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Learning how to improve health care delivery: the Swedish Quality Registers

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The large number of therapies and diagnostic procedures that are constantly introduced in clinical practice requires a system to generate valid and timely evidence on their benefits and risks. Without a proper scientific assessment of the benefit-risk of clinical interventions, clinical practice may be misguided and limited resources may be squandered. Diagnostic tools may be used haphazardly rather than in a logical sequence that optimizes sensitivity, specificity and cost-effectiveness. New surgical procedures— such as radical prostatectomy for treatment of early prostate cancer – may be used on hundreds of thousands of patients in the absence of clear evidence of benefit [1]. Generic drugs may be underutilized at the expense of more costly but equally safe and effective brand name drugs [2].

The increasing number of people for whom these technologies become available, together with the increasing global burden of non-communicable diseases – stroke, diabetes, heart disease, cancer, etc [3] - makes the need to compare their effectiveness and safety even more urgent. The term “comparative effectiveness research” was coined to encompass all clinical and epidemiologic research activities that, like evidence-based medicine, seek to provide reliable evidence on the benefits and risks of health interventions [4]. The goal is to make health care systems more rational by providing the best care while reducing the wasting of resources.

Ideally, health care systems would be designed in such a way that the data generated during routine clinical practice could be utilized to learn about the long-term benefits and risks of clinical interventions in the general population, including groups traditionally excluded from randomized trials like pregnant women, children, and the elderly. While an attractive concept, “learning health care systems” are difficult to implement in practice. Common problems are the lack of mechanisms to track individual patients across different health care providers and the lack of procedures to ensure the completeness and validity of data collection.

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The Swedish Quality Registers, admirably described by Emilsson *et al.* in this issue of the Journal [5], are a key contribution to a learning healthcare system. As their name implies, these registers were established to improve the quality of health care in Sweden. Their original goal was to “examine and improve the delivery of health care”, e.g., by monitoring adherence to guidelines and comparing performance across hospitals, levels of care and administrative units. Today they are formidable resources for comparative effectiveness research, not the least because their data can be linked with multiple nation-wide registers and health databases, which allows virtually complete follow-up of hospitalizations, surgical procedures, drug prescriptions, cancer incidence, immigration, and cause of death. In addition, this information can be complemented with the abstraction of data from hospital records and the retrieval of pathological specimens.

The Quality Registers take advantage of Sweden’s publicly-funded health care system, national registration numbers (an individually unique identifier), enthusiastic practitioners, and supportive citizens [6]. Emulating the Swedish registers, or in fact any large-scale, population-based research activities, in countries without these conditions may be challenging. However, regardless of the feasibility of establishing similar registries abroad, there remains the question of how to maximize the impact of Swedish Quality Registers. Notwithstanding several key publications that have emanated from them, it seems to us that the Quality Registries are a largely untapped resource. We now offer some suggestions to broaden and deepen the use of Swedish Quality Registers.

1. Foster external collaboration. Like for any complex database, using the Swedish Quality Registers requires knowledge that international investigators cannot easily acquire. Therefore, substantial responsibility rests on Swedish investigators to encourage external users to use the data, while ensuring that appropriate measures are taken to preserve privacy and to follow standard authorship guidelines.
2. Improve methodologic competence. An appropriate use of the data for comparative effectiveness research requires careful consideration and handling of biases arising from confounding, measurement, and selection [7]. This may require specific training in epidemiologic methods for researchers and practitioners. As recently stated “epidemiology is not just an expansion of statistics or good training in medicine or biology that you can jump into. It is a discipline with distinct intellectual elements and a core of principles that are essential.” [8].
3. Conduct periodic assessments of data quality. Validation studies [9] are essential to ensure that information on outcomes, exposures, and confounders is accurate, and to bolster confidence in the results. At the very least, validation studies can be used to conduct informed sensitivity analyses.
4. Conduct ancillary observational studies. Beside cohort analyses based on already recorded data, the Quality Registers are a cost-effective strategy to conduct nested case-control or case-cohort studies for which additional data collection (hospital records, histopathology specimens) is necessary. When DNA information is available, such studies could also speed up genetic discovery through sampling of extreme phenotypes [10].

5. Conduct nested randomized trials. Enrollment and follow-up of patients in randomized trials is often complex and expensive; many randomized trials never reach their targeted number of participants. As illustrated by Emilsson *et al.*, the Quality Registers offer an ideal infrastructure for enrolling and following patients in randomized clinical trials, including population-based pragmatic trials that reflect every-day-practice and lifestyle interventions [11]. In combination with other health databases, the registers can provide post-randomization data to adjust for deviations from study protocol during the follow-up [12].
6. Complement the registers with other data sources. In addition to linkage with national other health, vital statistics and social registers (which is already done), cell phones and social media data can provide information not systematically recorded in the Quality Registers, like symptoms, quality of life, compliance, side effects following drug prescriptions, lifestyle changes, and major life events. In addition, for rare conditions, pooling resources with similar data from other countries would expand the impact of the Swedish Quality Registers. Supplementing these registers with other data sources requires adequate measures to preserve confidentiality and perhaps the implementation of emerging developments in the realm of “Big Data”.

In summary, the Swedish Quality Registers can become a global resource to improve clinical care and a model for other learning healthcare systems. But this is unlikely to happen without a strategic plan and willingness to overcome isolationism. Time is ripe for action.

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References

1. Adami HO. The prostate cancer pseudo-epidemic. *Acta Oncol.* 2010; 49:298–304. [PubMed: 20397765]
2. Kassirer, JP. On the Take: How Medicine’s Complicity with Big Business Can endanger Your Health. New York, NY: Oxford University Press; 2004.
3. Hunter DJ, Reddy KS. Noncommunicable diseases. *N Engl J Med.* 2013; 369:1336–43. [PubMed: 24088093]
4. Institute of Medicine. Initial National Priorities for Comparative Effectiveness Research. Washington, DC: The National Academies Press; 2009.
5. Emilsson L, Lindahl B, Köster M, et al. Review of 103 Swedish healthcare registries. *J Int Med.* 2014 in press, [Epub ahead of print].
6. Adami HO. A paradise for epidemiologists? *Lancet.* 1996; 347:588–89.
7. Thygesen LC, Ersboll AK. When the entire population is the sample: strengths and limitations in register-based epidemiology. *Eur J Epidemiol.* 2014; 29:551–558. [PubMed: 24407880]
8. Williams MA. A conversation with Dimitrios Trichopoulos. *Epidemiology.* 2014; 25:765–68. [PubMed: 25051313]
9. Ludvigsson JF, Andersson E, Ekbom A, et al. External review and validation of the Swedish national inpatient register. *BMC Public Health.* 2011; 11:450. [PubMed: 21658213]

10. Lee S, Abecasis GR, Boehnke M, Lin X. Rare-variant association analysis: Study designs and statistical tests. *Am J Hum Gen.* 2014; 95:5–23.
11. Ioannidis J, Adami H-O. Nested randomized trials in large cohorts and biobanks: Studying the Health Effects of life style factors. *Epidemiology.* 2008; 19:75–82. [PubMed: 18090999]
12. Hernán MA, Hernández-Díaz S, Robins JM. Randomized trials analyzed as observational studies. *Ann Intern Med.* 2013; 159:560–2. [PubMed: 24018844]