



THE UNIVERSITY OF BRITISH COLUMBIA

Faculty of Pharmaceutical Sciences



## Misguided randomized trials: The role of observational studies

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***Wednesday, January 23, 2019 at 12:00 noon***

***Robert Sindelar Seminar Room 3340***

***Faculty of Pharmaceutical Sciences, UBC, 2405 Wesbrook Mall***

Observational studies are often used to uncover new indications for drugs already on the market. For example, hormone replacement therapy (HRT) to treat menopausal symptoms was reported in several observational studies during the 1980s and 1990s to also significantly reduce the incidence of coronary heart disease. This hypothesis was disproved in 2002 by the large-scale Women's Health Initiative randomized trial. I will discuss recent examples of observational studies that reported impressive effectiveness of drugs in other indications and I will describe their distortion from time-related biases, such as immortal time bias. Such observational studies will need carefully scrutiny before embarking on long and expensive trials of new indications for existing drugs.