**CHALLENGES AND OPPORTUNITIES FOR THE THREE RS IN VACCINE QUALITY CONTROL: A CANADIAN CASE STUDY**

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**BACKGROUND**

In many industrialized countries, alternative methods for testing the safety and efficacy of vaccines are being considered as a means to reduce animal use. This consideration is a result of a growing interest in the ethical implications of animal experiments, public concern over animal welfare, and the desire to reduce the use of animals in research. The Three Rs (Replace, Reduce, Refine) are guiding principles for ethical animal experimentation, which are being increasingly applied to vaccine testing in Canada. The implementation of alternative methods in vaccine quality control testing may be facilitated in Canada.

**CASE STUDY**

We have conducted a case study to observe the perceptions of current stakeholders on alternatives to animal experimentation in implementing the Three Rs in vaccine quality control testing. The study was conducted in 2008, and the data have been analyzed using content analysis.

**Participants**

- The study population included 16 participants: 10 from government, 6 from industry.

**Methodology**

- Descriptive survey designed to collect data on attitudes and perceptions of stakeholders on the implementation of the Three Rs in vaccine quality control testing.

**Method: Interviews**

- Interviews were based on twelve open-ended questions that addressed the Three Rs in vaccine quality control testing. Understanding these questions and the current status of implementation of the Three Rs was a key objective of the study.

**Participants' Perceptions**

- Participants perceived the Three Rs as a means to reduce animal use in vaccine quality control testing.

**Methodology: Interviews**

- Interviews were conducted using snowball sampling and purposeful sampling (Palys & Atchison, 2007).

**Challenges**

- Regulatory Testing
  - The desire for harmonization is strongest within industry as it is easier to perform and interpret results.
  - Regulatory authorities require comparability studies to show that a new method is comparable.
  - There are two concerns: one is that the ELISA used in the D/T serological assay has been validated.
  - The ELISA used in the D/T serological assay is highly variable.

**Opportunities**

- The Domino Effect: Acceptance of test data between countries, which would reduce or eliminate repeat testing.
  - The desire for harmonization is strongest within industry as it is easier to perform and interpret results.

**References**


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**Figure 1**

50% of government and 67% of industry participants cited “So the closer we get to small molecule testing, typically, but not always, the closer are they to...” as a challenge to implementation of the Three Rs.

**Figure 2**

50% of government and 67% of industry participants cited “The closer we get to small molecule testing, typically, but not always, the closer are they to...” as a challenge to implementation of the Three Rs.

**Figure 3**

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