Seminar

Qualitative Research and Info Sys

By

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Executive Summary:

This paper is prepared to complete the research on the topic qualitative research. The research has been completed by studying the research articles and research publications online. At the end of the research we have studied a case of ECOPHARM a Bulgarian Pharmaceutical company established in 2001. We applied the basic research studies completed in this paper on the Ecopharm to test the validity of work.

Qualitative research is not a new approach of testing the products in the market. Companies have been spending enormous amount of resources on the qualitative research just to ensure they grasp the opportunity in the market before competitors.

Gertrude Selznick mentioned that behind every quantity there lies a quality. What Selznick meant is that if the quality is not brought into the data gathering, then the quantity is not that would produce any desired results.

A wide range of tested qualitative research methods are available to address these challenges. The selection of method, or combination of methods, will be tailored to the questions being studied and the setting for research. Typical methods include:

Naturalistic inquiry and participant observation ;Case study research ;Structured observations of meetings and events; Content analysis of documents; Collection and analysis of other archival, administrative and performance data; Focus groups; Cognitive interviews; Mail and telephone surveys.

Finally, we applied the theoretical approach to the biotech firm Ecopharm based in Bulgaria just to ensure our research is beneficial in the real world to researchers and scholars.

Qualitative Research:

The following paragraph is mentioned by Dr. Mittman[1] in his white paper published by the department of veteran's affairs workshop on the topic Qualitative Methods and Rigorous Management Research.

Dr. Mittman wrote that "the role, benefits and appropriate use of qualitative research methods in the basic and applied social and clinical sciences have been discussed extensively in the research literature. The field of health services research, in particular, has benefited from several insightful, comprehensive discussions of qualitative research methods and their appropriate use.[2] Proponents have convincingly argued that qualitative methods contribute findings and insights that cannot be derived from "conventional or quantitative" research methods and that research in the clinical, social and policy sciences requires careful application of both types of approaches to properly study their phenomena of interest."

Shoshanna Sofaer in her paper Qualitative Methods: what are they and why use them[3] published in HSR: Health Services Research 34:5 Part11 (December 1999) quoted Gertrude Jaeger Selznick, PhD as saying "Behind every quantity there must lie a quality". What Selznick tried to explain here is that any data must have a quality collection system behind other wise the quantity is not a reliable and would not produce the desired results.

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[1] Brian S. Mittman, PhD, Senior Social Scientist, Center for the Study of Healthcare Provider Behavior VA Greater Los Angeles Healthcare System (152), 16111 Plummer Street, Sepulveda, California 91343.

[2] Several excellent references are provided in the Workshop bibliography, including the special issue of *Health Services Research* devoted to "Qualitative Methods in Health Services Research" (Volume 23, No. 5, Part II, December 1999).

[3] HSR: Health Services Research 34:5 Part two (December 1999), page 1101

Joseph Newman in his article[4] mentioned that "qualitative research, especially of the kind which has so recently come to the fore as "consumer motivation" research promises to add substantially to our knowledge in this area.

Burleigh B. Gardner and Sidney J. Levy in their paper[5] mentioned that "with the findings of qualitative research, management can see its product in a clearer perspective."

Uses and value of qualitative research:

Qualitative research is characterized by an emphasis on describing, understanding, and explaining complex phenomena - on studying, for example, the relationships, patterns and configurations among factors; or the context in which activities occur. The focus is on understanding the full multi-dimensional, dynamic picture of the subject of study.

Its approaches contrast with quantitative methods that aim to divide phenomena into manageable, clearly defined pieces, or variables. Quantification is good for separating phenomena into distinct and workable elements of a well-defined conceptual framework. But when we focus research on what we already know how to quantify, (e.g., what can be reliably quantified), we may miss factors that are key to a real understanding of the phenomena being studied. The downside of quantification is that it does not always support (as well as qualitative methods) understanding of complex, dynamic, and multi-dimensional wholes.

Qualitative methods are useful, not only in providing rich descriptions of complex phenomena, but in constructing or developing theories or conceptual frameworks, and in generating hypotheses to explain those phenomena.

[4] Joseph W. Newman, Looking Around: Consumer Motivation Research," Harvard Business Review, January-February, 1955, page 135

[5] The Product and the Brand, Harvard Business Review, March-April 1955, page 33,

Methodological challenges in qualitative research techniques:

Key challenges to conducting rigorous qualitative research range from instrument development through data collection to data analysis. In addition, results need to be documented and reported using formal accepted methods.

For example, typical deficiencies are unfocused instrument development and lack of supporting theory. Rigor related to instrument protocol development requires attention to validity, intrusiveness (the Hawthorne effect) and triangulation. In addition, attention must be paid to distinguishing between collecting subjective and objective data, information on the formal vs. the informal organizational structures and processes and the differences between collecting facts vs. opinions vs. interpretations.

Planned, systematic, comprehensive data collection requires variable definitions and measures, document coding form protocols, administrative database specifications and survey instrument question libraries. In the data collection phase, problems can be minimized through pilot-testing and pretesting, validity/quality checks, triangulation and monitored flexibility. Sole reliance on subjective data, self-reports, etc. can reduce validity. Some tips to insure rigor in data collection management include training of all data collection staff and conducting immediate post-collection coding for time/memory sensitive data. Other methods to ensure the validity of data include tape recording interviews, performing real time data entry and editing, using paired interviewers, and implementing quality assurance for each instrument. And, to avoid further problems, incomplete, missing or unusable data should be corrected immediately.

Pitfalls related to data analysis include using ad hoc, emergent, exploratory, informal analyses that may lead to inappropriate conclusions and unpublishable results. Rigorous analysis

requires an *a priori* theoretical model and hypothesis, a formal framework guiding data collection and analysis and adherence to the formal framework and research best practices.

Finally, reporting requires results structured by hypotheses and an analysis plan. Reports need to include data syntheses and summaries with a focused analysis of the data. Conclusions must have a documented basis and systematic formal analysis methods, and validity must be documented.

Key qualitative research methods:

A wide range of tested qualitative research methods are available to address these challenges. The selection of method, or combination of methods, will be tailored to the questions being studied and the setting for research. Typical methods include:

- Naturalistic inquiry and participant observation
- Case study research
- Structured observations of meetings and events
- Content analysis of documents
- Collection and analysis of other archival, administrative and performance data
- Focus groups
- Cognitive interviews
- Mail and telephone surveys

Naturalistic inquiry, or ethnography, has its roots in anthropology and sociology and involves long-term exposure to a setting or a group of people. Extensive use of unstructured observations and conversations documented by detailed field notes form the basis for this type of research, often considered the purest form of qualitative research. Naturalistic inquiry is used

when situations are unique or complex, when the level of uncertainty about the questions to ask is high and when there is little or no theory to direct the investigator.

A subset of this type of inquiry involves participant observation in which the investigator becomes a part of the setting or the process being studied. (Sofaer) reports that she was able to learn more from attending a few group meetings in a particular setting than she could have by using more structured qualitative methods such as interviews or surveys.

Case studies are the preferred strategy when 'how' or 'why' questions are being posed, when the investigator has little control over events, and when the focus is on a contemporary phenomenon within some real-life context. The case study is especially appropriate when the boundaries between phenomenon and context are not clearly evident. The case study copes with the technically distinctive situation in which there will be many more variables of interest than data points, and as one result relies on multiple sources of evidence, with data needing to converge in a triangulating fashion.

The case study approach can involve a single event or multiple cases and can be short or long term. However, rather than requiring total immersion in the setting or culture, sampling of sites, experiences and/or informants is typical. The methods used in case study research are similar to those of naturalistic inquiry. However the data collection is often more structured, using key informant interviews, structured observations of events and interactions and the collection and content analysis of relevant documents (e.g., to help establish the facts, the assumptions, values and priorities, or to illuminate differences in perceptions). Case studies often also include quantitative data for background or to help generate questions to ask informants (e.g., data on demographics, heath status, utilization, finances, etc.).

Structured Observations of Meetings: This involves attending meetings of the group that you wish to research. This can also be extended to observation of individuals in their daily work routine or on special tasks. The purpose of observing is to learn what is going on at the meeting and witness the group dynamic in process. This can be a rich information source as it can give researchers insight into the group.

Content Analysis of Documents: This is a non-intrusive form of research. This involves reviewing documents, memos or other pieces of written information for content and themes. By examining written word, the researcher is studying one type of communication that occurs in the selected sample.

Collection and analysis of other archival, administrative and performance data: This method also is non-intrusive. Information that has been previously collected, or secondary data, is reviewed to gain a better understanding into the topic. This information is part of the organization's history and can be a valuable key to understanding the past.

Focus groups usually explore specific issues. The focus group brings together individuals chosen to meet a specific profile. They may be homogenous along some dimensions and heterogeneous along others and a structured, yet informal, setting is used to explore a limited number of questions. Focus groups, unlike individual interviews, provide the added dimension of the interactions among members. Focus groups are often combined with more quantitative approaches such as surveys that can be administered at different points in the group discussion and even used as grist for additional discussion.

Cognitive interviews are typically used in survey development. One-to-one interviews are conducted (with people meeting the criteria for completing a particular survey) as the individuals complete the instrument being tested. This method helps investigators understand

how people perceive and interpret language and their own experiences as they refine the survey instruments.

Mail and telephone surveys are a method of collecting information by sending surveys via email or postal mail. Participants return completed forms to the researcher or an outside vendor. Surveys may ask respondents to rate items on a scale (e.g., Likert scale of 1-5). Some surveys also allow respondents to write their feelings or attitudes about a particular event or to elaborate in more detail on an item, or to express suggestions, etc.

Applied side of Qualitative Research:

Ecopharm[6] is a Bulgarian pharmaceutical company established 5 years ago as a legatee of the German company ASTA Medica on the Bulgarian pharmaceutical market. Ecopharm represents exclusively a number of prominent pharmaceutical producers in Bulgaria. As a fast growing company Ecopharm launched 5 own generic products last year.

Why to run clinical trials in Bulgaria?
For the last 9 years the number of clinical trials in Bulgaria has increased more than 10 times. Starting with 10 authorized studies in 1995, in 2004 in the hospitals were conducted 148 studies, and most of them were part of international projects, conducted simultaneously in several countries. The prevalent percentage is for phase III studies. In 2004 the number of submitted applications for running clinical trials has been increased 41% compared to the submitted in 2003. In Bulgaria the main therapeutically areas for conducting clinical trials are oncology, psychiatry, and cardio-vascular system diseases.
Currently in Bulgaria are conducted 5% of the worldwide clinical trials. There is a remarkable tendency for constant growth of the number of clinical trials.

[6] http://www.ecopharm.bg/lang_en/

Theme in reasons:

- The application of The Declaration of Helsinki as fundamental document for guaranteed human rights in Bulgaria
- The established standards for drug manufacturing
- Synchronization of national laws and regulations to worldwide recognized requirements for running clinical trials, i.e. the studies are performed according to the GCP guidelines and ICH Topic E 6 guidelines for GCP
- Availability of highly skilled professionals with medical expertise, English-speaking specialists, experienced in clinical trials, providing high quality activities.