

A Practical Approach to Strengthening Observational Studies:

Addressing Immortal Time Bias at QU CMED



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In medical research, randomized controlled trials (RCTs) are often considered the gold standard for evaluating treatment effectiveness. By randomly assigning participants to different groups, RCTs help ensure that any observed differences in outcomes can be attributed to the treatment itself. However, RCTs are not always feasible due to their high costs, time requirements, and ethical considerations. As a result, researchers frequently turn to observational studies, which are more accessible and reflective of real-world clinical practices. Despite their advantages, observational studies are prone to biases, one of the most notable being *immortal time bias*. This bias can distort results, leading to misleading conclusions. A team of researchers at QU CMED, led by Professor Suhail A. Doi and PhD scholar Jazeel Abdulmajeed, has developed a new method called the *Iterative Time Distribution Method (ITDM)*, which aims to address this issue and improve the reliability of observational studies.

Understanding Immortal Time Bias

Immortal time bias arises when the follow-up periods in a study are not properly aligned between treatment groups. This misalignment can create an artificial advantage for the treated group, making it seem like they have better outcomes simply because they had a period during which they were not at risk for the outcome. For example, in a study on bariatric surgery, participants are only considered “exposed” after undergoing the procedure. The time before the surgery, when they are not yet at risk for adverse events, must be accounted for. If this pre-surgical time is ignored, the surgery group may appear healthier than they truly are, skewing the results.

The Iterative Time Distribution Method (ITDM)

To tackle this issue, Professor Suhail Doi and Jazeel Abdulmajeed have developed ITDM, a method designed to better align follow-up times



between treatment groups. ITDM builds on the existing *Prescription Time Distribution Method (PTDM)* but introduces an iterative process that repeatedly checks and adjusts the timing of exposure. This iterative approach ensures a more accurate alignment of follow-up periods, reducing the risk of immortal time bias and providing a clearer comparison between treatment groups.

Advantages of ITDM

Traditional methods like PTDM often rely on a single adjustment, which may not fully eliminate immortal time bias. In contrast, ITDM's iterative process allows for more precise alignment of follow-up times, minimizing residual bias and improving the accuracy of comparisons. This method is particularly valuable because it can be applied across a wide range of medical conditions and treatments, making it a versatile tool for researchers. By bringing observational data closer to the rigor of randomized trials, ITDM enhances the credibility of findings in fields where RCTs are difficult to conduct.

Bridging the Gap Between Observational Studies and RCTs

While ITDM cannot fully replicate the conditions of randomization, it offers a more robust approach than traditional single-step corrections. By

iteratively realigning follow-up times, ITDM helps approximate one of the conditions of an RCT, where the only difference between groups should be the treatment itself. This makes large observational datasets more reliable and useful, particularly in fields like oncology and cardiovascular medicine, where timely RCTs may be challenging to implement.

Conclusion

This is an area of methodological research in epidemiology that has resulted in a new research method with the expectation that it will be utilized worldwide and in Qatar. Observational studies are essential in medical research, especially when RCTs are impractical. However, they are often hindered by biases like immortal time bias. The introduction of ITDM by Professor Suhail Doi and Jazeel Abdulmajeed represents a significant step forward in addressing this issue. By systematically redistributing person-time and aligning follow-up periods, ITDM improves the accuracy and reliability of observational data. While it does not solve all the limitations of observational research, ITDM provides a practical and effective tool for producing more credible evidence. As the demand for real-world data grows, methods like ITDM will play a crucial role in advancing medical research and improving patient outcomes.