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Cardiovascular disease surveillance in the comparative effectiveness landscape

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As the leading cause of death in the Western world, cardiovascular disease (CVD) constitutes an enormous public health problem.[1] The last four decades have been characterized chiefly by the postponement of CVD events and CVD related deaths until older age. Thus, the burden of CVD is increasing in parallel with the increase in life expectancy.[2] Within this context, identifying persons with CVD, measuring its incidence and outcome and how these vary over time and across populations is essential. A central goal of this monitoring (otherwise termed surveillance) has been to understand the determinants of the trends in CVD and in particular the respective responsibility of primary prevention versus that of the care of established disease in the genesis of the CVD trends. A direct extension of surveillance is its application to assess the effectiveness of care and the response to interventions designed to improve the quality of care.

Over the first year of its existence, the journal *Circulation: Cardiovascular Quality and Outcomes* published three important papers that illustrate the clinical relevance of surveillance and the applicability of trend studies to care improvement.

The paper by Lewsey et al constitutes a classic example of CVD surveillance.[3] The authors present much needed data on recent (1986-2005) trends in the epidemiology of stroke indicating that age and sex specific incidence rates of fatal and non-fatal hospitalized strokes in Scotland declined in men from 235 (95%CI 229 to 242) to 149 (144 to 154) and in women from 299 (292 to 306) to 182 (177 to 188). The decline in incidence of hospitalized stroke varied by age but overall this equated to a relative reduction in the risk of stroke of 31% in men and 42% in women. Declines in the incidence of both hospitalized and fatal strokes contributed to the overall decline. However, since outpatient events were not included, it cannot necessary be inferred from these data that all strokes have declined.

The paper by Roe et al uses a surveillance-like approach to evaluate the approaches to percutaneous coronary intervention among patients with non–ST-segment elevation myocardial infarction and examined the patterns of drug-eluting stent (DES) in 2 large registries CRUSADE (1/06–12/06) and ACTION–GWTG (1/07–6/08).[4] before and after reports in September 2006 of the risks of late stent thrombosis after DES placement. A

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dramatic decline in the use of DES was noted from 90% to 60% over a time period coinciding with the publication of these alarming reports. This change was not related to other measurable hospital or patient characteristics, thereby leading to the interpretation that management can change swiftly when dissemination is broad and widespread. Finally, the paper by Nestler et al, illustrates how trend studies can be used to assess the effectiveness of interventions in clinical practice. The authors reports their experience in designing a system of care to meet the American College of Cardiology/American Heart Association Guidelines for door to balloon time in treating ST-elevation myocardial infarction (STEMI).[5] Recognizing the multidisciplinary nature of the task at hand, the investigators implemented a multitiered protocol including activation by a single call system of the cardiac catheterization laboratory by the emergency medicine physician, catheterization laboratory staff arrival within 20-30 minutes of activation; and real-time performance feedback within 48 hours. To assess the effectiveness of the intervention, the temporal trends in key indicators (door to balloon time and percentage of patients with door to balloon time meeting guidelines) were monitored. The comparison of the pre and post implementation groups demonstrated favorable trends in both indicators after the implementation of the protocol. Importantly, this improvement was sustained over the subsequent 4 years. In this example, the analysis of trends established 2 pivotal components of improvement in care: the effectiveness and the sustainability of practice redesign interventions.

What do these three studies have in common? They address three questions fundamental to the assessment of the quality of care: what is the burden of disease and is it changing over time? How do providers respond to new information? How effective is a given intervention?

In all three cases, trend analyses are used to address those questions. As we contextualize these papers to reflect on the application of surveillance for the purpose of monitoring not only disease but also care, we must remind ourselves of key methodological points related to the observational nature of surveillance studies. Surveillance studies constitutes a comprehensive approach designed to track disease at the community level, less costly and more efficient than cohort studies.[6] CVD surveillance typically tracks CVD deaths, the incidence and outcomes of myocardial infarction and/or stroke,[7] which is essential to monitor CVD trends and prevent CVD. As there is currently no national CVD surveillance system, CVD surveillance is carried out in individual community surveillance programs. These share several common methodological features. They are mainly retrospective, observational by design and rely on diagnostic codes for case finding and potential cases are validated using standardized approaches. In the US, selected community surveillance studies that reported on CVD trends include the Atherosclerosis Risk in Communities (ARIC) study,[8] the Minnesota Heart Survey (MHS),[9] the Olmsted County Study,[10] and the Worcester Heart Attack Study.[11]. By evaluating trends in the occurrence and outcomes of disease, surveillance studies can provide important insights into the potential determinants of trends. For example, the decline in the incidence of stroke in Scotland reported in the paper by Lewsey,[3] suggest that primary prevention and in particular blood pressure control played in major role on the genesis of this favorable trend. However, as acknowledged by the authors, these observations are not immune to confounding due to other factors, sometimes unmeasured and thus that cannot be accounted for, such that causal relationship should be hypothesized rather than assumed to be present. This need for interpretative

caution is even more salient when surveillance methodology is extended beyond the evaluation of the occurrence of disease to that of the quality and effectiveness of care. Indeed, in both the Roe and the Nestler studies[4, 5] the trends observed certainly could reflect a causal association with the exposure of interest (widespread publication of alert data as in the paper by Roe or an intervention as in the paper by Nestler paper) but as acknowledged by the authors, the results could also reflect confounding by a number of other factors that could have been operational during the same time period. Such confounders can be anticipated, measured and adjusted for analytically or unmeasured and hence challenging to account for. These methodological challenges must be addressed for surveillance studies to fulfill their potential as resources to monitor the quality of care.

According to the Institute of Medicine, quality of care is defined as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”[12] The implication of this statement for surveillance studies is that it is essential to include quality-of-care indicators into surveillance activities. In order to achieve this goal, several methodological requirements must be met: firstly, the scope of data collection must be adequately broad to reflect relevant data from a clinical, patient-centric and public health standpoint. Indeed, relevant patient-centric indicators such as health status measures must be included in surveillance activities as well as resource utilization indicators. Within this context, the ability of monitor adherence to medical therapy is critically important. Data elements must be standardized with an a priori commitment to linkage of data sources and there must be a rigorous and ongoing evaluation of the validity and reliability of the data collected. The ambitious goal of designing a national surveillance system for CVD could be operationalized in a stepwise manner by leveraging the growing use of electronic health records. In order to do so, surveillance systems must lead to the creation of a body of shared knowledge with a commitment to data standardization and to the concept of collaboration and “team science”, which is vital for scientific and public health research.[13] While undoubtedly ambitious, these goals constitute an imperative, given the unabated burden of CVD in the world and its enormous impact on society and health care costs. The creation of a comprehensive data network focusing on CVD surveillance will contribute to the creation of a platform for comparative effectiveness research in CVD.

The Institute of Medicine defines comparative effectiveness research as “the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition, or to improve the delivery of care. The purpose of comparative effectiveness research is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels”.[14] A key underpinning of this definition is the focus on “real life” data that can be directly applied to clinical practice. The ongoing national conversation on comparative effectiveness research has underscored that this objective will challenge conventional approaches to design and analyze randomized clinical trials[15] as well as observational studies.[16, 17] CVD surveillance studies constitute a unique source of data to monitor CVD in populations and, if reengineered with comparative effectiveness research in mind, have the unique potential of linking population disease burden with the monitoring of care. This reengineering will require the purposeful design of

data collection and management procedures, as well as innovative statistical methodology to fully leverage this potential. The aforementioned body of work published in the first year of *Circulation: Cardiovascular Quality and Outcomes* constitutes defining steps in this direction.

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