Quality by Design Principles Document for Dissemination & Implementation Science

INTRODUCTION

Dissemination and Implementation (D&I) science is the study of translation of research findings into practice in order to improve health outcomes in the broader community (Colditz, 2012). This toolkit adapts the principles of Quality by Design (QbD) to support proactive discussions and decision making at the time of study development about (1) what aspects of the study are critical to generating reliable data and providing appropriate protection of research participants ("critical to quality" [CTQ] factors) and (2) what strategies and actions will effectively and efficiently support quality in these critical areas. The document generally assumes that a clinical study will address a relevant scientific question for which there is a legitimate research need and is not intended as a primer on how to design a clinical study.

We have developed questions to consider for each CTQ factor to *support evaluation of the factor's relative importance for a particular study* as well as to *inform subsequent evaluation of what events may occur that would be likely to significantly impede the conduct of the study, place trial participants at unnecessary risk*, or *impede usability of the resulting data* (in other words, to become "errors that matter"). These discussions can then be used to develop *formal plans to avoid these events (*e.g., through tailoring study design or implementation) or mitigate their consequences.

The document is an adaptation of a similar QbD tool, CTTI Quality by Design project - Critical To Quality Factors Principles Document.

Part A: Design - *important for projects that have not undergone scientific peer review*
Part B: Conduct
Part C: Analysis
Part D: Dissemination

PART A: STUDY DESIGN

Factor	Considerations

Design	**Is the design appropriate for the study goals?**
	
	Considerations in D&I study design:
	1. Does an evidence-based intervention or practice exist?
	
	- If Y→ *effectiveness research*: examining how efficacious intervention works in real-world settings and its variations
	  o Role of D&I: implementation outcomes can be studied as contributing factors; implementation outcomes can be primary or secondary aims using hybrid design
	- If Y, is the evidence-based practice applied adequately? D&I research is the primary focus
	- If N→ *innovation development, safety testing, efficacy testing (not D&I)*
	
	2. Can the exposure be assigned?
	- If N → *observational* (cohort, cross-sectional, case-control)
	- If Y, can the exposure be *randomized*?
	    If Y→ *experimental* (RCT, cluster RCT, stepped wedge, adaptive, hybrid design)
	    If N→ *quasi-experimental* (controlled before/after, interrupted time series design, regression-discontinuity design
	
	References:
	Morshed, A., Tabak, R., Taranhike, I., Baumann, A., & Proctor, E. Intro to D&I. [Internet]. St. Louis, MO: Washington University; 2016 October. Eight toolkits related to Dissemination and Implementation. Available from http://toolkitsc.herokuapp.com/
	
	https://cpb-us-w2.wpmucdn.com/sites.wustl.edu/dist/6/786/files/2017/08/DIRC-intro-toolkit-2016.12.9-edits-1l2x1m8.pdf

	Lewis, E., Baumann, A., Gerke, D., Tabak, R., Ramsey, A., Small, S. & Proctor, E. D&I Research Designs. [Internet]. St. Louis, MO: Washington University; 2017 July. Eight toolkits related to Dissemination and Implementation. Available from https://sites.wustl.edu/wudandi https://cpb-us-w2.wpmucdn.com/sites.wustl.edu/dist/6/786/files/2017/07/DIRC-designs-toolkit_7-27-17-2ir4zjl.pdf **Which type of Implementation Science Design is used?** | Hybrid design type	Intervention effectiveness focus	Implementation outcomes focus
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Hybrid 1	Primary	Secondary
Hybrid 2	Equal focus	Equal focus
Hybrid 3	Secondary	Primary	
Conceptual Model and Theoretical Justification?	**Is there a clear conceptual framework/theory/model that informs the design and variables being tested?**
Implementation Outcomes	**Does your project have implementation outcomes? What are the endpoints used to measure them?** **Acceptability:** Extent to which implementation stakeholders perceive a treatment, service, practice, or innovation to be agreeable, palatable, or satisfactory. **Adoption:** Intention, initial decision, or action to try or employ an innovation or evidence-based practice. Adoption may also be called "uptake." **Appropriateness:** Perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation or evidence-based practice to address a particular issue or problem. **Cost:** Financial impact of an implementation effort. May include costs of treatment delivery, cost of the implementation strategy, and cost of using the service setting. **Feasibility:** Extent to which a new innovation or practice can be successfully used or carried out within a given agency or setting. **Fidelity:** Degree to which an intervention or implementation strategy was delivered as prescribed in the original protocol or as intended by program developers. May include multiple dimensions such as content, process, exposure, and dosage. **Penetration:** Extent to which an innovation or practice is integrated within a service setting and its subsystems. **Sustainability:** Extent to which a recently implemented practice is maintained and/or institutionalized within a service setting's ongoing, stable operations. https://cpb-us-w2.wpmucdn.com/sites.wustl.edu/dist/6/786/files/2017/07/DIRC-aims-toolkit-2017.03.23-1jeq1vl.pdf https://cpb-us-w2.wpmucdn.com/sites.wustl.edu/dist/6/786/files/2017/08/DIRC-implementation-outcomes-tool-dg_7-27-17_ab-27xbrka.pdf https://www.re-aim.org/about/what-is-re-aim/implementation/ https://www.re-aim.org/about/what-is-re-aim/adoption/
Service Outcomes	**Does your project have service outcomes? What are the endpoints used to measure them?** - Efficiency - Safety - Effectiveness - Equity - Patient-centeredness

	- Timeliness https://cpb-us-w2.wpmucdn.com/sites.wustl.edu/dist/6/786/files/2017/07/DIRC-aims-toolkit-2017.03.23-1jeq1vl.pdf https://www.re-aim.org/about/what-is-re-aim/effectiveness-or-efficacy/
Stakeholder Engagement	**Is there a clear engagement process for key stakeholders (refer to A-C from CFIR model)?**
Reach	**How will this project reach the targeted population?** - The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program, and reasons why or why not. https://www.re-aim.org/about/what-is-re-aim/reach/improving-reach/
Maintenance	**Is this project sustainable within the institution/healthcare system? How will it be sustained?** At the setting level, the extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies. Within the RE-AIM framework, maintenance also applies at the individual level. At the individual level, maintenance has been defined as the long-term effects of a program on outcomes after a program is completed. The specific time frame for assessment of maintenance or sustainment varies across projects. https://www.re-aim.org/about/what-is-re-aim/maintenance/

PART B: STUDY CONDUCT

Factor	Considerations
Identification of Barriers and Facilitators	**Identify factors that affect implementation outcomes and tailor implementation strategies to overcome negative factors (barriers) and enhance positive factors (facilitators)** - Instruments for measuring barriers: Multiple-factor Assessment Instruments including combinations of innovation, provider, patient, organizational, & structural/community-level constructs; single factor assessments - Instruments for measuring facilitators https://cpb-us-w2.wpmucdn.com/sites.wustl.edu/dist/6/786/files/2017/08/DIRC-BarriersFacilitators_Toolkit-1gc9m0a.pdf
Organizational Constructs	- Is the organization ready to implement change? Do the organization's members believe in their collective capability to change? - What is the organizational culture surrounding change? - How do the employees perceive the impact of their work? - To what extent do employees collectively perceived that the adoption, implementation, and use of the program is expected, rewarded, or supported by the organization? To what extent do they perceive it is important to implement? **Organizational Readiness for Change:** Organizational members' shared commitment to implement a change and belief in their collective capability to do so. **Organizational Culture:** The set of expectations and norms that influence behavior within an organization; it includes the historical values and collective experiences of the organization and is often viewed as "the way things are done around here." **Organizational Climate:** Employees' collective perceptions of the psychological impact of their work environment on their own functioning and well-being. This involves the perceived meaning of organizational practices and procedures, as well as perceptions of the kinds of behaviors that are rewarded or expected, aggregated at the organization level. **Implementation Climate**: The extent to which employees collectively perceive that the adoption, implementation, and use of an innovation such as an evidence-based program or practice is expected,

	rewarded, and supported by the organization. This refers to employees' shared perceptions of the importance of implementing a particular innovation within the organization. https://cpb-us-w2.wpmucdn.com/sites.wustl.edu/dist/6/786/files/2017/08/DIRC-implementation-organizational-measures-tool_12.9.16-edits-2253kxf.pdf
Implementation Strategies	**Have you developed an implementation strategy? If so, which category would it belong in?** **Evaluative and iterative strategies:** Assess for readiness and identify barriers and facilitators, Audit and provide feedback **Provide interactive assistance:** Provide facilitation, Provide clinical supervision, Provide local technical assistance **Adapt and tailor to context:** Promote adaptability, Tailor strategies, Use data experts **Develop stakeholder relationships**: Build a coalition, Identify and prepare champions, Conduct local consensus discussions **Train and education stakeholders**: Conduct educational meetings, Develop and distribute educational materials **Support clinicians**: Facilitate relay of clinical data to providers, Remind clinicians **Engage consumers**: Intervene with patients/consumers to enhance uptake and adherence, Use mass media **Utilize financial strategies:** Access new funding, Alter patient/consumer fees, Allow incentives/allowance structures **Change infrastructure:** Change physical structure or equipment, Change record systems Prusaczyk, B., Baumann, A., & Proctor, E. Implementation Strategies. [Internet]. St. Louis, MO: Washington University; 2016 October. Eight toolkits related to Dissemination and Implementation. Available from https://sites.wustl.edu/wudandi/ https://cpb-us-w2.wpmucdn.com/sites.wustl.edu/dist/6/786/files/2017/11/DIRC-implementation-strategies-tool-1v33amk.pdf
Feasibility of Proposed Research Methods	Do you have contingencies in place, should methods not work as planned?
Participant accrual and retention	- Describe the enrollment process. - How will participants be identified? How will they be reached? Are there stakeholders who can help with identification of eligible participants? - How will you retain participants?
Participant Safety	**Informed consent:** What are the key elements of the informed consent for this project? Have various stakeholders been involved in development of the informed consent? Does it use plain language principles (e.g. focus on symptoms rather than disease states)? How does the consent process fit in with study processes? Is there potential for vulnerable trial participants, those with impaired cognition or capacity? **Withdrawal Criteria:** Describe situations in which participants should or may be withdrawn. What are the steps required prior to deeming participant lost to follow up? Are there advocacy groups who should be involved?
Training	- Is there a training protocol in place for all stakeholders? - Will stakeholders need booster sessions? - How will you ensure consistent conduct? - Do staff need training for data collection?
Data Recording and Reporting	- Where will data be collected? - Can IT systems be leveraged for data collection? - Will data be captured in parallel with routine clinical assessments?

	- Will multiple data systems be utilized, requiring transfer and integration? - Where will data be stored? - Where and how will the data be used?
Data Monitoring and Management	- Identify departures from study conduct that may generate "errors that matter." - Which data are not critical to study analysis? - By what methods will data be monitored while the study is ongoing? At what frequency? - Will centralized statistical monitoring - Approaches be used in combination with onsite monitoring activities? - What functional lines will be involved in ongoing data monitoring? - Identify which function/individual is ultimately responsible for the decision to lock and unlock the database. - What types of issues is the monitoring plan designed to detect? Is it sufficiently comprehensive? - Define critical data elements for data management during protocol development
Dissemination	- Does team agree on the dissemination plan? Who are the targets of dissemination? How will information be used? - Plan for dissemination to the community? - How will information be communicated to study participants? - Who has rights to publish? - Agreement on authorship?

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Consolidated Framework for Implementation Research Constructs
[CFIR Website](#)

Construct		Short Description
I. INTERVENTION CHARACTERISTICS		
A	Intervention Source	Perception of key stakeholders about whether the intervention is externally or internally developed.
B	Evidence Strength & Quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.
C	Relative Advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.
D	Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.
E	Trialability	The ability to test the intervention on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.
F	Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.
G	Design Quality & Packaging	Perceived excellence in how the intervention is bundled, presented, and assembled.
H	Cost	Costs of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs.
II. OUTER SETTING		
A	Patient Needs & Resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.
B	Cosmopolitanism	The degree to which an organization is networked with other external organizations.
C	Peer Pressure	Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge.
D	External Policy & Incentives	A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.
III. INNER SETTING		
A	Structural Characteristics	The social architecture, age, maturity, and size of an organization.
B	Networks & Communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.
C	Culture	Norms, values, and basic assumptions of a given organization.
D	Implementation Climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.
1	Tension for Change	The degree to which stakeholders perceive the current situation as intolerable or needing change.
2	Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
3	Relative Priority	Individuals' shared perception of the importance of the implementation within the organization.
4	Organizational Incentives & Rewards	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect.

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5	Goals and Feedback	The degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals.
6	Learning Climate	A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.
E	Readiness for Implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.
1	Leadership Engagement	Commitment, involvement, and accountability of leaders and managers with the implementation.
2	Available Resources	The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time.
3	Access to Knowledge & Information	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.
IV. CHARACTERISTICS OF INDIVIDUALS		
A	Knowledge & Beliefs about the Intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.
B	Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.
C	Individual Stage of Change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.
D	Individual Identification with Organization	A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization.
E	Other Personal Attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.
V. PROCESS		
A	Planning	The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance, and the quality of those schemes or methods.
B	Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities.
1	Opinion Leaders	Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention.
2	Formally Appointed Internal Implementation Leaders	Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role.
3	Champions	"Individuals who dedicate themselves to supporting, marketing, and 'driving through' an [implementation]" [101] (p. 182), overcoming indifference or resistance that the intervention may provoke in an organization.
4	External Change Agents	Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction.
C	Executing	Carrying out or accomplishing the implementation according to plan.
D	Reflecting & Evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.