

# UNDERSTANDING REAL PRACTICE – THE APPLICATION OF OBSERVATIONAL STUDIES

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## SYNOPSIS

Pharmaceutical companies are subject to increasing competitive and regulatory pressures and would benefit from an evidence base that encompasses drug impact and value in real practice. In the future this evidence may be a regulatory requirement, with the need to provide evidence of product use outside of the clinical trial setting. Currently it can serve to support product claims, product value arguments and differentiation. In non-pharmaceutical scenarios there is evidence that respondent perception of behaviors can often miss major insights and key detail. Perceptions are consequently less specific than direct observation with follow up, resulting in potential product benefits not being realized due to inaccurate assumptions about real world practice or products inappropriately launched or positioned.

This case study illustrates that the administration of chemotherapy by nurses involves multiple steps and procedures, for example administering pre-medications, verifying drug doses, monitoring patient during infusion and patient consultation.

An observational approach was undertaken where the daily operations of outpatient oncology centers were observed, to more clearly define how the nursing staff and clinic operations were affected by various chemotherapy regimen infusion time and dosing regimens.

### The poster discusses:

- Design and data collection issues considered when setting up an observational study, e.g. sampling and ethics committee approval.
- A specific observational case study and the advantages of the proposed approach.
- Wider application of observational research in product design and marketing.
- The role of observational studies in a regulatory setting.
- The implications and potential benefits for improving marketing research design and application.

## DESCRIPTION OF CASE STUDY

- Administration of chemotherapy by nurses involves numerous tasks, including administering pre-medications, verifying drug doses, monitoring patients during infusion, and consultation.
- Nurses typically multi-task, attending to multiple patients and performing other clinic activities, particularly during the infusion period.
- Actual infusion times vary among regimens.
- The impact of differences in infusion time on nursing productivity is not well understood.

## OBJECTIVES

- To evaluate nurse activities during chemotherapy administration of various durations of infusion.

## METHODOLOGY

- Direct observation of nurses during administration of 227 chemotherapy infusions in 16 outpatient clinics in Canada, France, and the United Kingdom (UK).
- The study focused on patients with solid tumors, and included mainly lung, colorectal and breast cancer patients.
- Data collected included:
  - Scheduled and actual infusion times
  - Tasks performed by nurses
  - Associated time spent in these tasks.
- Data supplemented by interviews with clinic manager and nurse.

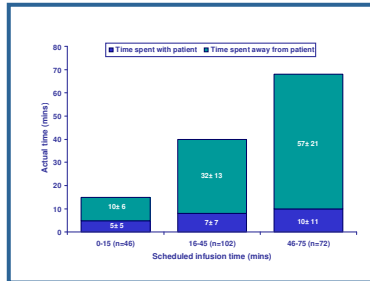
## CASE STUDY RESULTS

The average daily nurse to chemotherapy patient ratio was 1:6. Pre- and post-infusion times did not vary based on infusion duration, taking approximately 20 and 15 minutes, respectively. On average, infusions scheduled for <20 minutes were completed within 2 minutes of scheduled time, but those scheduled for 30-60 minutes took 7-10 minutes longer than scheduled. For infusions <15 minutes, nurses rarely performed activities not related to the patient. As infusion duration increased, nurses spent increasingly lower proportions of the total infusion time with the patient. With longer infusions, nurses attend to other patients and perform administrative tasks such as telephone calls and charting.

### Activities observed by phase:

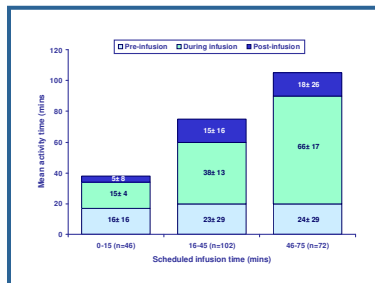
- Pre-infusion
  - Venous access
  - Verification of pre-medication doses
  - Administration of pre-medication
  - Verification of chemotherapy dose
  - Checking lines/equipment
  - Consulting with patient.
- During infusion
  - Monitoring or speaking with patient
  - Telephone calls and paperwork
  - Obtaining lab results
  - Attending to other patients.
- Post-infusion
  - Hydration
  - Consulting with patient
  - Nursing of patient (getting water, making comfortable, chatting)
  - Paperwork.

## Mean Time Spent with Patient During Infusion



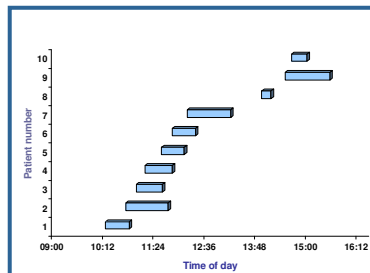
- For infusions  $\leq 15$  minutes, nurses rarely performed activities not related to the patient.
- With longer infusions, nurses attend to other patients and perform administrative tasks such as telephone calls and paperwork.

## Mean Time for Infusion Phases



Pre- and post-infusion phases only include time during which patient was in infusion room. Infusion >75 min not presented due to small number of observations.

## Infusion Times by Patient (Observed Infusions Only)



- Nurses currently process a number of patients at once in order to be able to maintain throughput.

## DISCUSSION

### Challenges in Obtaining Sites

#### The innovative nature of this research led to a number of challenges in recruiting clinic sites:

- Generally clinics were enthusiastic and interested, but we were able to proceed only 1 in 5 of sites contacted.
- In approximately 20 sites in each country the research did not proceed – a mixture of clinic rejection and Adelphi deciding not to proceed.
- Reasons for not proceeding with clinics were:
  - (Perceived) requirement for ethical approval and consequent delay
  - Clinics unfamiliarity with this type of research
  - Clinic too busy
  - Bureaucratic processes and hurdles
  - No fieldwork agency relationship with clinicians.
- In France, very difficult to attend large clinics.
- Difficult to conduct research of this kind in Germany.

### Challenges for Observation Days

#### There were a number of logistical issues encountered when conducting the observations:

- Small treatment rooms (little space for interviewer).
- Occasions when interviewer has to leave room immediately because of a crisis or sensitivity over observer presence.
- Difficult in observing and/or understanding all nurse activities (requiring nurses to 'explain' as they go along – if time/situation allowed).
- Set-up of some clinics, e.g.
  - Due to limited space/beds patient walks corridors of clinic during chemotherapy infusion, then returns to infusion unit. Also some patients infused in wheelchairs, television room. Nurse only checks up on patients if alarm sounds.
  - Nurse sets chemotherapy up in treatment room and then leaves patient completely unless patient presses call button (therefore nothing for interviewer to observe).

### Value of Observational Approach for this Study

- Investigating nurse behavior is perhaps intuitively qualitative by design.
- Qualitative research could establish the tasks carried out, estimations of duration and a perceived impact on their activities by infusion length.
- By using an observational approach, exact behavior was recorded and quantified by measuring the duration of each separate activity and when it was performed.
- Ultimately this allowed for a continuous period of nursing activity to be observed, quantified and analyzed.
- Analysis of the data could then show precisely how nurse activity is impacted upon by different infusion lengths.

### Value of Observational Approach for MR in General

Market research design could be improved by using an observational methodology in a pilot stage prior to the main stage large quantitative study.

It would help reduce redundancy by providing insight into the key areas and issues.

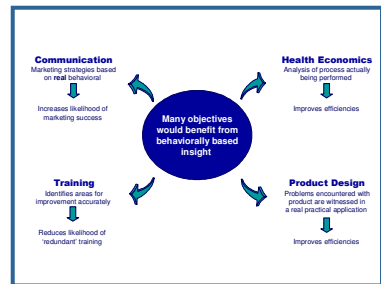
Smaller sample sizes could be used.

As many key decisions are made spontaneously, the interaction between people and the decision making process can be observed first hand.

The data gathered would be more robust than qualitative research because it is measuring actual behavior rather than perceived behavior. The respondent in an interview could easily forget tasks they have completed, whereas the observational approach captures everything.

However, qualitative research may well cover more detail as the respondent could be extensive with their responses, and cover activities that are infrequent and therefore less likely to be picked up on the day of the observation.

### Wider Application of Observational Research



### The Role of Observational Studies in a Regulatory Setting

The results of observational studies may be submitted alongside this clinical data when submitting an application to the FDA.

It does NOT play a substantial role in the application.

Anything to work as a claim would require the support of substantial evidence from well controlled studies.

However, when it is submitted, it is done so in order to promote the benefit of a drug.

It can give information about the context in which the drug may be used, e.g. a company may wish to show how the short onset/offset of their therapy provides a benefit to the health authorities in terms of costs, nurse time and patient flow.