ITATION OF A PROSPECTIVE INTERVENTIONAL RADIOLOGY DATABASE AS A QUALITY ASSURANCE MEASURE USING LESSONS LEARNED FROM THE LITERATURE

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Declaration of Conflict of Interest

The authors have no conflict of interest to declare

Outline

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Background

- Interventional Radiology (IR) is a rapidly growing specialty in Medical Imaging due to its non-invasive nature
- IR procedures carry the risk of various complications although the rate of occurrence is generally low[1,2]
- Despite good evidence regarding common complication types and frequencies, there is limited literature on how to reduce IR procedure-related complications

Background

- Previous work has shown that a validated data collection system for intra- and post-surgical observations is effective for quality evaluation of provided care[3]
- A clinical database offers standardized, accurate, and time efficient data allowing for monitoring of continuous parameters[3]
- By using a clinical database, trends in complication types and rates can be detected and procedures can then be implemented to rectify the issue

Objective

To design and implement a prospective database for patients undergoing IR procedures, taking into consideration the barriers and facilitators identified in the literature, in order to:

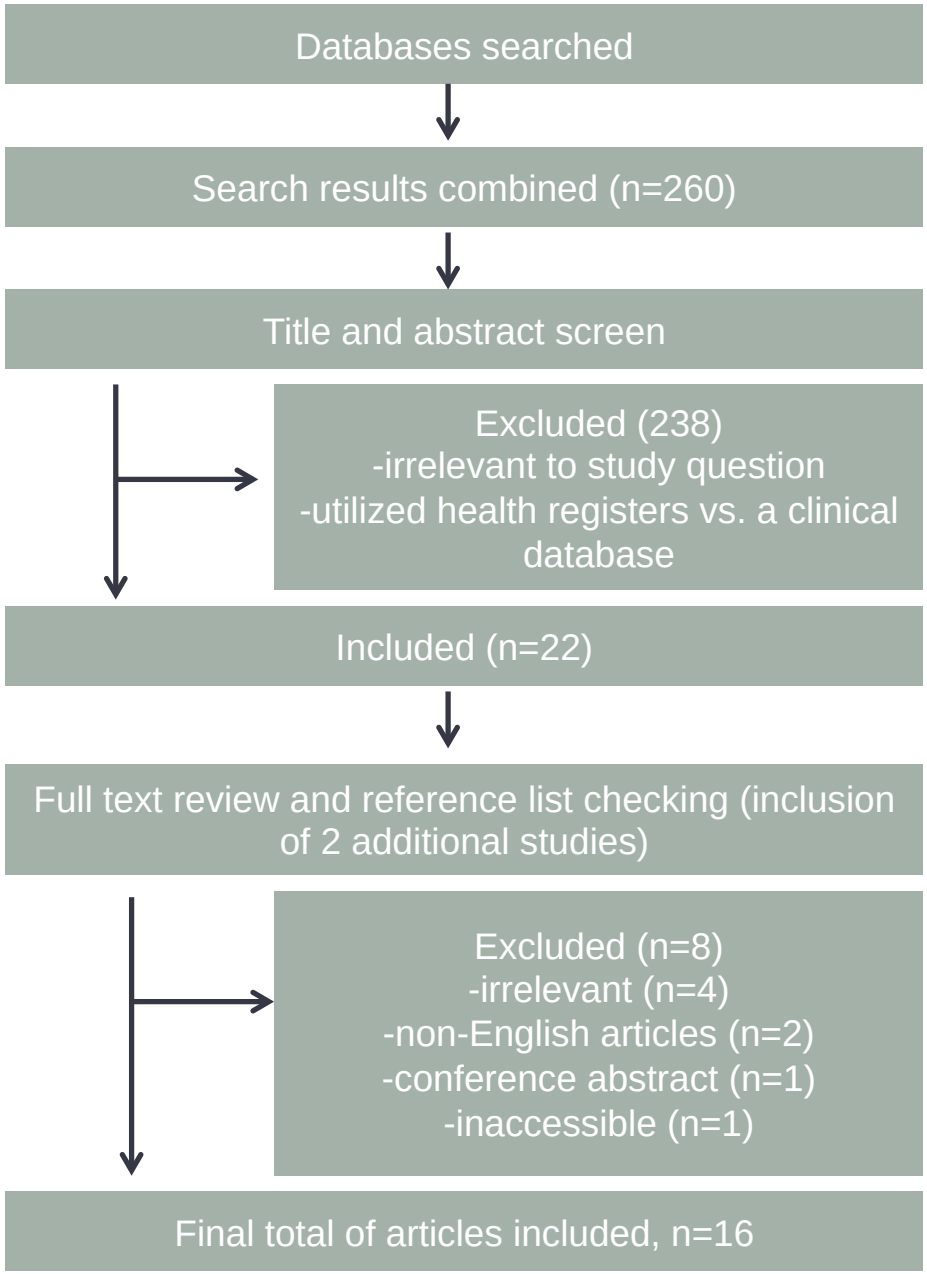
1) Assess complication types and rates

2) Perform across-time analyses to measure the impact of any modifications made to procedure protocol

3) Create a resource that can be used to address future research questions

Methods

- Studies examining the implementation of a prospective clinical database between 2000 and 2014
- Databases searched:
  - PubMed
  - EMBASE
  - Medline
  - Google Scholar
- Search terms:
  - “clinical”, “database”, “implementation”, “design”, “research”, “challenges”, “barriers”, “facilitators”



Results

Authors	Type/Setting of Database	Facilitators	Barriers
Harris et al., 2009	Variety of databases used by several research groups	-Previous successful implementation of a database at same institution	-Software expertise -Assuring confidentiality
Kessel et al., 2014	Radiation oncology	-Ability to perform simple and complex queries/analyzes -Web-based platform -Easily accessible	-Obtaining permission from data protection body -Cost of a computer specialist -Time to enter data -Buy-in/acceptance
Sharma et al., 2011	Multidisciplinary Vascular Birthmark Clinic in Calgary	-Staff input -Hiring administrative staff -Software available at institution -Reliable system -User-friendliness -Easily changing infrastructure	-Identifying data to be included -Balancing user-friendliness with comprehensive data storage -Data versus clinical expertise -Ethics approval -Privacy concerns -Adoption by staff -Maintenance
Mastrogiovanni et al., 2013	Stroke		-Cost -Data management -Privacy concerns -Staff buy-in

Results

Authors	Type/Setting of Database	Facilitators	Barriers
Birgegard, Bjorck, Clinton, 2010	Eating disorders	-Relevant, reliable, secure, portable, user-friendly -Pressure to know treatment outcomes -Existing infrastructure -Provides timely information -Cost-effective method to assess the quality of service provision -Regular feedback	-Technical expertise -Cost -Quality vs quantity of data -Clinical utility/buy-in -Organizational management
Wong et al., 2004	Neuroimaging	-Having separate user profiles -Easy to extract data -Creating an FAQ page -Reviewing and cleansing the data	-Time consuming -Missing data/incorrect entries -Security concerns -REB approval
Green, 2011	Overview of Danish experience with national clinical databases	-Pressure to report quality of care provided	-Funding/costs -REB approval
McConachie et al, 2008	Autism spectrum disorder	-Use of a stand-alone computer to ensure confidentiality -Hiring a database designer -Input from key stakeholders -Advertising -Keen leadership	-Staff turnover -Stable funding

Results

Authors	Type/Setting of Database	Facilitators	Barriers
Birch et al., 2001	Minimal access surgery	-Centralized server -Ease of data entry -Preselected values for variables -Staff input	-Laborious/time-consuming -Cost -Not enough data collected -Complex user interface
Sehgal & Davies, 2006	Thames Cancer Registry clinical database for colorectal cancer	-Pressure to monitor performance -Buy-in of key clinicians -Clinician involvement (ex. design, data cleaning/management)	-Competing priorities -Lack of resources -Lack of staff champion -Lack of clinician buy-in -Difficulty collecting certain items -Too many variables
Stow et al., 2006	Binational intensive care database	-Hiring research personnel -Funding/free software -Buy-in of clinicians, nurses, and data collectors	-Privacy concerns -Costs -Geographical constraints -Lack of champion to monitor data -Staffing issues -Buy in from administrators
Quintana et al., 2011	Pediatric oncology	-Training for data managers	-Inconsistent data collection methods/missing records -Slow or unreliable internet

Results

Authors	Type/Setting of Database	Facilitators	Barriers
Miyata, 2014	Japan's National Clinical Database	-Free -Easy to enter data -Use of a web-based system -Data entry by various staff members -Testing the database -Continually surveying users on how to improve system -Extracting data that does not require MD's judgement -Using opt-out consent	-Cost
Connolly et al., 2013	Monitoring of dronedarone	-publicly funded research personnel	
Zoccati, 2006	Nephrology	-Pressure to monitor treatment outcomes by organization	-Leadership ideals -Disappointments -Cost
Arlet et al., 2008	Adolescent idiopathic scoliosis	-Physicians championing data collection -Use of world wide web -Funding -Frequent meetings with key stakeholders -Can accommodate high user volume -Ease of use/data entry (by nurses/coordinators) -Error recovery features -Waived informed consent	-Time consuming -Inaccuracies -Amount of data collected

Discussion

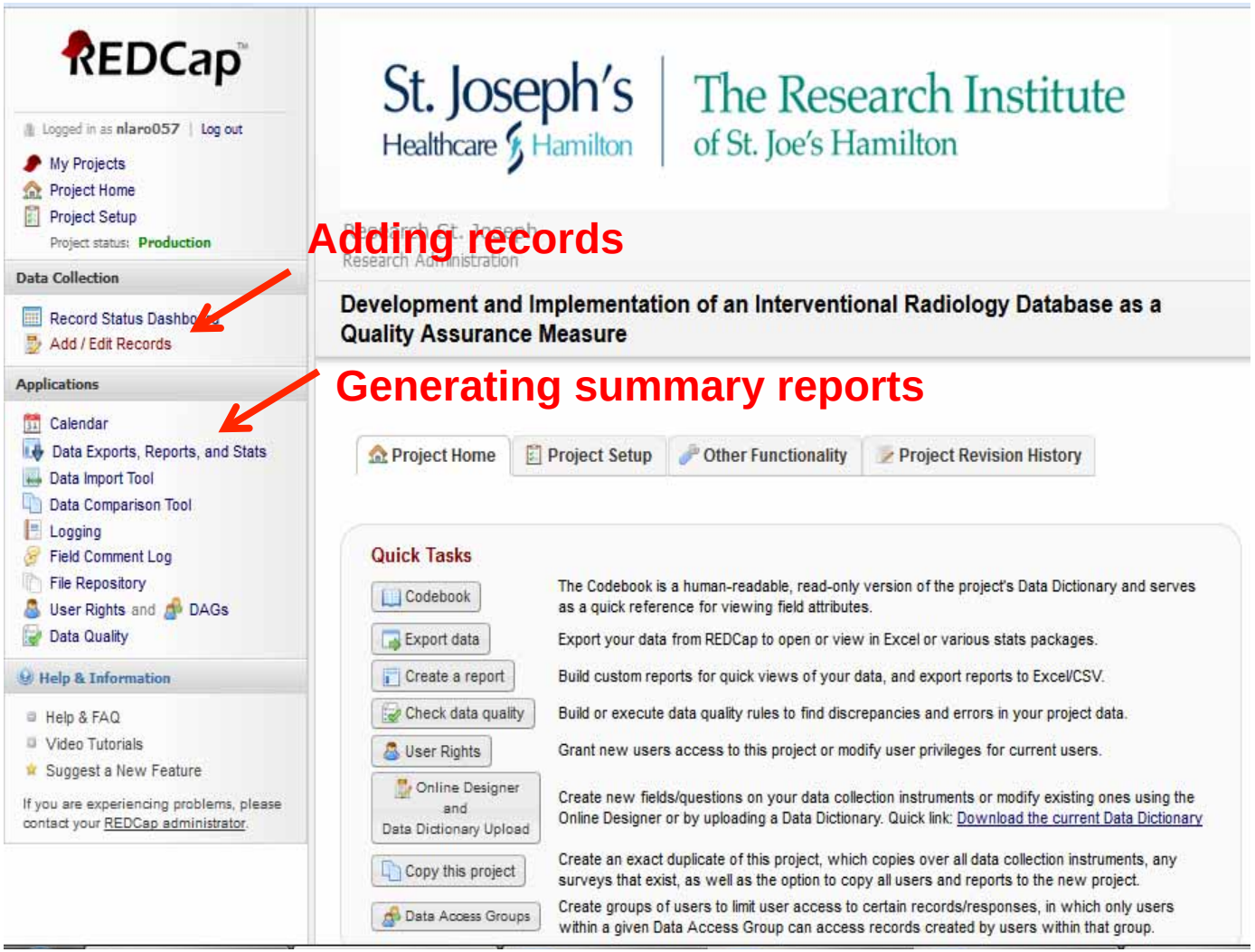
- Recurrent themes for facilitators to implementing a clinical database included:
  - Staff buy-in
  - Web-based platform
  - Regular feedback from study personnel
- Recurrent themes for barriers to implementation included:
  - Software requiring expertise
  - Costs
  - Time constraints
- These lessons and experiences on how to design and successfully implement a database were invaluable in the creation of a prospective clinical database at St. Joseph's Hospital in Hamilton, Ontario

Database Design

- Utilizes REDCap software (web-based)[4]
  - Previous success by the Thoracic Surgery team at McMaster
    - Facilitated ethics approval
  - Free
  - Technical support available for this software
- Interventional Radiologists and lead Radiation Technologist given accounts to enter data securely from any hospital computer
  - High-quality data will be inputted by these individuals
  - Easily accessible
- Utilizes drop-down lists and check boxes to facilitate data entry
  - Obtained from patient chart, and IR procedure checklist
- Study leads can generate data summaries to assess trends, identify missing entries, or identify input errors

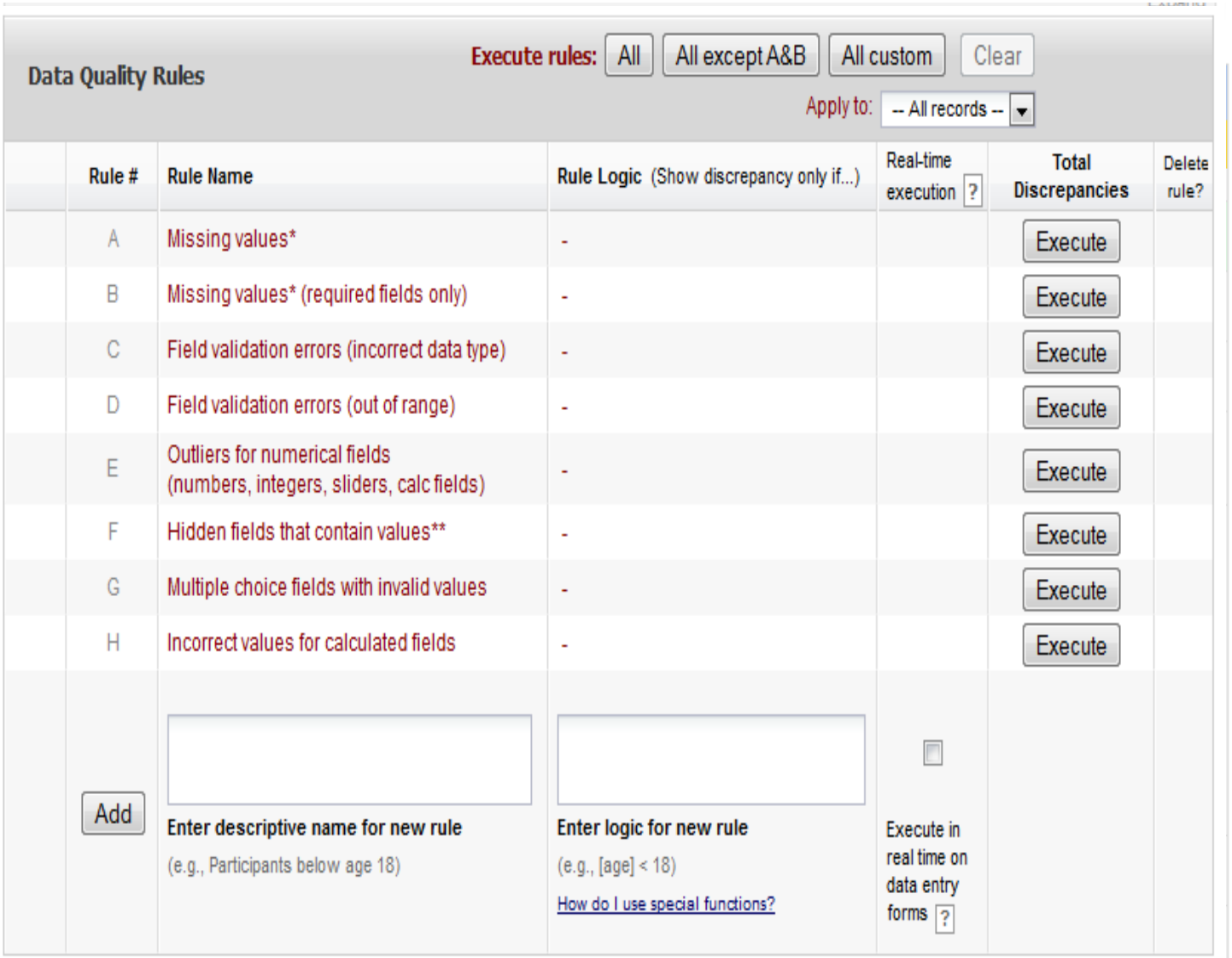
Database Design

- User-friendly homepage allowing for easy navigation



Database Design

- Data entry form contains check boxes and drop down lists to facilitate data entry
- Few variables with free text
- Quality assurance can be verified with this software



Data Quality Rules

Execute rules: All | All except A&B | All custom | Clear

Apply to: -- All records --

	Rule #	Rule Name	Rule Logic (Show discrepancy only if...)	Real-time execution ?	Total Discrepancies	Delete rule?
	A	Missing values*	-		Execute	
	B	Missing values* (required fields only)	-		Execute	
	C	Field validation errors (incorrect data type)	-		Execute	
	D	Field validation errors (out of range)	-		Execute	
	E	Outliers for numerical fields (numbers, integers, sliders, calc fields)	-		Execute	
	F	Hidden fields that contain values**	-		Execute	
	G	Multiple choice fields with invalid values	-		Execute	
	H	Incorrect values for calculated fields	-		Execute	
	Add	Enter descriptive name for new rule (e.g., Participants below age 18)	Enter logic for new rule (e.g., [age] < 18) How do I use special functions?	Execute in real time on data entry forms ?		

Database Implementation

- Database design with overview of functionality presented at two Interventional Radiology rounds at McMaster
  - Showcased ease of use
- Feedback obtained from Interventional Radiologists and Radiation Technologists
  - Resulted in the creation of additional variables
- Created a document that outlines how to enter patient data to facilitate data entry
- Database will be fully implemented in the near future

Conclusion

- Prospective clinical databases have been implemented successfully in a number of clinical settings
- Our database will serve as a useful quality assurance measure by prospectively tracking complication types and rates and by measuring the impact of modifications made to reduce these complications
- The successful design and implementation of this database continues to be guided by lessons learned in the literature

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References

1. Young, N.,Chi, K., Ajaka, J., McKay, L., O'Neill, D., Wong, K.P. (2002). Complications with outpatient angiography and interventional procedures. *Cardiovascular and Interventional Radiology,* 25: 123-126.
2. Riaz, A., Lewandowski, R.J., Kulik, L.M., Mulcahy, M.F., Sato, K.T., Ryu, R.K., Omary, R.A., Salem, R. (2009). Complications following radioembolization with yttrium-90 microspheres: a comprehensive literature review. *Journal of Vascular and Interventional Radiology,* 20: 1121-1130.
3. Ivanovic, J.A., Al-Hussaini, A., Al-Shebab, D., Threader, J., Villeneuve, P.J. (2011). Evaluating the reliability and reproducibility of the Ottawa thoracic morbidity and mortality classification system. *Annals of Thoracic Surgery,* 91: 387-393.
4. Harris, P.A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., Conde, J.G. (2009). Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics,* 42*(2)*: 377-81.
5. Kessel, K.A., Bohn, C., Engelmann, U., Oetzel, D., Bougatf, N., Bendl, R., Debus, J., Combs, S.E. (2014). Five-year experience with setup and implementation of an integrated database system for clinical documentation and research. *Computer Methods in Biomechanics and Biomedical Engineering,* 114*(2)*:206-217.
6. Sharma, V., Fraulin, F., Harrop, A.R., McPhalen, D.F. (2011). The opportunities and obstacles in developing a vascular birthmark database for clinical and research use. *Canadian Journal of Plastic Surgery,* 19*(4)*: 122-124.
7. Mastrogiovanni, A., Fitzgerald, K.A., Toglia, J., O'Dell, M. (2013). Trials and tribulations of establishing a stroke outcomes clinical database. Poster presentation at the 2013 American Congress of Rehabilitation Medicine.
8. Birgegard, A., Bjorck, C., Clinton, D. (2010). Quality assurance of specialised treatment of eating disorders using large-scale internet-based collection systems: methods, results and lessons learned from designing the Stepwise database. *European Eating Disorders Review,* 18*(4)*: 251-259.
9. Wong, S.T., Hoo, K.S., Cao, X., Tjandra, D., Fu, J.C., Dillon, W.P. (2004). A neuroinformatics database system for disease-oriented neuroimaging research. *Academic Radiology,* 11*(3)*: 345-358.
10. Green, A. (2011). Danish clinical databases: an overview. *Scandinavian Journal of Public Health,* 39*(7)*: 68-71.
11. McConachie, H., Barry, R., Spencer, A., Parker, L., Le Couteur, A., Colver, A. (2009). Dasl^{n}e: the challenge of developing a regional database for autism spectrum disorder. *Archives of Disease in Childhood,* 94: 38-41.
12. Birch, D.W., Park, A., Bailey, M., Witzke, W., Witzke, D., Hoskins, J. (2001). The development and implementation of a computerized database or clinical research in minimal access surgery. An international pilot study. *Surgical Endoscopy,* 15*(9)*: 1008-1010.
13. Sehgal, A. & Davies, E. (2006). Lessons from developing and running a clinical database for colorectal cancer. *Journal of Evaluation in Clinical Practice,* 12*(1)*: 94-101.
14. Stow, P.J., Hart, G.K., Higlett, T., George, C., Herkes, R., McWilliam, D., Bellomo, R., ANZICS Database Management Committee. (2006). Development and implementation of a high-quality clinical database: the Australian and New Zealand intensive care society adult patient database. *Journal of Critical Care,* 21*(2)*: 133-141.
15. Quintana, Y., Patel, A.N., Naidu, P.E., Howard, S.C., Antillon, F.A., Ribeiro, R.C. (2011). POND4Kids: a web-based pediatric cancer database for hospital-based cancer registration and clinical collaboration. *Studies in Health Technology and Informatics,* 164:227-231.
16. Miyata, H., Gotoh, M., Hashimoto, H., Motomura, N., Murakami, A., Tomotaki, A., Hirahara, N., Ono, M., Ko, C., Iwanaka, T. (2014). Challenges and prospects of a clinical database linked to the board certification system. *Surgery Today,* 44*(11)*:1991-1999.
17. Connolly, M., Menown, I.B., Hussey, S., Cinnamond, N., Damani, L. (2013). The dronedarone shared-care clinical model and database: a coordinated paradigm to optimize management of evolving clinical recommendations. *Advances in Therapy,* 30*(6)*:623-629.
18. Zoccali, C. (2006). Clinical databases in nephrology: research and clinical practice goals and challenges. *Journal of Nephrology,* 19*(5)*:551-555.
19. Arlet, V., Shilt, J., Bersusky, E., Abel, M., Ouellet, J.A., Evans, D., Menon, K.V., Kandziora, F., Shen, F., Lamartina, C., Adams, M., Reddi, V. (2008). Experience with an online prospective database on adolescent idiopathic scoliosis: development and impelentation. *European Spine Journal,* 17*(11*): 1497-1506.