The Active Risk Control (ARC) Toolkit

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The Active Risk Control (ARC) Toolkit

Version 2013

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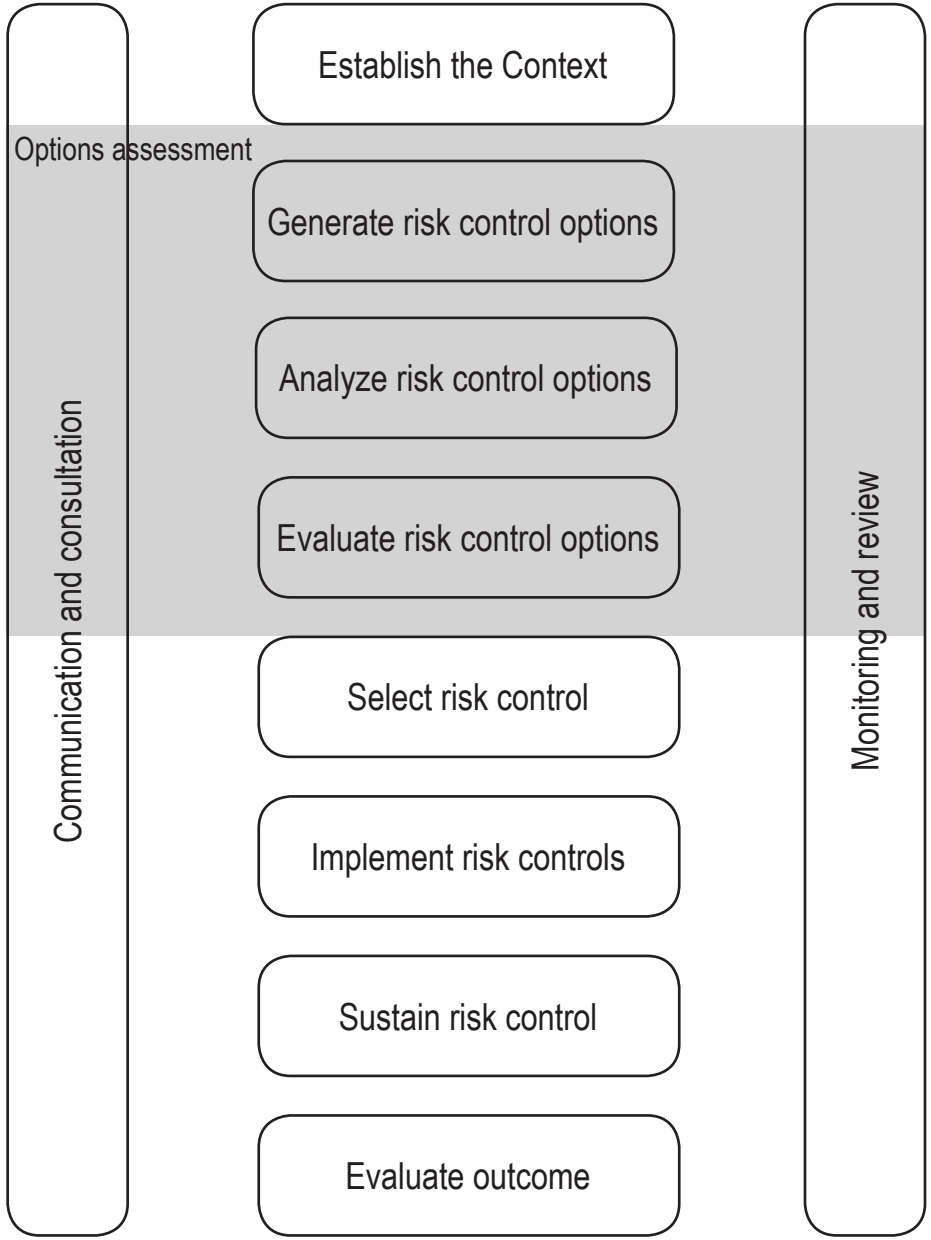
The Process for Active Risk Control

This toolkit is designed to be used as part of a broader approach to Active Risk Control, based on the Process for Active Risk Control (PARC). One key feature of both is a focus on stakeholder communication. Risk controls are more likely to succeed if those who will be involved are actively encouraged to provide input. The PARC is closely modeled on the Risk Management Process from ISO 31000 and is intended as an expansion of the Risk Treatment step in that process.



1.0 Background - Problem Framing

In this section, you will describe the risk to be controlled, translate the potential causes & contributing factors into solution-neutral problem statements, and define the criteria for successful control of this risk

1.1 Risk to be controlled, and potential causes / contributing factors as described in the risk assessment

1.2 Restate the risk and causes / contributing factors as solution-neutral problem statements

1.0 Background - Problem Framing

In this section, you will describe the risk to be controlled, translate the potential causes & contributing factors into solution-neutral problem statements, and define the criteria for successful control of this risk

1.3 Criteria for Success

Define successful control of this risk. The definition should be SMART (Specific, Measurable, Achievable, Realistic, and Time-bounded)

2.0 Generating Options for Active Risk Control (GO-ARC)

This structured brainstorming technique will help you generate a broader and stronger pool of risk control options to choose from

2.1 Eliminate the Hazard or the Target (Elimination)

Elimination can mean transferring the risk to another entity, substituting a less hazardous process, material medication, etc., or simply not using the hazardous process / materials, not delivering the hazardous service, etc.

Examples include:

–Transferring the risk of drug preparation from the ward to the pharmacy through unit dosing, or to the pharmaceutical company by procuring pre-filled syringes

–Substituting less dangerous drugs or other treatments

–Closing a low-volume ED where doctors are not getting enough practice to maintain their surgical skills

–No longer serving psychiatric patients, if elopement cannot be controlled

Risk Control Options	

2.0 Generating Options for Active Risk Control (GO-ARC)

This structured brainstorming technique will help you generate a broader and stronger pool of risk control options to choose from

2.2 Design Controls

With a focus on physical barriers, isolation, forcing functions, human factors, and failsafe design, design controls improve safety without relying on people to do the right thing.

Examples include:

–Walls or locked doors

–Isolation: Not just of patients, but also of processes

–Complete automation, or partial automation with forcing functions (e.g. software that prevents ordering a 10X overdose)

–Human factors / usability improvements like changing the layout of crash carts with standardized compartments so materials are easy to find

–New or standardized equipment –with usability testing first

–Failsafe/mistakeproof design (e.g. oxygen connectors that won't connect to the anesthetic gas lines)

–Permanent location changes

Risk Control Options	

2.0 Generating Options for Active Risk Control (GO-ARC)

This structured brainstorming technique will help you generate a broader and stronger pool of risk control options to choose from

2.3 Policies, procedures, training and other controls that depend on people taking the correct actions

Examples include:

–New or revised policies / procedures

–Checklists, signs, quick reference guides, and other memory aids

–Double-checking

–Automation without forcing functions (e.g. moving to computerized physician order entry without any forcing functions to prevent an order for 10x the correct dose)

–Patient safety alerts

–Awareness and persuasion campaigns

–Training and education

Note: Some studies have found that risk controls based on training and education may actually tend to make things worse; it is probably best to be sure there is a genuine training need before selecting this approach.

Risk Control Options	

2.0 Generating Options for Active Risk Control (GO-ARC)

This structured brainstorming technique will help you generate a broader and stronger pool of risk control options to choose from

2.4 Detection / Situational Awareness

These risk controls focus on knowing that something is going wrong, or is likely to do so, in time to prevent it, or reduce its impact.

Examples include:

–Observation, continuous or intermittent (e.g., hourly nursing rounds)

–Remote monitoring (e.g. telemetry, CCTV, RFID)

–Clinical alarms (ideally with usability testing first)

–Asking the patient to alert you if specific signs / symptoms occur

–Use of "daily goals" and/or multidisciplinary rounds so the care team knows the treatment objectives for each patient

–Post-discharge follow-up

–Auditing, surveys

–"Near miss" reporting

Risk Control Options	Hierarchy (Elim, Design, Admin)	Risk Control Options	Hierarchy (Elim, Design, Admin)

2.0 Generating Options for Active Risk Control (GO-ARC)

This structured brainstorming technique will help you generate a broader and stronger pool of risk control options to choose from

2.5 Preparedness

Preparedness is the state of being ready for predictable risks. Risk controls in this category involve having a response ready to go if the risk occurs. It means more than having a plan: It also means having the resources available and ready to be used to implement that plan.

Examples include:

–If a surgery is likely to lead to significant blood loss, making sure that matching blood is available and staged in an appropriate location for use

–Developing emergency operations plans detailing the response to events like severe flu pandemics, evacuations, active shooter scenarios, etc.

–Testing equipment shortly before use

–Identifying / training backups for important people and for important equipment (and ensuring people are trained to use the backup)

Risk Control Options	Hierarchy (Elim, Design, Admin)	Risk Control Options	Hierarchy (Elim, Design, Admin)

3.0 Options Analysis Worksheets

Worksheet 1 (Option 1)

3.1 Description of the Risk Control

Briefly describe what will be done, where and by whom, how long it will take, and how success will be defined and measured.

3.2 Mechanism of Action (How/ why is this expected to work?)

Briefly describe the hazard (potential root cause or contributing factor) the risk control addresses, and how the risk control is expected to reduce risk.

3.0 Options Analysis Worksheets

Worksheet 2 (Option 1)

3.3 Stakeholder Identification *Identify key stakeholders (groups and/or individuals). Include those who will implement this risk control, as well as those whose work will affect, or be affected by, the risk control*		

3.4 Force Field Analysis *Briefly describe the forces acting for and against the implementation and lasting success of this risk control (i.e., strengths / weaknesses, barriers / facilitators)*		
Forces in Favor of Success		Forces Against Success
	Success	

3.0 Options Analysis Worksheets

Worksheet 3 (Option 1)

3.5 Implementation Planning

Briefly describe how the risk control will be implemented and how successful implementation will be measured.

3.6 Sustainment Planning

Briefly describe how the risk control will be sustained and how successful sustainment will be measured (developmental evaluation).

3.5.1 *Briefly describe the resources required for implementation*

3.6.1 *Briefly describe the resources required for sustainment*

3.0 Options Analysis Worksheets

Worksheet 4 (Option 1)

3.7 Summative Evaluation Planning *Briefly describe how outcomes will be measured.*

3.7.1 *Briefly describe the resources required for summative evaluation*

3.8 Risk Control Score	*The formula is RCS = [(A-B+C)(D)(E/2)]/F*
A. Risk Reduction	
Risk reduction as a result of the risk control (Not counting side effects) **Score 1-6 (1 = negligible; 6 = very significant)**	1
B. Negative Side Effects	
New risks introduced as a result of the risk control **Score 1-6 (1 = negligible; 6 = very significant)**	1
C. Positive Side Effects	
Additional risks reduced as a result of the risk control; other positive benefits (e.g., savings) **Score 1-6 (1 = negligible; 6 = very significant)**	3
D. Robustness	
Score 1-3 **1 = Administrative Control;** **2 = Design Control;** **3 = Elimination of the Hazard or the Target**	2
E. Ease of Use	
How easy will it be to use this risk control, taking into account implementation, sustainment, evaluation? **Score 1-6 (1 = very difficult; 6 = very easy)**	6
F. Cost	
How much will this risk control cost, taking into account implementation, sustainment, evaluation? **Score 1-6 (1 = very inexpensive; 6 = very expensive)**	1
G. Risk Control Score (RCS)	
The RCS provides initial guidance on prioritizing risk control options.	18.00

List negative side effects
List positive side effects

3.0 Options Analysis Worksheets

Worksheet 1 (Option 2)

3.1 Description of the Risk Control *Briefly describe what will be done, where and by whom, how long it will take, and how success will be defined and measured.*

3.2 Mechanism of Action (How/ why is this expected to work?) *Briefly describe the hazard (potential root cause or contributing factor) the risk control addresses, and how the risk control is expected to reduce risk.*

3.0 Options Analysis Worksheets

Worksheet 2 (Option 2)

3.3 Stakeholder Identification *Identify key stakeholders (groups and/or individuals). Include those who will implement this risk control, as well as those whose work will affect, or be affected by, the risk control*		

3.4 Force Field Analysis *Briefly describe the forces acting for and against the implementation and lasting success of this risk control (i.e., strengths / weaknesses, barriers / facilitators)*		
Forces in Favor of Success		Forces Against Success
	Success	

3.0 Options Analysis Worksheets

Worksheet 3 (Option 2)

3.5 Implementation Planning

Briefly describe how the risk control will be implemented and how successful implementation will be measured.

3.6 Sustainment Planning

Briefly describe how the risk control will be sustained and how successful sustainment will be measured (developmental evaluation).

3.5.1 *Briefly describe the resources required for implementation*

3.6.1 *Briefly describe the resources required for sustainment*

3.0 Options Analysis Worksheets

Worksheet 4 (Option 2)

3.7 Summative Evaluation Planning *Briefly describe how outcomes will be measured.*

3.7.1 *Briefly describe the resources required for summative evaluation*

3.8 Risk Control Score	*The formula is RCS = [(A-B+C)(D)(E/2)]/F*
A. Risk Reduction	
Risk reduction as a result of the risk control (Not counting side effects) **Score 1-6 (1 = negligible; 6 = very significant)**	1
B. Negative Side Effects	
New risks introduced as a result of the risk control **Score 1-6 (1 = negligible; 6 = very significant)**	2
C. Positive Side Effects	
Additional risks reduced as a result of the risk control; other positive benefits (e.g., savings) **Score 1-6 (1 = negligible; 6 = very significant)**	3
D. Robustness	
Score 1-3 **1 = Administrative Control;** **2 = Design Control;** **3 = Elimination of the Hazard or the Target**	2
E. Ease of Use	
How easy will it be to use this risk control, taking into account implementation, sustainment, evaluation? **Score 1-6 (1 = very difficult; 6 = very easy)**	4
F. Cost	
How much will this risk control cost, taking into account implementation, sustainment, evaluation? **Score 1-6 (1 = very inexpensive; 6 = very expensive)**	3
G. Risk Control Score (RCS)	
The RCS provides initial guidance on prioritizing risk control options.	2.67

List negative side effects

List positive side effects

3.0 Options Analysis Worksheets

Worksheet 1 (Option 3)

3.1 Description of the Risk Control

Briefly describe what will be done, where and by whom, how long it will take, and how success will be defined and measured.

3.2 Mechanism of Action (How/ why is this expected to work?)

Briefly describe the hazard (potential root cause or contributing factor) the risk control addresses, and how the risk control is expected to reduce risk.

3.0 Options Analysis Worksheets

Worksheet 2 (Option 3)

3.3 Stakeholder Identification *Identify key stakeholders (groups and/or individuals). Include those who will implement this risk control, as well as those whose work will affect, or be affected by, the risk control*		

3.4 Force Field Analysis *Briefly describe the forces acting for and against the implementation and lasting success of this risk control (i.e., strengths / weaknesses, barriers / facilitators)*		
Forces in Favor of Success		Forces Against Success
	Success	

3.0 Options Analysis Worksheets

Worksheet 3 (Option 3)

3.5 Implementation Planning

Briefly describe how the risk control will be implemented and how successful implementation will be measured.

3.6 Sustainment Planning

Briefly describe how the risk control will be sustained and how successful sustainment will be measured (developmental evaluation).

3.5.1 *Briefly describe the resources required for implementation*

3.6.1 *Briefly describe the resources required for sustainment*

3.0 Options Analysis Worksheets

Worksheet 4 (Option 3)

3.7 Summative Evaluation Planning *Briefly describe how outcomes will be measured.*

3.7.1 *Briefly describe the resources required for summative evaluation*

3.8 Risk Control Score	*The formula is RCS = [(A-B+C)(D)(E/2)]/F*
A. Risk Reduction	
Risk reduction as a result of the risk control (Not counting side effects) **Score 1-6 (1 = negligible; 6 = very significant)**	1
B. Negative Side Effects	
New risks introduced as a result of the risk control **Score 1-6 (1 = negligible; 6 = very significant)**	2
C. Positive Side Effects	
Additional risks reduced as a result of the risk control; other positive benefits (e.g., savings) **Score 1-6 (1 = negligible; 6 = very significant)**	3
D. Robustness	
Score 1-3 **1 = Administrative Control;** **2 = Design Control;** **3 = Elimination of the Hazard or the Target**	2
E. Ease of Use	
How easy will it be to use this risk control, taking into account implementation, sustainment, evaluation? **Score 1-6 (1 = very difficult; 6 = very easy)**	4
F. Cost	
How much will this risk control cost, taking into account implementation, sustainment, evaluation? **Score 1-6 (1 = very inexpensive; 6 = very expensive)**	3
G. Risk Control Score (RCS)	
The RCS provides initial guidance on prioritizing risk control options.	2.67

List negative side effects
List positive side effects

3.0 Options Analysis Worksheets

Worksheet 1 (Option 4)

3.1 Description of the Risk Control

Briefly describe what will be done, where and by whom, how long it will take, and how success will be defined and measured.

3.2 Mechanism of Action (How/ why is this expected to work?)

Briefly describe the hazard (potential root cause or contributing factor) the risk control addresses, and how the risk control is expected to reduce risk.

3.0 Options Analysis Worksheets

Worksheet 2 (Option 4)

3.3 Stakeholder Identification *Identify key stakeholders (groups and/or individuals). Include those who will implement this risk control, as well as those whose work will affect, or be affected by, the risk control*		

3.4 Force Field Analysis *Briefly describe the forces acting for and against the implementation and lasting success of this risk control (i.e., strengths / weaknesses, barriers / facilitators)*		
Forces in Favor of Success		Forces Against Success
	Success	

3.0 Options Analysis Worksheets

Worksheet 3 (Option 4)

3.5 Implementation Planning

Briefly describe how the risk control will be implemented and how successful implementation will be measured.

3.6 Sustainment Planning

Briefly describe how the risk control will be sustained and how successful sustainment will be measured (developmental evaluation).

3.5.1 *Briefly describe the resources required for implementation*

3.6.1 *Briefly describe the resources required for sustainment*

3.0 Options Analysis Worksheets

Worksheet 4 (Option 4)

3.7 Summative Evaluation Planning *Briefly describe how outcomes will be measured.*

3.7.1 *Briefly describe the resources required for summative evaluation*

3.8 Risk Control Score	*The formula is RCS = [(A-B+C)(D)(E/2)]/F*
A. Risk Reduction	
Risk reduction as a result of the risk control (Not counting side effects) **Score 1-6 (1 = negligible; 6 = very significant)**	1
B. Negative Side Effects	
New risks introduced as a result of the risk control **Score 1-6 (1 = negligible; 6 = very significant)**	2
C. Positive Side Effects	
Additional risks reduced as a result of the risk control; other positive benefits (e.g., savings) **Score 1-6 (1 = negligible; 6 = very significant)**	3
D. Robustness	
Score 1-3 **1 = Administrative Control;** **2 = Design Control;** **3 = Elimination of the Hazard or the Target**	2
E. Ease of Use	
How easy will it be to use this risk control, taking into account implementation, sustainment, evaluation? **Score 1-6 (1 = very difficult; 6 = very easy)**	4
F. Cost	
How much will this risk control cost, taking into account implementation, sustainment, evaluation? **Score 1-6 (1 = very inexpensive; 6 = very expensive)**	3
G. Risk Control Score (RCS)	
The RCS provides initial guidance on prioritizing risk control options.	2.67

List negative side effects

List positive side effects

3.0 Options Analysis Worksheets

Worksheet 1 (Option 5)

3.1 Description of the Risk Control

Briefly describe what will be done, where and by whom, how long it will take, and how success will be defined and measured.

3.2 Mechanism of Action (How/ why is this expected to work?)

Briefly describe the hazard (potential root cause or contributing factor) the risk control addresses, and how the risk control is expected to reduce risk.

3.0 Options Analysis Worksheets

Worksheet 2 (Option 5)

3.3 Stakeholder Identification *Identify key stakeholders (groups and/or individuals). Include those who will implement this risk control, as well as those whose work will affect, or be affected by, the risk control*		

3.4 Force Field Analysis *Briefly describe the forces acting for and against the implementation and lasting success of this risk control (i.e., strengths / weaknesses, barriers / facilitators)*		
Forces in Favor of Success		Forces Against Success
	Success	

3.0 Options Analysis Worksheets

Worksheet 3 (Option 5)

3.5 Implementation Planning

Briefly describe how the risk control will be implemented and how successful implementation will be measured.

3.6 Sustainment Planning

Briefly describe how the risk control will be sustained and how successful sustainment will be measured (developmental evaluation).

3.5.1 *Briefly describe the resources required for implementation*

3.6.1 *Briefly describe the resources required for sustainment*

3.0 Options Analysis Worksheets

Worksheet 4 (Option 5)

3.7 Summative Evaluation Planning *Briefly describe how outcomes will be measured.*

3.7.1 *Briefly describe the resources required for summative evaluation*

3.8 Risk Control Score	*The formula is RCS = [(A-B+C)(D)(E/2)]/F*
A. Risk Reduction	
Risk reduction as a result of the risk control (Not counting side effects) **Score 1-6 (1 = negligible; 6 = very significant)**	1
B. Negative Side Effects	
New risks introduced as a result of the risk control **Score 1-6 (1 = negligible; 6 = very significant)**	1
C. Positive Side Effects	
Additional risks reduced as a result of the risk control; other positive benefits (e.g., savings) **Score 1-6 (1 = negligible; 6 = very significant)**	3
D. Robustness	
Score 1-3 **1 = Administrative Control;** **2 = Design Control;** **3 = Elimination of the Hazard or the Target**	2
E. Ease of Use	
How easy will it be to use this risk control, taking into account implementation, sustainment, evaluation? **Score 1-6 (1 = very difficult; 6 = very easy)**	4
F. Cost	
How much will this risk control cost, taking into account implementation, sustainment, evaluation? **Score 1-6 (1 = very inexpensive; 6 = very expensive)**	3
G. Risk Control Score (RCS)	
The RCS provides initial guidance on prioritizing risk control options.	4.00

List negative side effects
List positive side effects

4.0 Options Evaluation Matrix

Present risk control recommendations in ranked order, from highest to lowest priority, and illustrate the relationship between the risk controls and the hazards identified in Section 1.2 (Background 1)

	Hazards					
Risk Control Options						

Notes

Notes

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