Summary

- See attached

Appendix G: Poster

- See attached