Operationalization of Patient Safety Incidence Reporting and Learning System

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1. Two fundamental principles for Successful safety incident reporting systems

- They make risks visible.
- They prevent harm.

This is most likely to happen if five supporting processes are in place:

- Robust ways of identifying new and existing risks
- Clear prioritization of risks
- Mechanisms to escalate serious risks
- Methods for analyzing and investigating sources of risk
- Systematic monitoring of existing risks.

Reporting should also inform local responses to risks and drive the improvement in safety

- Setting of a clear safety agenda
- Communication of risks to relevant staff
- Allocation of accountability for resolving risks
- Engagement of local staff in risk analysis and improvement processes
- Production of actionable and practical information.

2. Creating a positive environment for reporting

- Must create first a positive culture in which reports are encouraged and valued, and staff are praised for participating
- Leadership commitment, policies, and practical steps should be in place
- Sources of actual and potential risk and harm in a health service heavily depends upon the observations and experience of the staff the at are close to the point of the care
- A positive reporting environment will be nurtured if education and training have equipped staff

3. Identification and recording of incidents

- Identifying and recording that an incident has occurred is the very first step in a reporting and learning process
- The recording or capturing of information about incidents usually takes place in one of four main ways

  - On a paper reporting form with or without the addition of later documentation;
  - On a paper reporting form with information subsequently transferred by a data clerk to an electronic record;
  - Directly by the reporter into an electronic record;
  - Into an electronic record after follow-up work that may involve further information gathering or investigation before data entry

4. Choosing the information to be captured

- Systems seek to capture and assemble information in three main domains:

  - Description (what happened), including patient characteristics, incident characteristics, and location;
  - Explanation (why it happened), including perceived causes of the event, contributing factors, and mitigating factors;
  - Remedial measures (the actions that were taken as a result), including reviewing processes and procedures, redesign, educational measures, and organizational changes

5. Uses of incident reports

- To formulate action to prevent (or reduce the risk of) a similar incident in the care setting where it occurred;
- To communicate information that could lead to the prevention of a similar incident elsewhere in a country's health system or globally;
- To aggregate with other reports to produce larger volumes of data capable of providing the maximum possible understanding of the problems in the system that led to the harm (or risk of harm);
- For education and training;
- For research, development and improvement;
- For public reporting and accountability;
- For open disclosure to patients and families

6. Review and investigation of individual incidents

6.1. Defenses (Swiss cheese Model)

6.2. Causes

- individual operator
- multi-operator teams
- equipment
- the organization and its management
- the regulator
- societal and cultural factors

6.3. Interactions (The common feature of most thinking on this subject is that errors, incidents, and accidents in complex systems are seen to result from more than one, usually multiple antecedents.)

6.4. The realities of reviewing incidents

7. Systemic insights from aggregated incident data

- Analyses of incidents in a database of reports will usually be based on aggregation into categories defined by the structured components of the reporting tool.

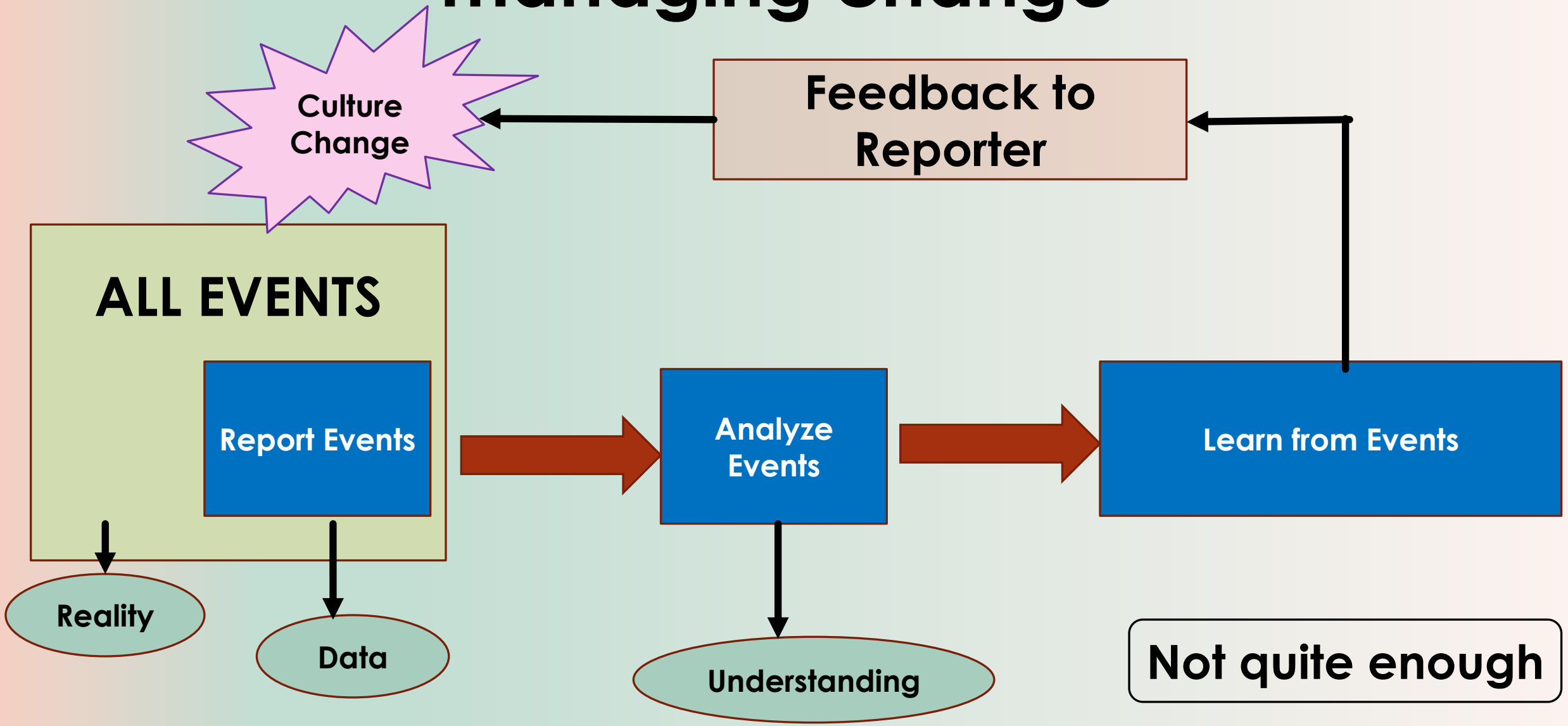
- Type 1: surveillance activity.
- Type 2: detecting major performance failures
- Type 3: probing for breakdowns in resilience
- Type 4: identifying new, serious sources of harm

8 Uses and limitations of aggregated patient safety incident data

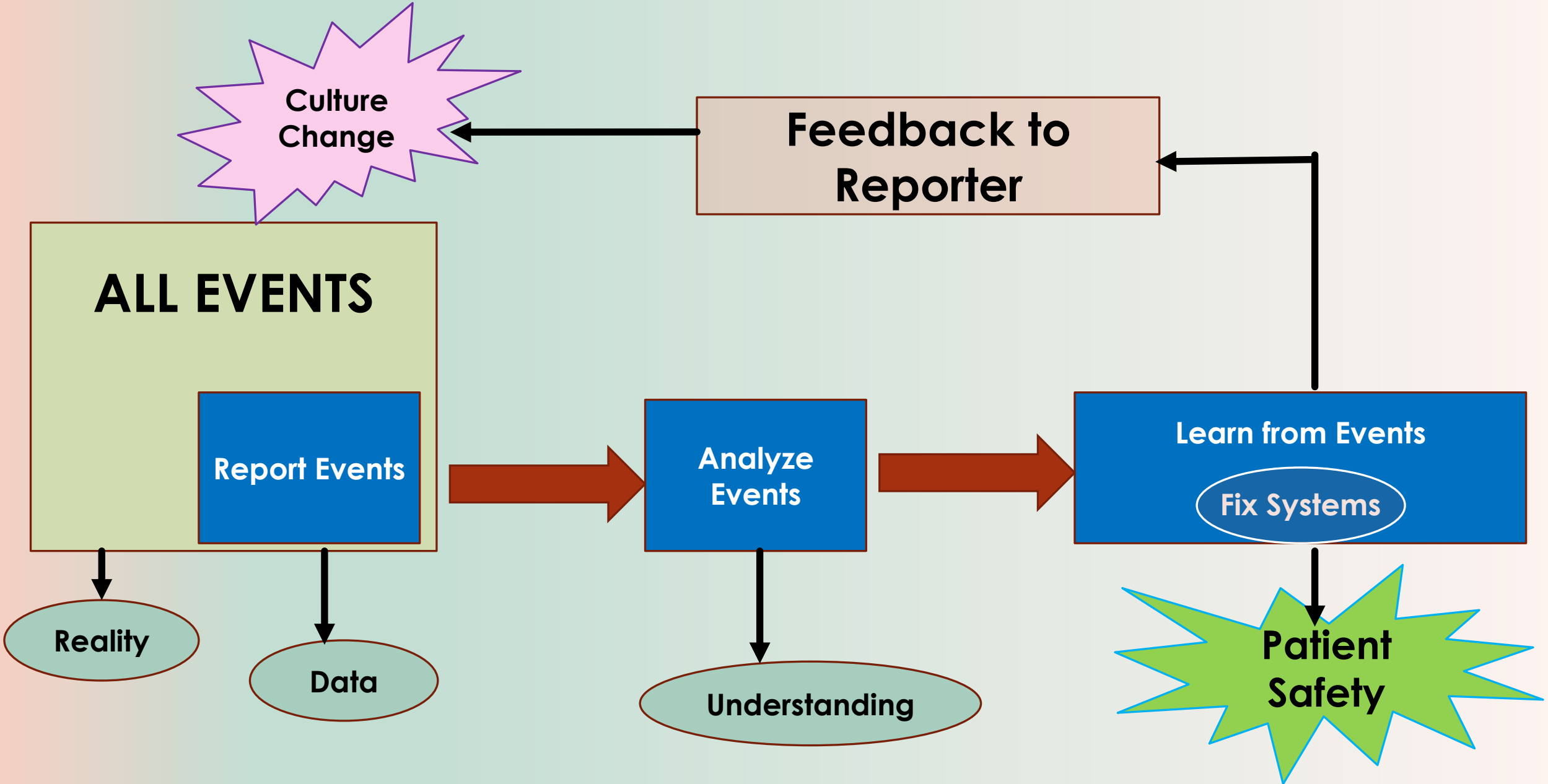
	ACTIVITY	SOURCE OF ANALYSIS	STRENGTHS	WEAKNESSES
	**Surveillance**	All incident types	Highlights broad patterns and trends	Weak on systemic insights; little immediately actionable
	**Performance assessment**	Incidents covering particular fields of care	Creates opportunity for system redesign and improved safety within a field of care	Requires extensive further investigation to assess nature of performance weaknesses
	**Breakdown in resilience**	Incidents pointing to failures in standards or control measures	Enables correction of breaks in defences	Causation can be wide ranging and restorative action complex
	**New and uncommon sources of serious harm**	Incidents of novel type showing clustering in time and space	Immediate opportunity to block harm and protect future patients	Needs highly active mining of data

Source: World Health Organization

9. Learning, formulating action, and managing change



An eye towards improvement……



10. Openness and independence of data analysis

Essential to have a clear policy on what range of reports, based on analysis of the reporting data, is produced. The first step in formulating such a policy is a determination of who will be the beneficiaries of the data. These are likely to be substantial in number and include:

- local providers of care
- health care professionals
- professional and educational bodies
- regulators
- insurers and payers
- patients and the public
- ministries of health
- parliamentary and other law-making and elected bodies
- clinical boards
- commercial bodies with a legitimate interest
- researchers
- innovators.

11. Information and clinical governance

- A rigorous information governance policy (with commensurate training) should be in place to underpin the recording, storage, and use of the data
- The areas covered will include confidentiality and data protection, anonymity, record management, information sharing, legality, public release of information, and other matters.
- The legal and regulatory framework in which this operates may vary from country to country.
- Any national or large-scale patient safety incident reporting and learning system that involves electronic capture, storage, and analysis will require a sophisticated information technology "back office" with skilled staff to manage all aspects of the data.

12. Engaging patients and families

- Incidents of harm in health care remark on their emotional power
- Best reporting systems include and encourage patient-generated reports
- Good practice around the world suggests that patients who suffer harm and their families should be fully informed about what has happened, how it happened and what will be done to prevent another similar occurrence

Thank you