The FUNCTIONAL RESONANCE ANALYSIS METHOD: FRAM

One way to introduce Complexity, Work as Done and Safety-II concepts to your Institution.

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Linear models in Patient Safety

Function A

Output

Input

Function B

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The Linear World of Patient Safety

“It depends.....”
The FRAM incorporates *non-linear* principles of complexity

**Health care as a complex adaptive system**

- Agents
- Inter-relating
- Rich relationships
- Non-linearity
- Self-organising
- Hierarchical
- Path-dependent
- Emergent behaviours
- A Feedback occurs
- Fractal, nested
- Heterarchical
- Individuals may only know local elements

[Braithwaite et al. 2014]
Work as imagined - work as done

Work-as-imagined is what designers, managers, regulators, and authorities believe happens or should happen.

Work-as-done is what actually happens.

Safety I: Failure is explained as a breakdown or malfunctioning of a system and/or its components (non-compliance, violations).

Safety II: Individuals and organisations must adjust to the current conditions in everything they do. Performance must be variable in order for things to work.
The FRAM: Inputs and Outputs
are only 2 out of 6 aspects

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The FRAM: 6 Aspects to a function

- **TIME**: Temporal aspects that affect how the function is carried out (constraint, resource).
- **CONTROL**: That which supervises or regulates the function, e.g., plans, procedures, guidelines or other functions.
- **INPUT**: That which activates the function and/or is used or transformed to produce the output. Constitutes the link to upstream functions.
- **OUTPUT**: That which is the result of the function. Constitutes the links to downstream functions.
- **PRECONDITION**: System conditions that must be fulfilled before a function can be carried out.
- **RESOURCES** (execution conditions): That which is needed or consumed by the function when it is active (matter, energy, competence, software, manpower).

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The FRAM: reflects Work as Done (pressures and culture)

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Complex non-linear model

Function B has multiple couplings
Case: feeding premature infants
FRAM makes way for Safety-II
Expressed breast milk mis-administrations per 10,000 feedings
Expressed breast milk mis-administrations per 10,000 feedings

2011 Root Cause Analysis

2012 RCA plus FMEA plus Quality Team consultants
Expressed breast milk mis-administrations per 10,000 feedings

- 2011 Root Cause Analysis
- 2012 RCA plus FMEA plus Quality Team consultants
- 2013 RCA plus FMEA plus 22 member committee

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FRAM of EBM administration

Barrier functions in red
Safety-II: when does it go right?
Case: missiles in the MRI suite - FRAM illuminates WAD
MRI safety zone regulations

ACR SAFETY ZONES

**Zone I**: All areas freely accessible to the general public without supervision. Magnetic fringe fields in this area are less than 5 Gauss (0.5 mT).

**Zone II**: Still a public area, but the interface between unregulated Zone I and the strictly controlled Zones III and IV. MR safety screening typically occurs here under technologist supervision.

**Zone III**: An area near the magnet room where the fringe, gradient, or RF magnetic fields are sufficiently strong to present a physical hazard to unscreened patients and personnel.

**Zone IV**: Synonymous with the MR magnet room itself. Has the highest field (and greatest risk) and from which all ferromagnetic objects must be excluded.
MRI safety controls

Door to MRI Suite

Badge authorization required

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I have completed a module on MRI safety and my badge will let me into the MRI suite.
MRI safety controls

Access magnet: Door and Chain
MRI safety controls

MRI Patient Safety Questionnaire

Dear Patient:

MRI is generally a very safe type of scanning, but there are some risks, particularly involving metal and the strong magnetic field in the scanner. It is vitally important that you answer these questions as accurately as possible to ensure your safety.

Date: 3/20/15

Patient's Weight: 200

Patient's Age: 37

(Please Circle Yes or No)

If scanning an extremity, which side, do you usually experience your symptoms? [ ] Left [ ] Right

Have you ever been a machinist, welder or metal worker? [ ] Yes [ ] No

Have you ever had a piece of metal in your eyes? [ ] Yes [ ] No

Do you have any shrapnel in your body? [ ] Yes [ ] No

Do you have a pacemaker? (Only Medtronic REVO’s are compatible) [ ] Yes [ ] No

Do you have an aneurysm clip? [ ] Yes [ ] No

Do you have dentures? [ ] Yes [ ] No

Do you have a hearing aid? [ ] Yes [ ] No

Do you have ear implants? [ ] Yes [ ] No

Do you have braces? [ ] Yes [ ] No

Do you have a tattoo? [ ] Yes [ ] No

Are you wearing eyeliner or nail polish? [ ] Yes [ ] No

Have you had a procedure to control a gastric bleed/intestinal hemorrhage, or have a Resolution Clip implanted? [ ] Yes [ ] No

Have you had fractured bones treated with metal rods, plates, screws, nails, or clips? [ ] Yes [ ] No

Are you wearing an "Arctic" wound dressing? [ ] Yes [ ] No

Are you wearing a Medication Patch (for pain medication/smoking cessation/iet)? [ ] Yes [ ] No

Do you have any implanted devices? [ ] Yes [ ] No

Could you be or are you pregnant? [ ] Yes [ ] No

Are you breast feeding? [ ] Yes [ ] No

Are you diabetic? [ ] Yes [ ] No

Are you claustrophobic? [ ] Yes [ ] No

Health Information Services Approval Date: 4/1/2013

Scan to: Questionnaire – MRI Patient Safety

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Critical Incident (*Safety-I*) despite barriers/controls
Linear Model: critical care patient to MRI suite

Critical Care Procedure for MRI - Transporting to the MRI Suite

Scheduling MRI for CC Patient
- MRI Ordered on CCS Patient
- MRI Tech Contacts RN to review MRI Patient Safety Checklist
- MRI schedules test time
- RN contacts RCP to inform of time.
- MRI contacts transportation to arrange orderlies.

Preparing patient and team for transport to MRI (mechanically ventilated)
- DECISION: Patients RN or SRT-RN to take patient to MRI:
  Decision based upon time of test and acuity of 1 or both of RNs patients.
- Attempt to suspend as many drips as possible.
- If possible, eliminate need for taking IV pumps.
- Determine if IV pump needed. NOTE: Heavy sedation or pressors will drive decision.

Preparation for MRI
- MR Ventilator is attached to 30 foot high pressure extension hoses to provide gases for ventilation.

Decision on Sedation
- If Fentany or Versed is used, can drip be suspended and bolus meds used for sedation?
- If bolus sedation to be used, RN to obtain 2 hours of medication for transport
- If Propofol used, IV pump required.

Decision on need for IV Pumps
- If Propofol or large dose sedation required, IV pump required.
- If Pressors required, IV pump required.

Type of IV Pump to be Used
- If complicated IV drips, SMART Pump selected for use.
- If RN unfamiliar with MR IV Pumps, SMART Pump selected.
- If SMART Pump selected, IV line changed to 30 feet (5 sets) of high pressure low volume line
- If RN comfortable with MR IV Pump, meds are then switched over from SMART pump to the MR IV Pump.

Mechanical Vent/Monitor
- MR Vent is identical in function to existing vents.
- MR Vent connected while patient in room.
- MR vent has 24 feet of tubing Standard transport monitor (X2) used for transport

Patient arrives in MR Suite
- Team prepares pt. for MRI room
- Patient is transferred to MR stretcher
- Aline disconnected from monitor.
- Leads switched to MR compatible.
- MR BP cuff placed.
- MR Monitor applied.
- ETCO2 applied
- If IV SMART Pumps used, SMART pump placed behind MR pass-through and line is passed through into MR suite and then connected to the patient. Care taken to not contaminate the line in process.
- MR Ventilator is attached to the 30 foot high pressure extension hoses to provide gases for ventilation.

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RCA and FMEA results: improve MRI safety

Proposal:

1. Improve signage with enhanced design scheme
2. Hospital-wide CBL on MRI safety
3. In-service nurses on MRI safety
4. Purchase MRI-safe ventilators and IV infusion pumps for each unit
RCA and FMEA results: improve MRI safety

Proposal:

1. Improve signage with enhanced design scheme

2. Hospital-wide CBL on MRI safety

3. In-service rehires on MRI safety

4. Purchase MRI-safe ventilators and IV infusion pumps for each unit
Let’s build a FRAM model…. review protocols, system, ethnography, interviews

Function: Patient to enter Zone 4
Ambulatory patient crosses Z-3 into Z-4 OVERVIEW
Now consider a non-ambulatory, critical care patient- a team and equipment are required
Critical care patient enters Z-4

TIME

NEW PRESSURES

TEMPORAL ASPECTS THAT AFFECT HOW THE FUNCTION IS CARRIED OUT

• Time is money
  • Pressure of “on-call” patients and keeping MRI schedule
  • Acuity of patient (nursing attention)
  • Additional UNIT pressures
  • Additional staff pressures

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Critical care patient enters Z-4

**NEEDED OR CONSUMED BY FUNCTION**

- Technologist
- No equipment, just patient
  - **Variability in equipment**
  - **Variability in use of equipment**
  - **Variability in staff roles required**
  - **Variability in staff awareness**
Critical care patient enters Z-4

**PRE-CONDITION**

**MUST BE FULFILLED:**
Door to Magnet is Open
- Chain can be operated by anyone (variability)
- Magnet Door can be operated by anyone (variability)

- Need to enter and leave magnet room through the door is highly variable
Critical care patient enters Z-4

VARIABILITIES
Final MRI safety intervention

• Linear control Solutions
  – Signage
  – Hospital wide CBL
  – In-service $$$$$$ plus morale burden on staff
  – New equipment

• WAD Solution
  – In this case, we want to control variabilities
  – Does not add staff tasks
  – $100,000 new Zone 3
Start with a method built on appropriate assumptions and build a model to illuminate solutions

“Essentially all models are wrong, but some are useful.”

GEP Box and NR Draper (1987)

Empirical Model Building and Response Surfaces, 424.
Summary methods and models

Linear: RCA, FMEA

- Assumes direct relationships
- Identify gaps/holes
- **Suggests barriers/ controls (adds steps)**
- May decrease monitored incidents- but have you reached point of diminishing returns and introduced new hazards?

Complex Non-linear: FRAM

- Assumes inter-dependent relationships
- Highlights variabilities
- **Consider variability reduction (OR support)**
- May give insight into plateau and shift of hazards

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How to study the FRAM

Erik Hollnagel’s text

Or, you can download English handbook:

http://functionalresonance.com
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Questions?

Fram in Antarctica in Roald Amundsen's expedition

1893-1912
## MRI Safety Zones

| ACR Zones | Occupants                                      | Hazards                                                        |
|-----------|-----------------------------------------------|                                                               |
| Zone I    | General Public                                | Negligible MRI hazards                                        |
| Zone II   | Unscreened MRI patients                       | Immediately outside area(s) of hazard                         |
| Zone III  | Screened MRI patients/staff                   | Potential biostimulation interference and access to magnet room |
| Zone IV   | Screened MRI patients under constant direct supervision of trained MRI personnel | Biostimulation interference, RF heating, missile effect and cryogens |
# METHODS are based on Models

<table>
<thead>
<tr>
<th>Model of STS</th>
<th>COMPLICATED LINEAR RCA/HFMEA</th>
<th>COMPLEX NON-LINEAR FRAM/STAMP</th>
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| Safety Principles | • Direct causality  
  • Latent conditions  
  • Sequence matters  
  • Retrospective matters | • Success=failure  
  • Variability  
  • Emergence  
  • Resonance  
  (combination of adaptations) |
| Goal of Safety Work | • Construct barriers/ gates | • Monitor/ manage performance variability |

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Pain Free Enters Z-3

PRECONDITION

CONDITION THAT MUST BE FULFILLED

• Team now must enter Zone 3
  - wide variability awareness
  - wide variability badge access
  - door remains open 15 seconds

Open for 15 seconds