ABSTRACT: Hybrid Time and Motion, Patient Survey and Chart Review Study Methodology: A Case Study of Subcutaneous Allergen Immunotherapy in the US and Canada

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Objectives:

Direct observation of healthcare processes through time and motion (T&M) studies is increasingly warranted to provide evidence of medication or device efficiency. This methodology can be leveraged to collect comprehensive data on patient characteristics, and health and care process outcomes. A hybrid T&M plus patient survey & chart review study design is described through case study presentation and summary of lessons learned.

Methods:

A prospective, observational, hybrid T&M study of subcutaneous immunotherapy (SCIT) administration was conducted at 12 sites (US and Canada).

Process time and supplies consumed were collected through observation of SCIT visits and serum preparation. Chart reviews provided medical history and resource utilization; trained

observers collected sociodemographics, loss of productivity, medication use, and travel time by survey. Site staff estimated time for administrative tasks related to SCIT.

Results:

Key considerations for study design and CRF development: comprehensive care process mapping and minimization of patient/site burden, handling treatment process variability, and maximizing generalizability of results. Site and observer recruitment, minimizing impact on treatment delivery, and ensuring uniformity of data collection methods across sites were main operational considerations.

An extensive study planning process along with nurse observers utilized for data collection led to successful completion of the study at six sites/country (primary care, allergists, otolaryngologists), with 670 patients. The final robust dataset consisted of observed treatment delivery steps and timings for staff and patients at SCIT visits (2–8 and 4–32 min respectively, plus 2–33 min post-injection wait), patient-reported travel times (34–50 minutes), and detailed information regarding number/type of allergens per patient through chart review.

Conclusions:

T&M methodology allows for prospective data collection of observed processes, providing data on process efficiency and cost drivers that are often otherwise unavailable. This approach can be successfully combined with medical chart review and patient and site questionnaires to optimize evidence generation.