What is Old is New Again: Pragmatism, Marvin Zelen, and Advanced Care Planning

By: Nicholas M. Pajewski, PhD

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Tuesday, April 19th| 3:30PM - 4:30PM

There is significant current interest in conducting embedded pragmatic clinical trials (ePCTs) in order to drive comparative effectiveness research, speed up clinical implementation, and promote a Learning Health System environment. The goal of this talk is to describe the design and results of the IMPACT trial (Gabbard et al. JAMA Intern Med. 2021 Mar 1;181(3):361-369), which tested whether a nurse navigator–led advanced care planning (ACP) pathway integrated with a health care professional–facing electronic health record (EHR) interface increased the frequency of ACP discussions and their documentation across 8 primary care practices in North Carolina. IMPACT had several highly pragmatic design features. First, the trial utilized an entirely electronic, automated mechanism to identify vulnerable older adults that might benefit from ACP, utilizing a passive digital risk score for frailty integrated within the EHR. Second, all follow-up for the primary outcomes in the trial was facilitated by the EHR, supplemented with healthcare utilization data from a national admission, discharge, and transfer data network. Finally, IMPACT utilized an uncommon individual-level randomized effectiveness design, first proposed by Marvin Zelen in 1979. Patients were randomized prior to any study involvement, with only patients randomized to the intervention group approached for informed consent. All patients selected for the study were then passively followed via the EHR for study outcomes, under a waiver of consent for patients randomized to the usual care group and those that declined participation in the intervention group. I will discuss pros and cons of this design relative to common alternatives including cluster randomized and stepped wedge designs.

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Please contact Chelsea Rowley for additional event information at Crowley@mcw.edu.