Why the need to have access/control of PACS images while in the sterile field?

(1) WORK FLOW IS DISRUPTED AND OPERATIVE TIME PROLONGED WHEN IMAGES ARE NOT WITHIN REACH

Once the operator is under sterile conditions, working with pre- and intra-operative imaging becomes very limited [1,2]. As a workaround, the operator may break scrub mid-procedure and enter the control room to directly conduct image review, although this routine disrupts workflow and prolongs procedural time, especially when multiple visits to the control room are needed in the same procedure. Alternatively, nurses and/or assistants could manage the computers in the control room to display/manipulate a patient's imaging data according to the operator's verbal commands. However, this setup inherently creates communication barriers between the operator and the assistants, contributing to further increase in procedural time, patient inconvenience, physician cognitive load and team tension [3–5].

A. Some physicians prefer having direct control of PACS to allow their *professional vision* to guide the image review, not achievable by proxy [6,7]

> *Interviews with radiologists regarding their experience of intraoperative images review have been documented in a recent study. When giving verbal commands to an assistant (radiographer) to select and manipulate the imaging records, the radiologists expressed that, because of the fine granularity of selection and movement, articulating the selection precisely is non-trivial and dependent on the professional vision of the radiologist.*
>
> *In one account, a radiologist said, "…We can say 'oh I want to see such and such an artery', but sometimes you just want to see a tiny bit of an artery and that's when we like to get hold of the mouse… Because what we see and what they see… obviously the radiographers are not specifically doing it to look for the pathology – we're looking for the pathology… Undoubtedly sometimes when we actually sit down there and go through the imaging again, particularly in some of the longer more difficult cases, you go through it you may actually spot something that you didn't see at all at the time." [7]*

B. Operative time is prolonged by making repeated trips to the control room to review images

i. Physicians leave the sterile field/suite 5-10 times per case to review PACS images in interventional procedures, which may extend operative time by 20+ minutes*

> *Data were collected using questionnaire format from Interventional Radiologists at Vancouver General Hospital. Responses from the questionnaire indicate that up to 80% of all procedures require visiting the control room to review images, which are not conveniently accessible via the visual interface in the sterile field. In particular, these physicians reported that they make 5-10 trips to the control room to review image records for vessel access in more interventional oncology procedures, adding as much as 20+ minutes to a case that may run for 2-3 hours.*

ii. Physicians break scrub in more than 50% of the procedures to review images outside the sterile field/suite in complex procedures*

> *Data collected from Interventional Radiologists at Vancouver General Hospital also reflected that they break scrub in more than half of the procedures for the purpose of reviewing images in the control room. Furthermore, it takes around 5 minutes to re-scrub on every return trip to the angio suite, followed by a few more minutes to mentally re-engage into the procedure.*

* denotes internal data kept on file at NZ Technologies, Inc.

Why the need to have access/control of PACS images while in the sterile field?

C. The process of conveying verbal information in the clinical setting (e.g., between a physician and an assistant) could be cumbersome and prone to communication failure

i. A single episode of image review as the assistant takes instructions from the physician could reach seven minutes [1,6]

In a study that explores a developing technology with a noncontact computer mouse system, the authors documented an actual scenario whereby a surgeon directed image review by giving verbal commands to an assistant in front of the workstation to reach a certain anatomical location. Reportedly, it took the assistant 7 minutes to complete the task. Authors of the study commented that this approach is sub-optimal for two reasons: (1) it requires the surgeon to dedicate significant attention to giving orders and verifying their execution; and (2) the risk for error is high.

ii. Communication failures reportedly occur 2.7 times in every surgical procedure, 1.4 times every hour[5]

Over 3 months in the winter of 2003, communication patterns were analyzed during 48 procedures (reaching 90 hours of surgery time) in general and vascular surgery, inclusive of breast, thyroid, colorectal, hepatobiliary, vascular, transplant, and laparoscopy procedures at the University of Toronto. In total, 421 communication events were noted, of which 129 were categorized as communication failures. Further analysis identified that the two most common 'types' of failure are: i) suboptimal timing of an exchange that information was requested or provided too late to be maximally useful; and, ii) exchanges involving missing or inaccurate information. 36.4% of failures resulted in visible effects on system processes including inefficiency, team tension, resource waste, workaround, delay, patient inconvenience and procedural error. The authors concluded that communication failure could jeopardize patient safety by increasing cognitive load, interrupting routine, and increasing tension in the OR.

iii. 21.3% of hospital errors that led to patient injury are attributable to verbal miscommunication[8]

In a review of a total of 444 surgical malpractice claims at the Brigham and Women's Hospital, 258 cases were found to have involved an error that led to patient injury. Among these cases, 60 were identified to have resulted from communication breakdown. 92% (55 cases) of which were attributed to verbal communication. Further analysis identified the most common mode of error-prone verbal communication involves a single transmitter and a single receiver. Attending surgeon was the most common team member involved.

(2) TRAFFIC IN AND OUT OF THE OPERATING ROOM POSES RISKS TO CONTROL OF INFECTION

The operating room (OR) is an isolated, positively pressured environment designed to recirculate air through filtered ventilation ducts [9] and maintain a pressure gradient over adjacent hallways and rooms, thereby preventing airborne contaminants from entering [10]. However, traffic in and out of the OR with repeated door openings disrupts the pressured system, which could contribute to increased contamination of the OR and elevated risk for surgical site infection (SSI) [9].

A. **Traffic in and out of the OR compromises maintenance of the positive pressure environment within the OR**

i. Among orthopaedic and general surgery cases, the average number of door swings per hour reportedly ranges from 37-135, and approaches one occurrence every other minute. In cardiac surgery, the mean rate of door openings is 19.2 per hour, and 22.8 per hour if prosthetic devices are involved[11].

In response to an unexplained increase in SSI rates at the University of Michigan, a study was conducted to evaluate traffic in the OR. Various surgical specialities were considered, including ortho/neuro, plastic, cardiac, and general. The study reported a total of 3071 door openings in 28

cases, 19-50 times/hr, with 50-70% occurring after incision. Additionally, door openings increased with case length, but have exponential relationship with number of people in OR.[9]

In an observational study, data were collected during 80 primary and 36 revision total joint arthoplasty procedures. Average door openings were 60 in primary cases and 135 in revisions, yielding per minute rates of 0.65 and 0.84, respectively.[12]

Furthermore, a UK-based study described the pattern of OR traffic in a cardiac center using an electronic door counter. Among the 46 cases observed, there were 4273 door openings. Authors concluded that door opening disturbs OR airflow and results in increased air and wound contamination. It is also described as a contributor to surgical mistakes. Current levels of traffic are unacceptably high and represent a modifiable risk factor for SSI and error[13].

ii. Negative pressure resulting from door opening in the OR has been reported in 40% of surgical cases, with a total door open time of 9.5 minutes/case [10]

Several orthopaedists evaluated the number and duration of OR door openings during hip and knee arthroplasty procedures and the effect of the door openings on room pressure. Room pressure and door status were monitored electronically, while the OR staff were unaware that data were being collected. Results showed that doors were open, on average, 9.5 minutes cumulatively per case. In 77 of 191 cases, positive pressure was defeated, allowing air flow to reverse into the OR. Total time with the door open significantly affected the minimum pressure recorded in the room (P<.02), but did not significantly affect average room pressure (P=.7). The authors concluded that the number and duration of door openings showed a significant association with length of surgery; however, door openings threaten positive pressure, potentially jeopardizing OR sterility.

B. Foot traffic and OR door openings predict the extent of microbial contamination

i. Foot traffic in the OR correlates positively with bacterial count, as does the number of persons present in the OR [14]

Data were collected in three parallel ORs of equal size, each equipped with an upward air-displacement system. Sampling and data collection of foot traffic and bacterial count were done during the daytime and in most of the cases once a week, over a seven-month period. In 52 of the 91 air samples collected (57%), the bacterial count (in colony-forming units, or CFU) values exceeded the recommended level of <10 CFU/m^3. A strongly positive correlation was exhibited between the total CFU/m^3 per operation and total traffic flow per operation after controlling for duration of surgery. A weaker, yet still positive correlation was also found between bacterial count and the number of persons present in the OR.

ii. Frequency of door openings increases with bacterial count in the OR, while the length of the procedure correlates with the amount of dust particulates in the OR [15]

The air quality during 23 surgical operations was studied in three conventionally ventilated ORs. Microbiological (bacterial) counts were taken using both passive and active sampling methods. Air dust particles, ≥0.5 and ≥5 mm in size, were measured using a light-scattering particle analyser. The overall dust load was mainly (98%) composed of fine particulate matter, which positively correlated with operation length. The door opening rate averaged 0.94 times/minute in operations that averaged 55 minutes in length. The frequency of door-opening was a positive predictor of raised bacterial counts.

C. Frequency of door openings is linked to incidence of infections in open surgical procedures [16]

Retrospective study of 180 consecutive total knee replacement (TKR) surgeries performed during a 2-year period revealed that 10 patients (5.6%) developed a superficial (n=3, 1.7%) or deep (n=7, 3.9%) SSI. Additionally, left knees became infected more often (9/92, 9.8%) than right (1/88, 1.1%).

Investigation of the operating room revealed 3 problems: there was significant traffic through the door on the left of the patient; a nonstandard horizontal-flow air conditioner had been installed above that door; a tool-washing sink was in use on the other side of that door. After imposing corrective measures, including locking the OR door, SSI rate was re-evaluated and decreased substantially.

D. Practices guidelines from various clinical specialties recommend limiting the number of door openings

Joint Commission of the Society of Interventional Radiology, Association of Radiologic and Imaging Nursing, and Association of Perioperative Registered Nurses [17]*:*
The outside doors to the IR suite should remain closed during procedures to decrease the transmission of microorganisms into the suite and potentially onto the sterile field, which may contribute to SSIs. Ideally it would be best if the number of times the doors inside the IR suite are opened were limited only to necessary tasks (e.g., bringing in additional supplies or personnel exiting for imaging runs. In clean procedures (e.g., aortic stent grafts and chest port placements), all doors leading to the IR suite should be kept closed throughout the entire procedure to decrease the potential for the transmission of microorganisms.

Society for Cardiovascular Angiography and Interventions [18]*:*
The doors to the catheterization laboratory should be kept closed, except as necessary for passage of equipment, personnel, and the patient. After a catheterization procedure has started, the number of personnel allowed to leave or enter should be kept to a minimum

Association of Professionals in Infection Control - Guide to the Elimination of Orthopedic Surgical Site Infections[19]*:*
The doors to the OR should be kept closed except during movement of patients, personnel, supplies and equipment, in order to maintain positive pressure. Talking and the number of people present in the OR should be minimized during procedures since movement, talking, and uncovered skin areas can contribute to airborne contamination.

(3) INFECTION BRINGS SUBSTANTIAL BURDEN ON PATIENTS AND HOSPITALS

Among the 27 million+ surgical procedures performed in the United States each year [20], approximately 1.7 million heathcare associated infections (HAIs) are reported, of which over 20% are SSIs. Studies show that SSIs lead to both increased length of hospital stay and health care costs [21,22]. It has been estimated that over 8,200 deaths occur from SSIs annually [23].

A. CDC estimates over 370,000 cases of SSI each year

The Center for Disease Control and Prevention estimated that healthcare associated infections (i.e., an infection that a patient acquires during the course of receiving treatment for other conditions) account for approximately 1.7 million cases and 99,000 associated deaths each year in US hospitals alone. Of these infections, 22% (or 370,000 cases) are surgical site infections (SSIs) [24]

B. SSI increases hospital length of stay by 9.7 days and costs by $20,842 per admission on average

In a review of 6,891 cases of SSI among the 723,490 surgical hospitalizations, an SSI increased length of stay by 9.7 days and increased costs by $20,842 per admission. When, projected these results to the national level, the estimates of SSI would result in an additional 406,730 hospital days and hospital costs would exceed $900 million. An additional 91,613 patient readmissions for treating the SSIs would account for an estimated 521,933 extra days of care at a cost of approximately $674.4 million. [24,25]

Why the need to have access/control of PACS images while in the sterile field?

C. Infection rates associated with interventional procedures are typically low, but increase substantially in complex cases

i. Bacterial infection occurs in 0.11% of patients undergoing invasive, nonsurgical, coronary procedures

In a case series of over 22,000, patients undergoing invasive, nonsurgical, coronary procedures from 1991 to 1998, the overall rate of bacterial infection (within 72 hours of the procedure) was in 0.11%. Among the patients with infections, the duration of hospital stay was significantly increased by 15 days. The overall mortality rate was 0.009% overall, but increased to 8.0% for the 25 patients with bacteremia [18,26]

ii. Bacterial infection occurs in 0.64% and septic complications in 0.24% of patients undergoing percutaneous transcatheter coronary angioplasty (PTCA) procedures[18,27]

Among the 4,217 PTCAs performed in 3,473 patients between 1990 to 1994, there were 91 cases of positive blood culture within 7 weeks after the procedure, of which 27 were related to PTCA, 32 unrelated to PTCA, and 32 considered indeterminate. The most common organisms causing PTCA-related bacteremia were Staphylococcus aureus (14 patients). Septic complications, which included femoral artery mycotic aneurysm, septic arthritis, and septic thrombosis, occurred in 10 patients (0.24%). Independent risk factors for PTCA-related bacteremia included duration of procedure (odds ratio [OR] 2.9; p = 0.04), number of catheterizations at the same site (OR 4.0; p = 0.015), difficult vascular access (OR 14.9; p = 0.007), arterial sheath in place > 1 day (OR 6.8; p = 0.025), congestive heart failure

iii. Complex percutaneous cardiac interventions involving use of numerous devices are associated with almost 20% risk of bacterial infection[18,28]

Complex PCI cases often requires introduction of numerous devices into and out of the arterial circulation and this may result in an increased risk of bacteraemia or even septicaemia. In a series of 147 patients undergoing complex PCI, blood cultures showed 26 (17.7%) cases of detectable bacteremia immediately and additional 18 (12%) cases within 12 hours after the procedure. While the infections did not result in any sequalae, the infection rates appear much higher than the incidence associated with noncomplex cases.

iv. Infection rates associated with interventional procedures in gastroenterology and hepatology could reach as high as 40%[29]

Literature published in English from January 1960 to August 2010 pertaining to the infectious complications of IR in gastroenterology and hepatology patients was examined by electronic search. Percutaneous transhepatic cholangiogram (PTC) and biliary drainage, trans-arterial chemo-embolization (TACE), transjugular intrahepatic portosystemic shunting (TIPS), imaged guided drainage of an intra-abdominal abscess and radiologically inserted gastrostomy (RIG) are among the most common procedure performed by IR. For PTC, bile duct drainages will be categorized as "dirty" in up to 30% of cases of malignant obstructions and 60% of benign obstructions. In the latter instance, the risk of infectious complication can be as high as 40%. The mortality rate for biliary drainage is approximately 2%, with sepsis and hemorrhage being the two leading causes of death. The reported rate of abscess formation post-TACE is 2.6% or less; however, the mortality rate when this occurs can be up to 50%. Post TIPS bacteraemia has been documented in up to 35% of patients [17] and pyrexia is seen in approximately 10% of patients in the peri-procedural period. The rate of infectious complications of RIG insertion varies from 0.3% - 2.3%. In patients with ascites, the rate is 7.7 times higher than in those without.

Why the need to have access/control of PACS images while in the sterile field?

References

1. Gratzel C, Fong T, Grange S, Baur C. A non-contact mouse for surgeon-computer interaction. *Technology and health care : official journal of the European Society for Engineering and Medicine*. 2004;12(3):245-257.
2. Iannessi A, Marcy P, Clatz O, Fillard P, Ayache N. Touchless intra-operative display for interventional radiologist. *Diagnostic and interventional imaging*. 2014;95(3):333-337.
3. Juhkne BJ. *Evaluating the Microsoft Kinect compared to themouse as an effective interaction device for medicalimaging manipulations*. Ames, IA: Iowa State University; 2013.
4. Firth-Cozens J. Why communication fails in the operating room. *Quality & safety in health care*. 2004;13(5):327.
5. Lingard L, Espin S, Whyte S, et al. Communication failures in the operating room: an observational classification of recurrent types and effects. *Quality & safety in health care*. 2004;13(5):330-334.
6. Johnson R, O'Hara K, Sellen A, Cousins C, Criminisi A. *Exploring the Potential for Touchless Interaction. Proceedings of ACM CHI 2011*. 2011:3323-3332.
7. O'Hara K, Gonzales G, Sellen A, et al. Touchless interaction with medical imageslets surgeons maintain sterility duringsurgical procedures. *Communications of the ACM*. 2014;57(1):71-77.
8. Greenberg CC, Regenbogen SE, Studdert DM, et al. Patterns of communication breakdowns resulting in injury to surgical patients. *Journal of the American College of Surgeons*. 2007;204(4):533-540.
9. Lynch RJ, Englesbe MJ, Sturm L, et al. Measurement of foot traffic in the operating room: implications for infection control. *American journal of medical quality : the official journal of the American College of Medical Quality*. 2009;24(1):45-52.
10. Mears SC, Blanding R, Belkoff SM. Door Opening Affects Operating Room Pressure During Joint Arthroplasty. *Orthopedics*. 2015;38(11):e991-4.
11. Wahr JA, Prager RL, Abernathy JH3, et al. Patient safety in the cardiac operating room: human factors and teamwork: a scientific statement from the American Heart Association. *Circulation*. 2013;128(10):1139-1169.
12. Panahi P, Stroh M, Casper DS, Parvizi J, Austin MS. Operating room traffic is a major concern during total joint arthroplasty. *Clinical orthopaedics and related research*. 2012;470(10):2690-2694.
13. Young RS, O'Regan DJ. Cardiac surgical theatre traffic: time for traffic calming measures? *Interactive cardiovascular and thoracic surgery*. 2010;10(4):526-529.
14. Andersson AE, Bergh I, Karlsson J, Eriksson BI, Nilsson K. Traffic flow in the operating room: an explorative and descriptive study on air quality during orthopedic trauma implant surgery. *American journal of infection control*. 2012;40(8):750-755.
15. Scaltriti S, Cencetti S, Rovesti S, Marchesi I, Bargellini A, Borella P. Risk factors for particulate and microbial contamination of air in operating theatres. *The Journal of hospital infection*. 2007;66(4):320-326.
16. Babkin Y, Raveh D, Lifschitz M, et al. Incidence and risk factors for surgical infection after total knee replacement. *Scandinavian journal of infectious diseases*. 2007;39(10):890-895.
17. Chan D, Downing D, Keough CE, et al. Joint Practice Guideline for Sterile Technique during Vascular and Interventional Radiology Procedures: From the Society of Interventional Radiology, Association of periOperative Registered Nurses, and Association for Radiologic and Imaging Nursing, for the Society of Interventional Radiology corrected Standards of Practice Committee, and Endorsed by the Cardiovascular Interventional Radiological Society of Europe and the Canadian Interventional Radiology Association. *Journal of vascular and interventional radiology : JVIR*. 2012;23(12):1603-1612.
18. Chambers CE, Eisenhauer MD, McNicol LB, et al. Infection control guidelines for the cardiac catheterization laboratory: society guidelines revisited. *Catheterization and cardiovascular interventions : official journal of the Society for Cardiac Angiography & Interventions*. 2006;67(1):78-86.
19. Association of Professionals in Infection Control. *Guide to the Elimination of Orthopedic Surgical Site Infections: an APIC guide*. 2010.
20. Graves EJ, Gillum BS. Detailed diagnoses and procedures, National Hospital Discharge Survey, 1994. *Vital and health statistics. Series 13, Data from the National Health Survey*. 1997(127):1-145.
21. Boyce JM, Potter-Bynoe G, Dziobek L. Hospital reimbursement patterns among patients with surgical wound infections following open heart surgery. *Infection control and hospital epidemiology*. 1990;11(2):89-93.
22. Poulsen KB, Bremmelgaard A, Sorensen AI, Raahave D, Petersen JV. Estimated costs of postoperative wound infections. A case-control study of marginal hospital and social security costs. *Epidemiology and infection*. 1994;113(2):283-295.
23. Klevens RM, Edwards JR, Richards CL, JR, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. *Public health reports (Washington, D.C. : 1974)*. 2007;122(2):160-166.
24. Hopper WR, Moss R. Common breaks in sterile technique: clinical perspectives and perioperative implications. *AORN journal*. 2010;91(3):350-64; quiz 365-7.

25. Lissovoy G de, Fraeman K, Hutchins V, Murphy D, Song D, Vaughn BB. Surgical site infection: incidence and impact on hospital utilization and treatment costs. *American journal of infection control*. 2009;37(5):387-397.
26. Munoz P, Blanco JR, Rodriguez-Creixems M, Garcia E, Delcan JL, Bouza E. Bloodstream infections after invasive nonsurgical cardiologic procedures. *Archives of internal medicine*. 2001;161(17):2110-2115.
27. Samore MH, Wessolossky MA, Lewis SM, Shubrooks SJ, JR, Karchmer AW. Frequency, risk factors, and outcome for bacteremia after percutaneous transluminal coronary angioplasty. *The American journal of cardiology*. 1997;79(7):873-877.
28. Ramsdale DR, Aziz S, Newall N, Palmer N, Jackson M. Bacteremia following complex percutaneous coronary intervention. *The Journal of invasive cardiology*. 2004;16(11):632-634.
29. Halpenny DF, Torreggiani WC. The infectious complications of interventional radiology based procedures in gastroenterology and hepatology. *Journal of gastrointestinal and liver diseases : JGLD*. 2011;20(1):71-75.