Value Demonstration: Time & Motion Studies

Quantification of the Impact of Increased Efficiency on Patient Outcomes and Healthcare Delivery

Time and Motion (T&M) studies are observational studies that are designed to quantify efficiency-related outcomes associated with the administration of medications or the implementation of medical devices. These studies can quantify the impact of increased efficiency on multiple outcomes such as:

• The allocation of resources and time spent on healthcare delivery
• Patient flow through healthcare settings
• Resource utilization.
T&M methodology consists of decomposing a process into its main tasks, and designing a protocol and case report form to evaluate time spent on these tasks. T&M employs direct on-site observation by trained observers using manual timing techniques (e.g., stopwatches) to repeatedly measure task durations to estimate total process time.

An example of a T&M study conceptual framework in support of an intravenous-to-subcutaneous drug formulation switch is shown in Figure 1.

**Time and Motion Studies – Why are they Useful?**

<table>
<thead>
<tr>
<th>Variables of Interest</th>
<th>Definition</th>
<th>Outcomes of Interest</th>
<th>Efficiency Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Time in Room</td>
<td>Time Patient spends in Treatment Room</td>
<td>Patient Time Saved</td>
<td>Resource Savings</td>
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<tr>
<td>Chair Time</td>
<td>Time Patient spends in Fusion Chair</td>
<td>Chair Time Saved</td>
<td>Increased Throughput</td>
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<td>“Active” HCP Time</td>
<td>Time ‘Actively’ spent by HCP on Pre-Defined Tasks</td>
<td>HCP Time Saved</td>
<td>Short-term Cash-flow Impact</td>
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<td></td>
<td></td>
<td>Consumable Avoided/Saved</td>
<td>Long-term Cost Impact</td>
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**Efficiency benefits may include:**

- A switch in drug formulation (e.g., from intravenous to subcutaneous or oral)
- A switch in standard of care (e.g., from physician-administered to patient self-administration of drug)
- Advance in imaging software/technology resulting in faster image processing and outcomes interpretation

The challenge is how to measure efficiency-related outcomes with a view to create or strengthen value messages in support of launch and commercialization of a new product. Unlocking the value of efficiency is particularly important within the current healthcare environment:

- Cost containment strategies within a context of government budgetary pressures are increasingly common
- Managers face pressure to optimize facility resources and care delivery to improve patient care whilst maximizing spending efficiency

Outputs from T&M studies can be used as inputs to pharmacoeconomic analyses to generate economic value messages through "monetarizing" time using long-term “opportunity cost” or short-term “facility cost/revenue” approaches, aimed at various audiences (nurses, physicians, facility managers, payers):

- Micro-costing (including activity-based costing) analyses
- Facility efficiency and patient throughput models
- Cost-effectiveness and budget impact models

Collection of T&M endpoints can also be combined with chart data extraction to study treatment patterns or patient/HCP questionnaires to study satisfaction, preference, or quality of life.

UBC has the expertise to create user-friendly tools built in MS Excel or accessible through web-based interfaces, allowing users to explore time and cost impact based on centre-specific inputs. Such models can generate the following results:

- Time/resource use per single process, or extrapolated over time for a single patient or an entire facility
- Absolute and relative difference in time and cost for comparator processes
- Impact of comparator processes on facility revenue

Innovative biopharmaceutical products, medical supplies, or devices may show similar efficacy, effectiveness, and safety profiles compared to standard-of-care options. Their differentiating features, however, may be related to increased efficiency. This is of particular importance to payers, physicians and patients when:

- Drug formulations are simplified
- Innovative medical devices which may result in reduced patient treatment or wait times are implemented
- Healthcare delivery processes are streamlined

**Time and Motion studies help fulfill evidence requirements**
UBC Approach

UBC understands the unique challenges associated with T&M study design and implementation. Through our extensive experience, UBC has developed a step-wise approach for the conceptualization, design, and conduct of scientifically robust T&M studies that are feasible to execute. The following task sets are key components of the UBC approach:

- Articulation of clear study objectives and hypotheses in line with the product profile
- Identification and resolution of key methodological issues such as:
  - Need for a statistically comparative study vs. a descriptive design?
  - Different potential predictors of process flow and time?
  - Sources of variability (e.g., between countries, between centers)?
  - Approach to manage confounding from patient or process-related characteristics?
  - Sample size?
- A unique approach to “mapping” of routine care patterns and generic practice flows with the aim to define T&M variables of interest.
- Implementation of study-specific site feasibility assessments involving a formal screening form that lists basic requirements for participation, both in terms of site layout as well as staff availability for performing observations.
- Deep understanding of competent authority and ethics committee requirements across Europe and North-America for non-interventional studies that focus on T&M-type outcomes as opposed to traditional patient-based outcomes.
- UBC has designed and executed various local and multinational T&M studies, including sub-studies to clinical trials, wholly descriptive process of care evaluations, and before-and-after drug or device launch studies.
- UBC also offers consulting services regarding the optimal design for the collection of “efficiency” data, as well as methods to integrate T&M outcomes within existing interventional study designs. UBC often runs single-centre “pilot” studies to inform the usefulness of a multi-centre design.

Experience

UBC has conducted Time & Motion studies in more than 20 countries across North America and Europe. The scale of these studies has varied from one-site to 35 sites. Sample sizes have also varied from fewer than 20 to more than 1000 process observations.
VALUE DEMONSTRATION:
TIME & MOTION STUDIES

Quantification of the Impact of Increased Efficiency on Patient Outcomes and Healthcare Delivery

*Blue indicates UBC Scientist.

Selected Recent Publications

**De Cock E, Dellana F, Khellaf K, Klatko W, Maduell F, Raluy M, Vila Giuseppe.**

Time savings associated with C.E.R.A. once monthly: a time-and-motion study in haemodialysis centres in five European countries. Journal of Medical Economics 2013. [accepted for publication]

**Schiller B, Doss S, De Cock E, Del Aguila MA, Nissenson AR.**


**Payne, K, Yeomans K, De Cock E.**


**Saueressig U, Kwan, J TC, De Cock E, Sapede C.**

**VALUE DEMONSTRATION:**
**TIME & MOTION STUDIES**

Selected Recent Presentations

*Blue indicates UBC Scientist.

**De Cock E, Tao S, Urspruch A, Pivot X, Knoop A.**
Time savings with trastuzumab subcutaneous (SC) injection vs. trastuzumab intravenous (IV) infusion: first results from a time-and-motion study (T&M).
2012 CTRC-AACR San Antonio Breast Cancer Symposium; December 4-8, 2012; San Antonio, TX.

**De Cock E, Carella A, Tao S, Wiesner C.**
Potential time savings with RITUXIMAB subcutaneous (SC) injection vs. RITUXIMAB intravenous (IV) infusion: results from interviews at 13 European sites as part of a time and motion study (T&M).
ISPOR 15th Annual European Congress; 3-7 November 2012; ICC Berlin, Berlin, Germany.

**De Cock E.**
Time and Motion Studies – What are they? Why are they useful? What are the challenges?
Webinar presented October 23, 2012.

**De Cock E, Payne KA, Sohal, J.**
Design and Operational Challenges with Time and Motion Studies Run Alongside Clinical Trials.
Presented at the 28th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE); August 23-26, 2012; Barcelona, Spain.

**Raluy M, Irgl H, De Cock E.**
Time savings with Q4W (once-monthly) C.E.R.A.: a time and motion study conducted in hemodialysis centres in five European countries.
ISPOR 13th Annual European Congress, 6-9 November 2010, Prague, Czech Republic.

**De Cock E, Van Nooten F, Raluy M, Muller K, Fabre J, Hargreaves J.**
Time and Supplies for Wound Management during and after Breast Reduction Surgery in Germany and The Netherlands: Prineo* vs. Standard of Care.

**De Cock E, Van Nooten F, Raluy M, Muller K, Fabre J, Hargreaves J.**

Costs of Administration of Intravenous Iron during Outpatient Hemodialysis: A Time and Motion Study.
American Society of Nephrology, November 4-9, 2008; Philadelphia, PA.

**Rogers J, Doss S, Schiller B, De Cock E, del Aguila M, Nissenson A.**
A time and motion study of anemia management in hemodialysis patients.
National Symposium 2007, April 22-25, 2007, Dallas, TX, USA.

**Van Bellinghen LA, De Cock E, et al.**
Comparing the provider time and costs for red blood cell transfusions in anaemia management of cancer patients using the activity-based costing (ABC) method in a French and Austrian setting. Award for best new investigator poster.

**De Cock E, Van Bellinghen LA, Standaert B.**
Assessing provider time for anaemia management of dialysis patients using time and motion methods: a multi-centre observational study in Europe.