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Measuring Total Steroid Dose using Real-World Data

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ABSTRACT

Real-world data provides valuable information for outcomes research. However, the data can be messy and there is no source document to verify or correct the data points. This poster illustrates how the real-world data is cleaned and handled. The goal of the analyses is to measure total steroid dose for each patient over a 90-day period. Days of supply, Quantity, and Strength are used to calculate the daily dose for each drug record. Data cleaning was done to handle missing or outliers. More importantly, it's critical to handle the overlapped prescriptions as they can be used sequentially or concurrently. Input from clinical experts such as pharmacists are valuable to make assumptions and decisions. Multiple overlapping scenarios, such as (1) same drug, same daily dose, same route vs. (2) different medication or same medication but with different daily dose, and the corresponding actions are detailed in this poster.

INTRODUCTION

Real-world data – such as administrative claims data, electronic medical records, registry - provides valuable information for outcomes research. Real-world data are considered as secondary data which means the data was not intended to answer specific scientific questions. For example, claims data are intended for billing purposes and not collected for prevalence analysis. Therefore, the data can be very messy and there is no source document to verify or correct the data points like clinical trial data. Outcomes research professionals need to find other ways to handle real world data, making meaningful assumptions and develop business rules, to be able to analyze the data and answer study questions. We used an example analysis to illustrate the effort and strategy. In this analysis, the study question was to measure total steroid dose for each patient over a 90-day period.

METHODOLOGY

PRE-HANDLING

To calculate drug dose, we need information from the following fields in the raw data: Days of supply, Quantity, and Strength. A few data cleaning steps were done for these variables. For example, we assign days of supply as 1 if it comes from procedure for medical administration records; and the strength was standardized. After the data cleaning, we calculate daily dose for each steroid record as (Strength)*(Quantity) / (Days of Supply).

OVERLAPPED PRESCRIPTIONS – DID PATIENT USED THEM ALL TOGETHER?

In the actual data, there are prescriptions overlapped with each other. It might overestimate the total dosage if we assume the overlapped prescriptions are used concurrently. And we also might underestimate the total dosage if we assume the overlapped prescriptions are used sequentially. We explored the data and sought input from clinical experts to make assumptions how patients used these prescriptions. We categorized the possible scenarios below and made decisions respectively.

STEP 1: SAME MEDICATION, SAME DAILY DOSE

If the two overlapping medication records are with the same medication and same daily dose. First, we determine if both records are on the same prescription date.

STEP1.1 - SCENARIO 1.1: SAME PRESCRIPTION DATE

If both records are same medication/daily dose/prescription date, we further check if they have the same days of supply.

If the days of supply are the same, we remove the duplicates. For example, a drug A record (Rx1) is 60mg/day for 30 days (filled date is Jan 01, 2020) and the other drug A record (Rx2) is 60mg/day for 30 days (filled date is Jan 01, 2020). Only Rx1 will be kept.

If days of supply are different, then we keep the record with the longest days of supply. E.g., Rx1 is 60mg/day for 30 days (filled date is Jan 01, 2020), Rx2: 60mg/day for 60 days (filled date is Jan 01, 2020). Only Rx2 will be kept.

The above scenarios are mainly to deal with duplicate observations we sometimes see in claims.

STEP 1.2 - SCENARIO 1.2: DIFFERENT PRESCRIPTION DATE BUT WITH OVERLAP

Next, if both records are same medication/daily dose but are on different prescription date, we assume that the prescription was refilled early for later use and push out the date of the later Rx.

STEP 2: DIFFERENT MEDICATIONS OR SAME MEDICATIONS BUT DIFFERENT DAILY DOSE

The rest of the scenarios are overlapping records between different medication and/or different daily dose. Similarly, we check if the two records are on the same date.

SCENARIO 2.1: SAME PRESCRIPTION DATE

If the records are on the same date, the decision will be based on the total daily dose (summing up daily dose for all Rx's). If the total daily dose is greater than maximum allowed daily dose (as the clinical expert suggested). We assume that the Rx's are given with the direction that they should be used sequentially (e.g., according to the tapering schedule). Therefore, the one with the lower daily dose will be pushed out. The rationale is that in the context of steroid tapering, the goal is to slowly decrease a steroid dosage over time. If daily dose is the same and we have oral and injections/IV then we push out the oral one.

If the total daily dose is less than or equal to the maximum allowed daily dose, we assume the two prescriptions were prescribed to be taken together to create a higher dose. No action is needed.

SCENARIO 2.2: DIFFERENT PRESCRIPTION DATES

Finally, if the records are on different dates. We assume this is a change in treatment or a change in dose. We will discard the remaining dose for the earlier one.

Once all the steps above are applied sequentially, we summed up the dosage during the 90-day period as the patient's total dose for the downstream analysis.

CONCLUSION

We can see how messy the real-world data is and the complicity to come up with comprehensive business rules to cover all possible scenarios. These exploration/decisions need to be done before making the comparison between treatment groups. This takes cross-functional collaborations – programmers, scientists, and clinical experts – we were able to communicate efficiently and stay on the same page, even we all have very different expertise and background. It will never be perfect, but we need to make sure the business rules are clinically making sense.

CONTACT INFORMATION

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