Protocol Title: Online Surveys to Assess the Perception and Performance of Imaging and Associated Aspects

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I. Overview

In this exploratory, survey-based study, we will investigate the background, perception, current use practices, potential unmet needs and/or challenges in regard to imaging procedures, imaging technology, or any other aspect related to the broader field of imaging. To do this, we plan to recruit volunteer participants to complete online surveys.

II. Objectives

1. We aim to understand the background, perception, current use practices, potential unmet needs and/or challenges in regards to imaging procedures, imaging technology, or any other aspect related to the broader field of imaging.

2. We strive to increase information available in the topics of interest stated above. These findings will guide our research development, preparations for clinical trial design, and special interest groups. Additionally, these findings will serve as reference data for appropriate scientific publications.

III. Background/Rationale

Understanding the environment in which a business is operating is essential for business success. Taking this concept from the business world to the clinical research domain, clinical researchers must understand the environment in which and for which they are developing clinical trials and clinical innovations. Although commonly used in consumer assessments, survey tools are underutilized within the clinical research community, even though they aid in the understanding of clinical and scientific perceptions. We have realized this as part of our online social media studies in the overall field of imaging. Using online survey tools can effectively and efficiently query true opinions or perceptions which might not be so objectively obtained in person to person or other interactions.

Understanding clinical perception and clinical practices outside of the local environment is also essential for assessing the feasibility for innovative and transformative changes in the imaging environment.

IV. Procedures: Research Design

A. Sample

Volunteer population

- Consists of volunteers agreeing to complete the survey tool
- It is anticipated that the surveys will be completed by participants that can be considered stakeholders, such as physicians, technologist's physicists, imaging scientists, administrative staff, or others with interest in the topic.
- We do not exclude the participation of patients; however, they are not typically the target population.

Inclusion Criteria

- Male and female participants who have access to the online survey tool and can read and write in English
- We are not putting any age restriction on the participation of the survey as the age is not relevant in any way for the survey.

Exclusion Criteria

- None, as this is voluntary

B. Measurement / Instrumentation

Survey tools

The survey will be administered via Survey Monkey or equivalent electronic web based tools. Participants will be recruited through professional contact, e-mail lists, webpages, electronic mailing, or social media posting. Participants will be completely anonymous, and no PHI will be accessed, used, or disclosed during the study.

C. Detailed study procedures

Subject enrollment

Anyone with the link to the survey will be able to complete the survey.

Administration of informed consent

We are adding the following statement to the survey, which will be displayed prior to beginning the survey questions: "Your participation in this research is voluntary, and if you decide not to participate, you may withdraw any time without being penalized. This online survey will take approximately 5-10 minutes. Your responses are confidential, and we will not collect any

identifying information. If you have any questions about the survey, please contact Dr. Michael Knopp, MD, PhD at Knopp.16@osu.edu or survey@wcibmi.org. By clicking yes, you are agreeing to participate in the survey."

Withdrawal from the study

The subject can withdraw at any time from the study by not completing the survey, and their information up to that point will not be recorded.

Compensation for participation in the research

There is no compensation for participation in the research.

Enrollment and participation choices

Enrollment will be limited to 5,000 participants; however, we anticipate a significantly lower number of participants for each survey.

Survey tool

The surveys access information that may be shared by special interest groups, such as working groups within specific societies. Information may also be made available on online social media, postings, or targeted emails.

Subject participation choices

Subjects are given the option to complete the survey. Therefore, completion of the survey is mandatory in order to be a participant in the research.

Location of performance of research

The research is done on online. Anyone with the link can complete the survey wherever internet access is available.

Testing procedures and data recording

We intend to develop many surveys similar to the two surveys attached, which serve as the initial surveys and also as samples for anticipated upcoming surveys in order to obtain information of specific topics. All the information obtained from each respondent is collected using SurveyMonkey, which saves the data into a secure database. Only authorized users can abstract from the database the responses for each of the survey questions. Hardcopies may only be created for temporary purposes as part of data analysis and will be subsequently disposed.

Data analysis and analytics

As this is an exploratory trial, we have no prior data available to develop a detailed analysis plan. Initially, analytics will be descriptive.

Data sharing

Research findings may be presented at scientific meetings and may be included in scientific publications. Collected data will have no identifiable information. The data may be shared with collaborators as appropriate after defining data use agreement.

D. Risk, Benefits, Safety, and Confidentiality

Risks

There are no apparent risks from participation in the survey tools. Theoretically, a data breach could occur; however, no identifying information will be used in this research.

Benefits

There are no apparent personal benefits of participation in the surveys tools. However, there is a benefit of contributing to the generation of knowledge to benefit society. Additionally, the local facility may be able to update future research based on findings of this study.

Safety Monitoring

There will be no specific safety monitoring. Data safety will be monitored according to institutional policies.

Confidentiality of Records

Collected data will have no identifiable information but may be shared with collaborators as appropriate after defining a data use agreement.

E. Internal Validity

Managing and verifying the internal validity is an important task in this exploratory research program in order to develop the appropriate methodology to be validated in prospective clinical trials. We will assess the different factors impacting internal validity of the data sets we generate. For the specific factors, we will address the following considerations. The following text uses material presented at https://en.wikipedia.org/wiki/Internal_validity and is hereby specifically acknowledged.

Temporal precedence

This describes the potential lack of clarity regarding how one experience may influence a subsequent experience as that might be a cause and effect relationship.

Confounding

A major threat to the validity of causal inferences is confounding. Observations in one variable may relate to another manipulated variable. Where spurious relationships cannot be ruled out, hypotheses would have to be appropriately developed.

Selection bias

Researchers and participants bring to the experiment a myriad of characteristics, some learned and others inherent, for example, sex, weight, hair, eye, and skin color, personality, mental capabilities, and physical abilities, and also attitudes like motivation or willingness to participate. Since the survey will be sent out via invite through working groups, societies, shared links etc., there is potential for selection bias based on shared characteristics of these groups. Selection bias refers to the problem that, at pre-test, differences between groups exist that may interact with the independent variable and thus be 'responsible' for the observed outcome.

During the selection step of the research study, if an unequal number of test subjects have similar subject-related variables, there is a threat to the internal validity. If subjects in two groups to be compared are dissimilar with regard to the independent variable but are alike in one or more of the subject-related variables, it may jeopardize the internal validity.

Self-selection to participate in this research can have a negative effect on the interpretive power of the dependent variable; this is especially known for online surveys where individuals of specific demographics opt into the test at higher rates than other demographics.

History

Events outside of the study/experiment or between repeated measures of the dependent variable may affect participants' responses to experimental experiences. Often, these are large scale events (natural disaster, political change, etc.) that affect participants' attitudes and behaviors such that it becomes impossible to determine whether any change in the dependent measures is due to the independent variable or the historical event.

Maturation

Subjects may change during the course of the experiment or even between measurements. Both permanent changes, such as physical growth, and temporary changes, like fatigue, provide "natural" alternative explanations; thus, they may change the way a subject would react to the independent variable. So, upon completion of the study, the researcher may not be able to determine if the cause of the discrepancy is due to time or the independent variable.

Repeated testing

Repeatedly measuring participants may lead to bias. Participants may remember the answers, or they may be conditioned to know that they are being tested. Repeatedly taking (the same or similar) tests usually leads to score gains.

Instrument change

The instrument used during the testing process can change the experiment, an aspect that we will manage via device quality control to the greatest extent possible. This also refers to observers

being more concentrated or primed, or having unconsciously changed the criteria they use to make judgments. This can also be an issue with self-report measures, such as facility perceptions given at different times. In this case, the impact may be mitigated through the use of retrospective pretesting. If any instrumentation changes occur, the internal validity of the main conclusion is affected.

Differential attrition

This error occurs if inferences are made on the basis of only those participants that have participated from the start to the end. Participants may have dropped out of the study before completion, possibly even due to the study or experiment itself. If this attrition is systematically related to any feature of the study, such as the administration of the independent variable or the instrumentation, or, if dropping out leads to relevant bias between groups, a whole class of alternative explanations may be possible that account for the observed differences.

Selection-maturation interaction

This occurs when the subject-related variables, color of hair, skin color, etc., and the time-related variables, age, physical size, etc., interact. If a discrepancy between the two groups occurs between the testing, the discrepancy may be due to the age differences in the age categories.

Experimenter bias

Experimenter bias occurs when the individuals who are conducting an experiment inadvertently affect the outcome by non-consciously behaving in different ways to members of control and experimental groups. It is possible to eliminate the possibility of experimenter bias through the use of double blind study designs, in which the experimenter is not aware of the condition to which a participant belongs.

F. Data Analysis

Data will be abstracted from excel worksheets. Descriptive statistical methods will be predominately used.

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