Supplemental Course 6

Regulatory Science

Presentation Contents

- Introduction
- Module 1: Introduction to Regulatory Science
- Module 2: Roles and Responsibilities of Regulatory Scientists
- Module 3: Current Regulatory Science Research in Human Care Licensing

Module 1

Introduction to Regulatory Science

Learning Objectives

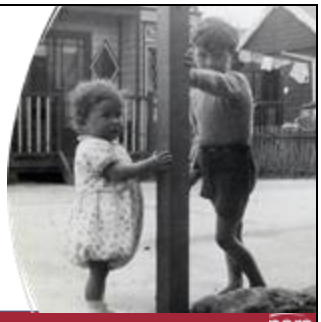
- Explain the meaning, history, and foundation of regulatory science.
- Explain the importance of regulatory science to human care licensing.

What Is Regulatory Science?

Science is the systematic study of the structure and behavior of the physical and natural world through observation, experimentation, and the testing of theories against the evidence obtained.
[Oxford Languages Dictionary]

Historical Foundation

The term “regulatory science” first occurred in 1970 shortly after the formation of the Environmental Protection Agency (EPA).



Importance of Regulatory Science

There have been discoveries since the beginning of time. Everyone and everything in some way has been impacted through scientific research.

Activity: How are you Affected by Science?

What revelations that came from scientific studies impacted how you interacted with others or managed your personal behaviors?

Connecting Regulatory Science to Human Care Licensing

Regulatory science in the human care industry is a field that uses scientific methods to inform, evaluate or develop tools, methods, standards, and systems that support a better understanding of safety, quality, and effectiveness of licensing systems.

The Emergence of Regulatory Science in Human Care Licensing

Dr. Richard Fiene's life's work serves a blueprint advocating for research scientists to explore the potential to improve outcomes for all adults, children and families in human care settings.

Applying Regulatory Science to Standard Development:

The goal of licensing is to ensure consumer protection and risk reduction.

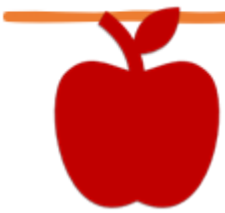
- Laws and regulations protecting individuals in human care are rarely proactive.
  - Focus should be placed on the scientific evidence needed to evaluate rules or regulations for the performance.

Regulatory Science in Safety and Efficacy

"The empirical results show that tougher regulations appear to be associated with higher quality and price...First, there is a significant amount of input substitution in response to regulations: a tougher regulation on one input affects the use of other inputs as well as the regulated input. For example, regulations that require higher staff qualifications cause centers to employ fewer staff members per child. Second, tougher regulations induce greater violation, indicating that enforcement is far from perfect. Third, other research suggests that many of the regulated inputs are in fact not very productive in improving quality. The only input that has been found to have robust positive effects on quality is recent staff training in early childhood development."

Regulatory Science in Monitoring and Enforcement

Rossi et al. (1999)...found that while assessors utilized the same characteristics when making decisions, the decisions themselves varied greatly. More recently, some agencies have begun to employ various risk assessment tools throughout child welfare to improve decision making of child removal and placement into out of home care (Cuccaro-Alamin et al., 2017). However, Cuccaro-Alamin et al. (2017), highlight the fact that while standardized tools are often more effective than simple clinical judgement, there are also multiple operational and statistical limitations to using those tools including the tool's validity and reliability, the usability and cost, limited accuracy, and inconsistent use amongst others. (Stevens, Fiene, Blevens & Salzer, 2020)



Knowledge Check

Knowledge Check

Learning Objective: Explain the meaning, history, and foundation of regulatory science.

Question #1

Regulatory science ignores the impact rules have on policy and licensing systems.

a. True
b. False

Knowledge Check

Learning Objective: Explain the meaning, history, and foundation of regulatory science.

Question #2

Regulatory Science focuses on two pillars including “do no harm” and “do good”.

a. True
b. False

Knowledge Check

Learning Objective: Explain the meaning, history, and foundation of regulatory science.

Question #3

Scientific discoveries currently dictate all policies and procedures followed by regulated human care facilities.

a. True
b. False

Knowledge Check

Learning Objective: Explain the meaning, history, and foundation of regulatory science.

Question #4

The term “regulatory science” first occurred in 1970 shortly after the formation of the Environmental Protection Agency (EPA).

a. True
b. False

Knowledge Check

Learning Objective: Explain the meaning, history, and foundation of regulatory science.

Question #5

Regulatory science has evolved primarily because policy makers and regulators struggle with limiting judgement when making policy decisions resulting in overly protective approaches to licensing oversight.

a. True
b. False

Knowledge Check

- **Learning Objective:** Explain the importance of regulatory science to human care licensing.

Question #6

Regulatory science can be effective to support rule development because:

a. New laws and regulations protecting individuals in human care are rarely proactive.
b. Rules are often created based on an event rather than evidence.
c. Perceptions of potential harm or damage can influence rules without justifiable evidence.
d. All the above.

Knowledge Check

- **Learning Objective:** Explain the importance of regulatory science to human care licensing.

Question #7

Regulatory science in the human care industry is a field that:

a. Tell policy makers what to do.
b. Use scientific methods to assist in better understanding the safety, quality, and effectiveness of licensing systems.
c. Justify policy positions of state or provincial governments.
d. Guarantees better outcomes for staff.

Knowledge Check

Learning Objective: Explain the importance of regulatory science to human care licensing. .

Question #8

One of the key areas where this work focuses on is: :

a. Influencing policy to ensure greater financial benefits to consumers.
b. Identifying potential risks associated with the design to ensure correction before harm is done.
c. Control all procedures and practices of the licensing agency.
d. All the above

Knowledge Check

Learning Objective: Explain the importance of regulatory science to human care licensing.

Question #9

Regulatory agencies focus on the practical aspects of creating and applying regulatory requirements to ensure compliance while regulatory science is more concerned with the scientific basis for those regulations and the development of methodologies and standards used in regulatory decision-making.

a. True
b. False

Module 2

Roles and Responsibilities of Regulatory Scientists

Learning Objective

- Understand the ethical role that regulatory scientists play in licensing systems.
- Understand the importance of all aspects of research.
- Learn about the common scientific methods currently used in the licensing field.

Understanding the Role of the Regulatory Scientist

Regulatory science consists of more than simply using data and analytics to guide decisions regarding licensing systems and practices – They also need to be knowledgeable regarding their ethical obligations to any study!

Activity: Responsibilities and Standards of Regulatory Scientists

Have there been times when you were asked to conduct, participate, or provide feedback in a new process?

Understanding and Maintaining Research Standards

- Regulatory science aims to provide systematic steps that are transparent to everyone when conducting research.
- Understanding the steps of conducting research as well as ethical practices are critical when considering regulatory research in any agency.

Internal Review Boards

You should include an IRB review when your study plan meets the definition of **research** (regardless of funding or location), involves **human subjects** and is intended to be **generalizable**.

IRB Definitions

- ✓ **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- ✓ **Generalizable knowledge** is when the purpose is to develop or test scientific theories or draw conclusions that are intended to be applied beyond the populations or situations being studied.
- ✓ A **human subject** is a living individual about whom an investigator (whether professional or student) conducting research:

Ethical Standards: Respect for Person and Autonomy

Informed Consent: Participants must be fully informed about the purpose of the research, the procedures, potential risks and benefits, and their right to withdraw at any time.

Confidentiality: Identifiable data should be kept confidential and protected from unauthorized access.

Anonymity: Personal information about a participant or subject should be kept secure to protect privacy.

Ethical Standards: Beneficent and Nonmaleficence

Beneficence: Act in ways that benefit others and promote their well-being.

- ✓ Safeguard the rights and safety of participants research subjects.
- ✓ Ensure the research itself does not impact that well-being.
- ✓ Provide valuable knowledge that improve outcomes for individuals.

Nonmaleficence: Researchers must avoid harm at all costs by not exposing them to unnecessary or avoidable risks and addressing any real or perceived harm promptly.

Ethical Standards: Justice and Fairness

Adhere to the principle of "respect for persons" by ensuring participants are treated with dignity and their rights are projected.

- **Avoiding exploitation**
- **Fair recruitment and subject selection**
- **Avoiding bias**
- **Ensuring the relevance of research questions**

Ethical Standards: Research Integrity

Ethical research builds trust in the scientific community and can lead to long-term benefits for individuals and communities by:

- ✓Avoiding Fabrication and Falsification
- ✓Transparency
- ✓Objectivity
- ✓Honesty and Accuracy

Activity: Identifying the Ethical Need

Questions & Answers

Communicating

- ✓Understand Your Audience
- ✓Use Clear and Concise Language
- ✓Leverage Visuals
- ✓Choose the Right Communication Channels
- ✓Follow-up and stay engaged

Design Steps Required for Regulatory Research Development

1. Research Questions.
2. Literature Review
3. Method Design
4. Data Collection
5. Analysis
6. Present Findings

Step 1: Identify Research Questions

And asking two or more things in one question	Keep each question focused on one topic at a time
Using words or phrases that steer respondents towards a particular response	Present options or topics in a balanced and impartial manner
A question that is too general or lacks focus	Ensure to pinpoint specific aspects and focus on a particular issue or problem
Using vague or ambiguous language	Include precision and detail in your wording to enhance clarity
Questions that are overly complex or ambitious and/or require resources or time you don't have	Ensure they are practical given your available date, resources, and time constraints

Step 2: Literature Review

Using unverified and unreputable materials	Use scholarly material from reputable sources
Adding findings and information that don't relate to your research question	Literature included in your review should always support your study and maintain focus directly related to your question.
Summarizing without fully analyzing and connecting the literature to one another	Thoroughly connect each piece of literature together to create an interconnected picture
Neglecting to carefully organize the structure of the review	Use clear headings, subheadings and transitions
Inadequately citing or improper referencing	Always, always, always cite your sources properly

Step 3: Research Design (Methods)

Doesn't align with your research questions or is not possible with the data	Carefully consider if the questions are suitable for the type of data and ensure you have the right resources
Using inappropriate or biased sampling techniques	Include sampling methods/size that represent the population and consider random sampling techniques

Step 4: Data Collection

Failing to identify and address errors, inconsistencies, and missing values	Employ robust data cleaning practices and procedures
Neglecting to collect all necessary data or collecting data from an incomplete sample	Consider developing a comprehensive data collection plan
Not verifying the accuracy and reliability of the data	Implement data validation techniques
Failing to comply with data privacy laws and regulations	Ensure that data collection and storage practices are complaint
Being more concerned about the amount rather than quality and relevancy	Focus on collecting high-quality, relevant data that is sufficient to answer the research question

Step 5: Data Analysis

Choosing the wrong statistical methods or misinterpreting results	Ensure the analytical tools you are using match your methods
Confusing correlation versus causation	Consider potential explanations for all observed relationships and be on the lookout for confounding variables
Analyzing data for the purpose of fitting a desired result	Ensure to use validation and avoid overfitting

Step 4: Present Findings

Findings should be:

✓Clear and concise
✓Enough – but not too much
✓Tailored to your audience
✓Supported with graphics

Activity: Which Design Step is it?

Find your match!

Frameworks

A theoretical framework guides the process of identifying and researching a problem.

- Ensures researchers have existing knowledge to make a hypothesis and choose appropriate methods.
- Regulatory Science commonly uses research frameworks that view individuals, families, and communities as interconnected systems.

1. Grounded Theory

- Various methods can be employed to interconnect information.
- The process is both iterative and dynamic meaning not one directional.

Image from Ulianiu, A., (2018).Training heWatchdogs to Bark: A theoretical framework to assist public sector practitioners in identifying, reporting and taking action against state crimes against democracy

Scan the QR code for more information on grounded theory

2. Context, Input, Process and Product

CIPP informs decisions through systematically collecting program information to identify strengths and limitations of policy and processes. It uses four stages of evaluation systematically to focus on continuous evaluation:

1. Context: Goals/Mission
2. Input: Plans/Resources
3. Process: Components/Practice
4. Product: Outcomes

Scan the QR code for more information on CIPP

3. Waterfall

Waterfall is a 5 step linear approach used when designing systems such as monitoring systems:

1. Requirement development
2. Design
3. Implementation
4. Testing
5. Deployment

Image from management.org (2025)

Scan the QR code for more information on Waterfall

4. Information Systems Theory

- Information Systems Theory uses models to understand how the interconnected parts of a system are designed, used and impact organizations and society. (Chatterjee, 2012).
- Information systems theory follows the same research steps as any other theory listed here and can be integrated dependably.

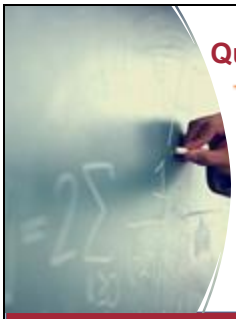
Analytical Tools

✓Qualitative: Descriptive data
✓Quantitative: Numerical data
✓Mixed Method: Combination

Qualitative Analysis Tools

There are five common qualitative analysis tools commonly used in human care regulatory science:

1. Thematic
2. Content Analysis
3. Narrative Analysis
4. Discourse Analysis
5. Interpretive Phenomenological Analysis (IPA)



Quantitative Analysis Tools

There are four common qualitative analysis tools commonly used in human care regulatory science.

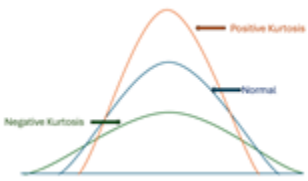
1. Phi Coefficient
2. CHI Square
3. Correlation Analysis
4. ANOVA

Characteristics of Regulatory Research Methods

All regulatory scientists should graph the data distribution to look for **kurtosis** and **skewness** in the data and depict if a **ceiling effect** is present or not.

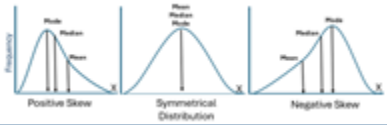
Kurtosis

Kurtosis describes the "tailedness" or "peakedness" to determine the presence and frequency of outliers in a dataset.



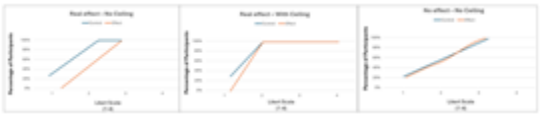
Skewness

When data is skewed, it means the data distribution is not symmetrical, creating an uneven curve on a graph making it difficult to accurately represent the data's primary tendency and impact statistical analysis.



Characteristics of Regulatory Research Methods

A ceiling effect refers to a situation where an independent variable no longer influences a dependent variable or the level in which the variance is no longer measurable.

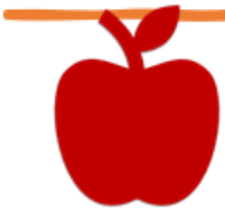


Activity: Which Analytical Tool is it?

Questions & Answers

Purpose of Methodological Design

Careful Method design ensures you can focus on the intended problem through carefully constructed research questions, grounded and appropriate theories, methods, and the right analytical tools



Knowledge Check

Knowledge Check

Learning Objective: Understand the ethical role that regulatory scientists play in licensing systems.

Question #1

It's not important when you submit your study plan to an Institutional Review Board (IRB) for review, just as long they review it before completion:

a. True
b. False

Knowledge Check

- **Learning Objective:** Understand the ethical role that regulatory scientists play in licensing systems.

Question #2

Researchers must avoid bias, prevent exploitation of vulnerable people and ensure the selection process is not based on discriminatory criteria are examples of:

a. Justice and Fairness
b. Understanding the Audience
c. Research Integrity
d. All the above

Knowledge Check

- **Learning Objective:** Understand the ethical role that regulatory scientists play in licensing systems.

Question #3

Individual data should be kept confidential and protected from unauthorized access:

a. True
b. False

Knowledge Check

- **Learning Objective:** Understand the importance of research steps.

Question #4

This is perhaps the most critical step when conducting research because it guide the direction of the entire design:

a. Literature Review
b. Identification of Research Questions
c. Method Design
d. Reporting
e. Analysis

Knowledge Check

- **Learning Objective:** Understand the importance of research steps.

Question #5

Using inappropriate or biased sampling techniques can lead to unrepresented sample and invalid results.

a. True
b. False

Knowledge Check

- **Learning Objective:** Understand the importance of research steps.

Question #6

It is during the_____ step that researchers need to be careful to understand when the data is showing a *relationship* between two variables rather than one variable directly *influencing* another.

a. Literature Review
b. Identification of Research Questions
c. Method Design
d. Reporting
e. Analysis

Knowledge Check

Learning Objective: Learn about the common scientific methods currently used in the licensing field.

Question #7

This theory was founded by Glaser and Strauss and uses well-known methodology including qualitative and quantitative data generation techniques that are multi-directional:

a. Context, Input, Process, Product (CIPP)
b. Waterfall Method
c. Grounded Theory
d. Information Systems Theory

Knowledge Check

Learning Objective: Learn about the common scientific methods currently used in the licensing field.

Question #8

A narrative analysis requires quantitative data

a. True

b. False

Knowledge Check

Learning Objective: Learn about the common scientific methods currently used in the licensing field. 9

Question #4

The primary purpose of methodological design in regulatory research is to provide a structured and systematic plan to keep a project on the right road.

a. True

b. False

Module 3

Current Regulatory Science
Research in Human Care Licensing

Learning Objectives

- Identify the overarching theoretical approaches to regulatory science in licensing.
- Summarize practices currently being modeled based on regulatory science discoveries.
- Explore areas where regulatory scientific advancements are needed.

Overview

Licensing theories explore the reasons behind and consequences of government regulations in:

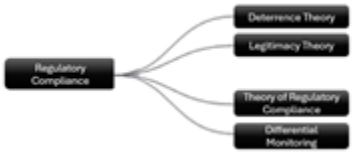
✓Adult Residential Care
✓Child Care
✓Child Welfare

These theories examine how licensing affects:

✓Agencies
✓Regulatory staff
✓Providers/caregivers
✓Consumers
✓The economy

Theories of Regulatory Science

We will focus on four main theories of regulatory compliance used specifically in human care licensing research.



Deterrence Theory

Deterrence theory suggests that individuals are less likely to engage in poor behavior if they fear the consequences of being caught and punished.

Legitimacy Theory

Compliance with the law is more likely when individuals perceive the regulations and their regulators as just and fair.

Theory of Regulatory Compliance

Dr. Fiene suggests there is a need within the regulatory science community to think through the best methods for measuring regulatory compliance including eight key elements or dichotomies:

Scan the QR code to read the full Article

Relative vs. Absolute Compliance

Absolute Paradigm:
All standards are equally important and aims for full compliance with all regulations.

Versus

Relative Paradigm:
All standards are not created equal and may have a differential impact on outcomes.

Substantial vs Monolithic Monitoring

Substantial Regulatory Monitoring:
Programs are monitored based on their past compliance history.

Versus

Monolithic Regulatory Monitoring:
Systems are considered a one-size-fits-all approach.

Differential Monitoring vs One Size Fits All

Differential Monitoring:
Tailoring monitoring efforts based on individual characteristics.

Versus

One-Size-Fits-All:
Applies the same approach to everyone, regardless of individual differences.

Do Things Well vs Do No Harm

“Doing Things Well”:
Focuses the 95% of the programs that are "doing things well“ and adjusting for the services needed to fit the needs of the other 5%.

Versus

"Doing No Harm”:
Focuses on the 5% of the non-optimal programs and imposes those systems to everyone.

Strength Based vs Deficit Based

Strength-Based Approach :
Nonpunitive and is not interested in catching programs not doing well.

Versus

Deficit-Based Approach:
Highlights the program's shortcomings to address deficits and minimize weaknesses.

Formative vs. Summative Monitoring

Formative Compliance Monitoring:
Assessing the continuous improvement process of their provider community.

Versus

Summative Compliance Monitoring
Evaluates a provider’s program to determine the overall mastery of compliance to all the licensing rules.

Program Quality vs. Program Compliance

Program Compliance:
Focuses on adhering to regulations and legal requirements to operate legally.

Versus

Program Quality:
Emphasizes the overall effectiveness and well-being of participants.

Non-Linear vs. Linear

Linear:
As compliance with rules increases positive outcomes for clients increases as well.

Versus

Non-Linear:
Client outcomes increase until substantial compliance is reached but doesn't continue.

Paradigm Summary

It's important to find the right balance between each of the paradigms and the systems' key elements to fit the needs of regulatory goals.

Activity: Which Paradigm Is It?

Questions & Answers

Differential Monitoring Approach

Differential monitoring adjusts the amount and frequency of monitoring activities based on a regulated entity's compliance history and identified risk profile.

Key Indicators

A carefully selected subset of regulatory rules or standards that have statistically demonstrated to predict overall compliance with the entire body of regulations.

Main Considerations
Full Year of compliance data
Identify those providers that are low or high compliance
count how many high compliance providers were out of compliance with the same items and how many low-group providers were out of compliance with the item.

Risk Assessment

This scoring system provides identifies areas that place clients at greatest risk for mortality or morbidity.

Required when a differential monitoring approach employs a *substantial* regulatory compliance scale; but it is not required when a full 100% regulatory compliance scale is used. (Fiene, 2024)

Quality Indicators

The Early Childhood Program Quality Improvement and Indicators Model (ECPQIM) is a comprehensive approach tying quality indicators with licensing indicators, risk assessment, and differential monitoring along with QRIS, accreditation, and professional development systems.

Main Considerations
Use the same statistical methods as the key indicator research
Key predictor performance indicators predicted overall performance
Creates a comprehensive system for both assessing and improving the overall quality

Validation

- Necessary evidence that licensing agencies are meeting regulatory standards.
- Assurances that licensing systems and monitoring tools are effective.
- Establish scientific credibility for new methods or processes.
- Ensuring that licensing and monitoring systems meet predefined standards and regulatory requirements.

Activity: Licensing Versus Placement and Protection

Which one is it?

Research Consideration Within Regulatory Science

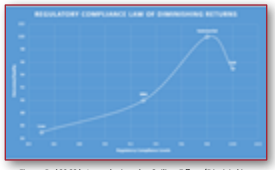
- The Regulatory Compliance Scale (RCS)
- The "ceiling effect" also known as the "theory of regulatory compliance diminishing returns"
- Uncertainty Certainty Matrix (UCM) .

Regulatory Compliance Scale

RCS	Definitions/Levels	Rule Violations
7	Full 100% Compliance	0 Violations
5	Substantial Compliance	1-3 Violations
3	Mediocre Compliance	4-9 Violations
1	Low/Non-Optimal Compliance	10+ Violations

Fiene, R. (2023). Theory of Regulatory Compliance, Regulatory Compliance Scale, and Differential Monitoring. doi 10.13140/RG.2.2.27748.39042

Theory of Diminishing Returns (Ceiling Effect)



Fiene, R. (2023). Introducing the Ceiling Effect/Diminishing Returns, Regulatory Compliance Scale, and the Quality Indicators Scale to Regulatory Science.

Eventually the added benefits of more compliance become insignificant and may even lead to negative consequences. Therefore, investing more resources to achieve perfect compliance won't significantly improve outcomes.

Uncertainty-Certainty Matrix

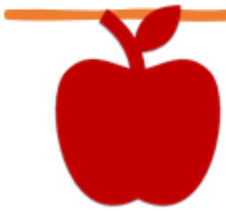
The UCM allows for the calculation of a coefficient that quantifies the level of agreement or disagreement, effectively indicating the degree of certainty or uncertainty associated with regulatory decisions.

UCM Matrix Logic		Decision Regarding	Regulatory Compliance
		[+] In Compliance	[-] Not In Compliance
Actual State of Compliance	[+] In Compliance	Agreement [++]	Disagreement [+-]
	[-] Not In Compliance	Disagreement [-+]	Agreement [--]

- A coefficient value closer to +1 signifies a high level of agreement (certainty)
- A value closer to -1 indicates significant disagreement (uncertainty)
- A value near 0 suggests a level of randomness

Activity: Reflecting to Make Connections

- How can/will you contribute to the field of regulatory science in human care licensing?
- What problems or further advancements would you like to see?
- What gaps in the current knowledge or empirical evidence still exist?



Knowledge Check

Knowledge Check

Learning Objective: Identify the overarching theoretical approaches to regulatory science in licensing.

Question #1

Differential Monitoring proposes that regulatory compliance is not always about achieving 100% adherence to all rules, but rather about finding a balance between "do no harm" rules and "best practice" standards

a. True

b. False

Knowledge Check

Learning Objective: Identify the overarching theoretical approaches to regulatory science in licensing.

Question #2

_____ theory focuses on preventing non-compliance through the fear of punishment, while _____ theory emphasizes the importance of trust with the oversight agency and acceptance of the law and its enforcement.

a. Deterrence & Regulatory Compliance

b. Relative & Differential

c. Deterrence & Legitimacy

Knowledge Check

Learning Objective: Identify the overarching theoretical approaches to regulatory science in licensing.

Question #3

There are twelve (12) key elements/dichotomies Fiene provides for us to consider in thinking about the implications of the theory of regulatory compliance

a. True
b. False

Knowledge Check

Learning Objective: Summarize practices currently being modeled based on regulatory science discoveries.

Question #4

Uses surveys to identify those areas that place clients at greatest risk for mortality or morbidity.

a. Key Indicators
b. Risk Assessment
c. Quality Indicators
d. Validation

Knowledge Check

Learning Objective: Summarize practices currently being modeled based on regulatory science discoveries.

Question #5

Uses statistical methods to predict the performance of a program:

a. Both 'b' and 'd'
b. Key Indicators
c. Validation
d. Quality Indicators
e. Both 'b' and 'c'

Knowledge Check

Learning Objective: Summarize practices currently being modeled based on regulatory science discoveries.

Question #5

Validation studies determine if a system or designed is working as intended and continue to meet the overall mission and goals of protection through prevention

a. True
b. False

Knowledge Check

Learning Objective: Summarize practices currently being modeled based on regulatory science discoveries.

Question #5

When the data are moved from frequency counts of violation data into these buckets/categories, this is called:

a. Uncertainty-Certainty Matrix
b. Theory of Diminishing Returns
c. Regulatory Compliance Scales
d. All the Above

Knowledge Check

Learning Objective: Summarize practices currently being modeled based on regulatory science discoveries.

Question #5

_____can help assess the validity and reliability of regulatory decisions and identify risks including potential bias in assessments.

a. Theory of Diminishing Returns
b. Uncertainty-Certainty Matrix
c. Regulatory Compliance Scales
d. A Leadership Meeting

Knowledge Check

Learning Objective: Explore areas where regulatory scientific advancements are needed.

Question #5

What gaps in research have been identified that need to be done to advance the field?

a. More empirical studies across all regulatory domains
b. Longitudinal studies to examine the impact on sustained compliance
c. Further refinement of measurement and statistical methods
d. All The Above

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