General Outline and Functionality of Software Tools: Goals & Analytics

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Disclosures

- Founding member of Center for the Assessment of Radiological Sciences (CARS) – 501(c)(3) and PSO
- I am an engineer

What I will cover

- Knowledge Based Learning Systems (KBLS)
  - Incident Reporting Systems (ICR)
  - Risk based process analytics systems – TG 100 tools – (repository)
  - Advanced capabilities
- Improved
  - Processes, technology applications and Radiation Therapy (RT) equipment and devices
  - Safety
  - Treatment quality
  - Industry and clinical collaboration
  - Safety culture

Knowledge Based Learning Systems (AKA Knowledge Based or Expert Systems)

- Computer program that reasons and uses a knowledge base to solve complex problems
- Comprised of three sub-systems
  - Knowledge base
  - User interface
  - Inference engine
- Recent developments in computer science (gaming theory and simulation) and big data analytics are capable of producing amazing results

Knowledge Base

- Must be designed to meet all functional use requirements
- Top level requirements
  - Improve RT safety
  - Improve RT treatment quality
  - Facilitate and encourage collaboration on process and technology development and equipment/devise design quality
  - Improve safety quality in RT/RO community
  - Easy to use – input and output ends
  - More

Knowledge Base – Incident Reporting System

- Key requirements*
  - Non-punitive
  - Confidential
  - Independent
  - Timely (and risk oriented)
  - Expert analysis
  - Credible
  - Systems-oriented
  - Responsive

* World Health Organization Draft Guidelines for Adverse Event Reporting and Learning Systems. WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerlan. 2005.

Timely and Risk Oriented

- Incidents, near misses and errors need to be analyzed quickly (Root Cause Analysis – RCA) by experts and results quickly disseminated to the RT/RO community (days not weeks or longer with an ultimate response time goal of hours)
- All hazardous (or potentially hazardous) events should be acted on regardless of their frequency.

Exert Analysis

- RCA performed by experts in RT/RO
- Develop specific recommendations to improve quality systems and/or quality management
- Provide immediate solutions to reporting clinics and feedback to vendors

System Oriented

- Look beyond the process and technology level for system level causes of problems
- TG 100 – high frequency of system level causes of potential failure modes
  - Lack of communication
  - Lack of formal procedures
  - Lack of time/stress

Responsive

- Drive real change – demonstrate that it improves safety and treatment quality – develop actual metrics to measure effectiveness

What's Possible?

Develop a KBLS That Effective Meets the Needs and Requirements of All RT/RO Stakeholders

Clinics

Device/ Software Companies

Regulators

CARS – KBLS

Enrich the ICR Data Base

- Expand ICR beyond incidents, good catches and errors to include
  - Problems with equipment/devices/software – feedback to Vendors
  - Suggestions for process improvements
  - Information on clinical “ work arounds”
  - Other

Risk based process analytics systems – TG 100 tools – (Repository)

- Expand Knowledge Base beyond Incident Reporting System – risk based process analyses results
- Clinics provide the results from TG 100 risk based process analyses
  - Process Maps
  - Failure Mode and Effects Analysis (FMEA)
  - Fault Trees
- Vetted by experts

- Stored in a “repository” in the KBLS
- An excellent source of information about clinical processes and technology issues – valuable information for vendors
- Proactive
- VRPUSC initiative – cross functional TG 100 tools analysis for IGRT including regulator, physicists from academic and community clinics, vendor engineer

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- Incident Reporting System + Risk Based Process Analytics data base outperform either when identifying high risk process step *

- Reference – Validating FMEA output against incident learning data:
A study in Stereotactic body radiation therapy. Yang F, Cao N, Young L, Howard J, Logan W, Arbuckle T, Sponseller P, Korssjoen T, Meyer J, Ford E, Med Phys. 2015 Jun;42(6):2777-85. doi:10.1118/1.4919440

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- Data analytics algorithms will identify trends, high risk areas of processes, problems with emerging technologies and device/equipment/software problems or issues

Knowledge Based Learning Systems - Capabilities

- Issue warnings and advisories quickly for clinical process and technology related problems
- Expert analysis (including RCA of all reported incidents)
- Minimum lag time between an incident being reported and recommended actions

- Should be searchable across treatment processes, technologies, treatment modalities, etc. – important for effective collaboration between vendors and clinics (both academic and non-academic)
- Provide knowledge for research
- Improve safety culture in RT/RO clinics by bringing the players in the RT/RO community closer together and eliminating the “silos” that exist in the community

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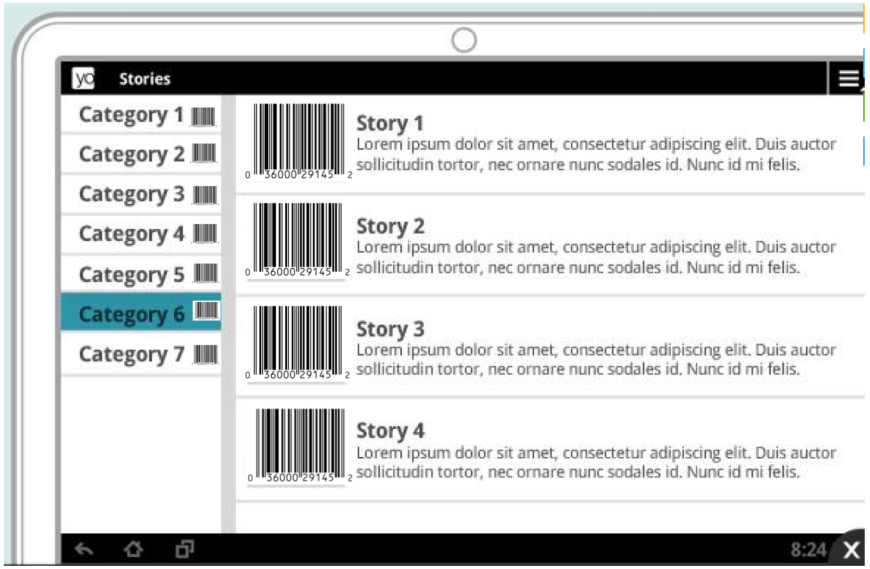
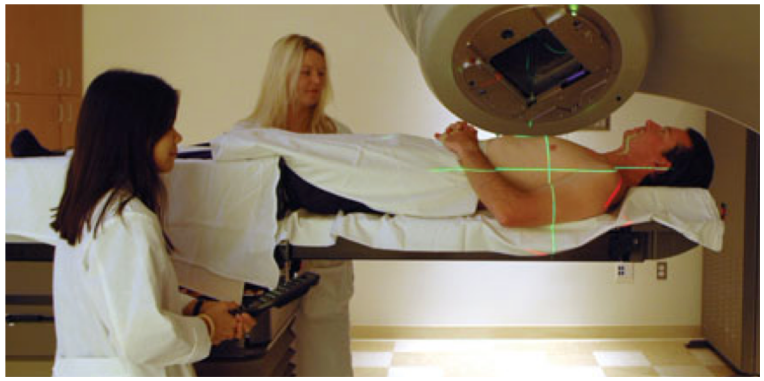
- Make it easy to enter data into the KBLS
- Use bar code and group technology analysis techniques to simplify input of data to the KBLS
- Facilitate and encourage the reporting of occurrences – especially in small clinics – who could use the most help





- Occurrence – specific treatment plan requires patient repositioning due to gantry interference when switching between beams.
  - Need to alert treatment staff that the treatment needed to be stopped for repositioning was known and indicated by a stop sign and the gantry stopped when it appeared on the screen
  - This particular treatment plan called for planar imaging and that required gantry movement that would impact the patient
  - For this combination of requirements and steps the system stop sign appeared on the screen but the gantry did not stop

- Potential impact – gantry impact with patient's head causing severe injury (once would be too many occurrences)
- Root cause unknown (design issue) but definitely requires immediate attention and RT community warned
- KBLS provide feedback to vendors involved

What the Future Might Be

- Example of Big Data Analytics – "Introduction to Watson and Watson Explorer Content Analysis", presented by Amit Saha, IBM at the 29th Annual Product Liability Conference, University of Wisconsin – Department of Engineering Professional Development, September 19-21, 2018
- "How content analytics helps manufacturers improve product safety and save lives"
- Auto manufacturers can now isolate and pinpoint the cause of safety issues through data from the National Highway Traffic Safety Administration (NHTSA) through basic out-of-the-box analysis tools.

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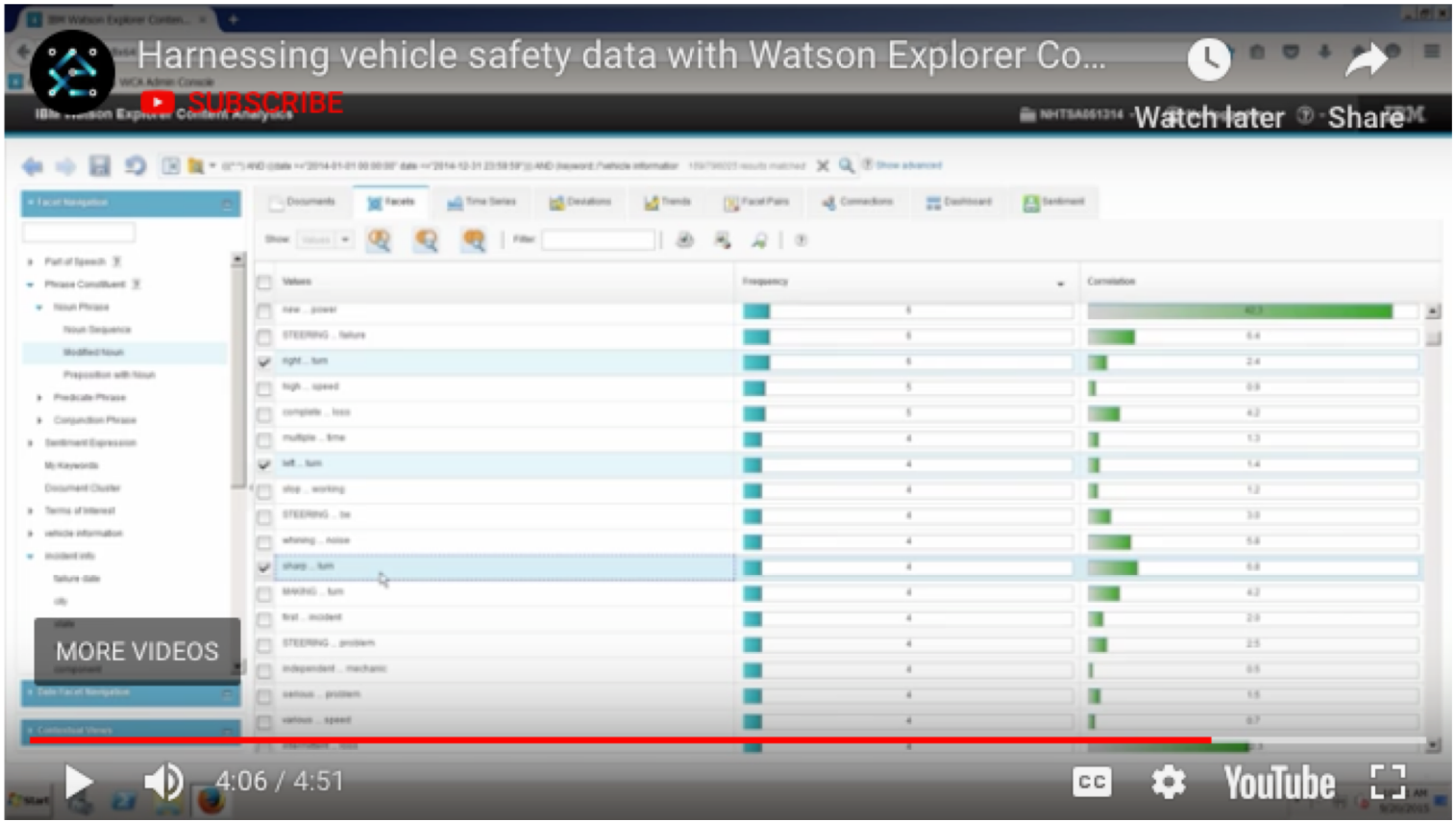

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- Automakers were able to identify a potential problem with the power steering assist for a number of car models across several car manufacturers!
- Recalls were issued prior to anyone being injured.

What the Future Could Be

- https://www.ibm.com/blogs/watson/2016/04/content-analytics-helps-manufacturers-improve-product-safety-save-lives/

Current State of Affairs

- RO-ILS ICR has been up and running for several years
- Incidents are being reported and analyzed
- Not currently capable of the advanced capabilities described
- CARS ICR also in use
- CARS currently developing a KBLS
- Looking for support and input from the vendor community and general healthcare community (EPIC)
- Opportunity for both CARS KBLS and RO-ILS to effectively co-exist