

Virtual Colonoscopy

**By Gordon Bleil, Lincoln Farnum, Chad Hodge, and
Amy Rubin**

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Problem Statement

In a perfect world the inconvenience of a fecal occult blood test, or the preparation and the minor indignities of a colonoscopy, wouldn't stop or even significantly delay the 130,000 Americans who currently get colon cancer each year from making an appointment and being screened before their polyps become cancerous. The fears and risks of the procedure wouldn't affect the plans of 25,000 Americans who, without screening, will die from colorectal cancer this year. They would otherwise go on to live their lives safely screened and treated long before there was any significant risk of fatality. In a perfect world.

But it's not a perfect world and those people not sufficiently comfortable, or sufficiently motivated, to have a fecal occult blood test or submit to a colonoscopy. They will go on to develop 130,000 new cases of colorectal cancer and from those cases, 60,000 people will die, many unnecessarily.

Vision Statement

Now we can make the world a little more perfect with a **virtual colonoscopy** (VC), also known as computed tomography colonography, to screen for colorectal cancer. A short outpatient visit and a ten to fifteen minute scan in our radiology department can replace all of the unpleasant preparations and the risks inherent in conventional endoscopy and intravenous anesthesia currently associated with a conventional colonoscopy. After the scan, our specially trained radiologists will read and report the results while the patient is still in the waiting room. In the event that any polyps are identified, the patient can be counseled and scheduled for a follow-up conventional colonoscopy.

As our patients share their experiences with friends and relatives, the ease of getting virtual colonoscopy will decrease anxiety-driven procrastination, and the segment of our patient population that formerly failed to be screened will decrease. They will make appointments and be screened at an improved rate. The increased frequency of screening among our patient population, better utilization of our computerized tomography equipment, and increased customer health and satisfaction will result.

Specific Objectives

To market and provide virtual colonoscopy for our patient population by:

- training a select group of individuals in performing and reading the scans
- marketing virtual colonoscopies to our primary care group providers
- advertising through articles, advertisements, and social networking to local populations
- develop new patient relationships through providing state of the art technology and excellent services

As a result:

- patients will receive more timely screenings
- improved outcomes will drive patient satisfaction
- patient satisfaction will drive other services
- costs will decrease as scale increases and outcomes improve
- new customer relationships will result from marketing and word of mouth
- enhanced utilization of computerized tomography equipment will amortize the costs of lease or purchase and drive patient costs down

Preferred Approach

Our preferred approach to making virtual colonoscopy (VC) available at this facility can be described as grass roots. The patient populations most likely to delay or defer colonoscopy screenings will best be reached through their primary care providers (PCPs) and contacts with those providers should serve as an entry point for our marketing efforts. Patients without primary care providers that contact our service will be referred to a local provider to establish appropriate overall health screening and to ensure appropriate follow up.

A program manager will serve as the focal point for outreach and through literature and educational programs highlighting the convenience, efficiencies, and economy of virtual colonoscopy will establish direct communications with PCPs.

In spite of the higher up-front costs, rationales for VC include a savings in patient time, procedure room costs, recovery room and anesthesiologists' time, and equipment preparation. VC also avoids the discomfort of an endoscope and the risks of bowel perforation and the attendant costs associated with loss of life and customer confidence. Additionally, conventional colonoscopy has been associated with a miss-rate of 18% of adenomas larger than 6mm. Results based on the largest multi-center independent trial that was conducted in the National Naval Medical Center, Walter Reed Army Medical Center, and the Naval Medical Center San Diego, indicates a 93.9% sensitivity and 96.0% specificity for polyps 8mm and larger¹. This is superior to optical colonoscopy and discussing these issues with PCPs should serve to encourage them to refer their patients to our new service.

In addition to literature, education, and outreach to PCPs, the VC Program Manager will initiate a direct marketing program to providers throughout the medical center and will present our program to medical staff and other meetings. An advertising budget will be identified to reach consumers in our community and through groups such as the AARP and online social networking sites such as Facebook and Twitter. Our target audience of patients over 50 years of age and especially those who have so far neglected colorectal screening is a large market and typically well-insured. We can serve their needs, address their natural concerns, maintain their health, and use the economies of scale to drive use of this new technology.

¹ Virtual Colonoscopy Shapes the Future, pg1

Expected Benefits to Stakeholders

The benefits that accompany such an advance, especially one that might overtake the current “gold-standard”, will have appreciable benefits for not only the patient, but to the entire system of healthcare.

Primary Care Physicians (PCP), Gastroenterologists, Colorectal surgeons and other stakeholders in Public Health will be able to enjoy the peace of mind that comes from knowing a higher proportion of the patients will be screened due to the less invasive procedure being offered through VC. The physicians will also be able to inspect the entire bowel, whereas the optical colonoscopy currently is unable to see about 10% of the bowel due to narrowing and concerns of perforation.

Patients will benefit from having a procedure that is lower in risk (avoidance of perforation risk), less invasive (no scope insertion), and will receive a faster result, that is more accurate. Patients will also be more likely to receive the lifesaving procedure earlier, and more often.

Payers, such as insurance companies and the government will reduce their overall expenses related to colorectal cancer as this new procedure becomes widespread. The per procedure cost will go up nearly \$300 to \$1200, but that number can go down with larger numbers of procedures performed and with more experience. By avoiding a significant number of complications that can occur from perforations, which include death, payers can realize a net decrease in costs related to colon cancer of about \$2.8 billion. This number is derived from the \$4.26 billion that this new procedure would cost insurers; subtract the \$7.1 billion they pay out in complications each year. Not only that, but this procedure can also do away with the need for an anesthetists' time since this is done in a CT scanner.

Hospital and practice administrators will see fewer lawsuits related to bowel perforation, death, or missed cancers by using this new procedure. This procedure comes with a sensitivity of 93.9% and specificity of 96%, which is better than the current “gold-standard”, and is able to see more of the bowel, and is less risky to the patient. Equipment that currently goes under-utilized can begin generating income for the facility, and less time will be spent in rooms, freeing them up for more procedures to generate other income.

Performance and Progress Measures

There are several measures that can be put in place to monitor the success of putting in place such a new procedure. From the patient's perspective, it would be ideal to find patients who have previously had a colonoscopy with your organization, as well as one with the new system, and interview them for their feedback on things such as time spent, money spent, invasiveness, and overall impressions. Compiling many of these can give you insight into the longevity of the system.

An administrator can compare costs of performing both procedures of the personnel time, equipment operation costs, costs from complications, lawsuits, and malpractice premium increases, as well as material costs. Once all those numbers are considered, after several months of use, a financial decision can be made as to the longevity of the system.

PCPs can gather data on the percent of patients who did not have their scheduled screening due to worry over invasiveness before the new system is in place, and then again after some time of use and word of mouth spreads. If there is a statistically significant increase, then there is cause to keep the system longer.

Potential Risks of Virtual Colonoscopy as a New Service

Inability to attract sufficient numbers – decreasing the benefit margin in comparison to optical colonoscopy. This will be addressed by advertising to patients and educating providers regarding benefits and availability. Targets for 3 and 6 months will be set, with the intent that it will have an ROI of about one year. This target is short due to the existing 64 slice CT scanner, decreasing the costs of implementation.

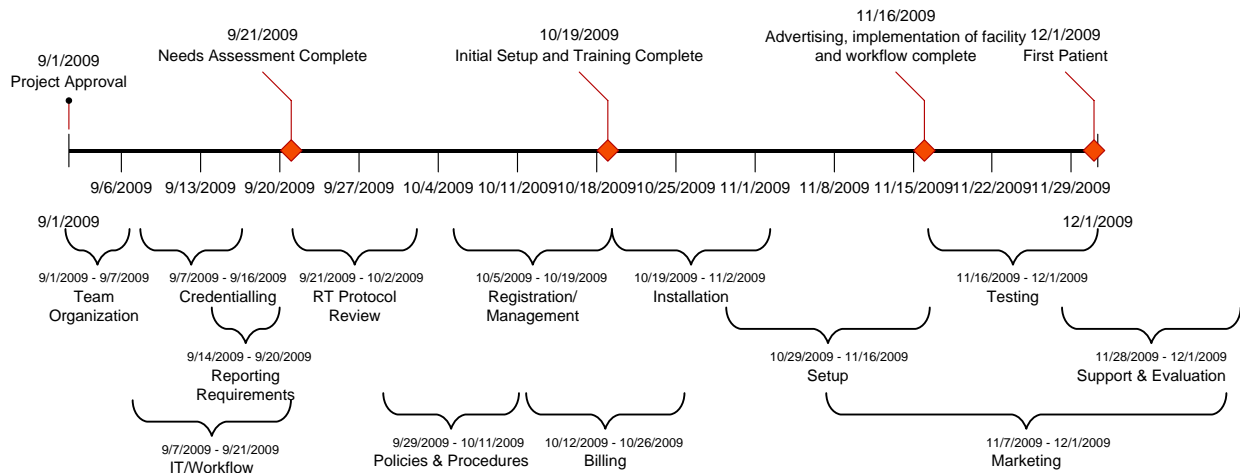
Poor implementation of sensitivity standard – leading to increased false positives and subsequent risks with follow up testing or missed diagnosis. This will be monitored and further training offered to providers if needed. We will consider Quality Assurance over-reads if any concerning trends in outcomes are noted.

Poor implementation of specificity standard – leading to increased numbers of follow up endoscopies or missed cancers, decreasing the overall benefit to the patient. This will be monitored and further training offered to providers if needed. We will consider Quality Assurance over-reads if any concerning trends in outcomes are noted.

Unknown risks due to low numbers of patients studies e.g. 'aftermarket' risks – such as perforation, infection, pain, bleeding, and contrast reactions. Any identified events related temporally or directed to the testing event will be evaluated for any possible relationship to the test. Any events that are attributable to the VC will be further evaluated regarding system and method errors. Corrections will be made and the events monitored until we can assure a stable risk environment.

Plan of work

Timeline – the implementation of this service would occur over 3 months with evaluation of service thereafter at 3 months, 6 months and one year. We would follow a standard business process for development. Details and Milestones are identified on the Timeline, and specifics are listed below.



Process Details:

- 1) Information Technology (IT) / Workflow Assessment** - review IT infrastructure, internet service, modalities, workflow and any special integration needs.
- 2) Physician Credentialing** - confirm appropriate radiologist skills and if not arrange appropriate training on site (via software vendor),
- 3) Report Requirements** - understand special needs required in reports such as a header format or specific ways to interpret in order to get optimal reimbursement, etc. (It is also important to get feedback from the clinicians on the quality of the reports after implementation)
- 4) Radiology Technician (RT) Protocol Review** - inform the RT team how they can be of help with positioning, anatomy, and pre-procedure clearance. Protocol training as needed.
- 5) Patient Registration and Image Management** - order request, patient registration and image management process protocol established with the staff responsible for these activities.

6) **Installation, Set up and Testing** - IT support person to deploy necessary interfaces and software; setup accomplished to conform to hospital policies & procedures; testing done on equipment with some test patients for practice.

7) **First Patient** - once the testing process is complete patient's can be scheduled for procedure. This may need to be flexible with limited scheduling if the system is not entirely set up.

8) **Policy and Procedures** - updating or creating site policy and procedures regarding interpretation services and staff steps involved in the order and image and report distribution processes.

9) **Support** - after implementation the quality assurance program is implemented, with review at 1 month, 3 months, 6 months and one year.

10) **Billing** - billing requirements, adjustments and the appropriate information to be obtained will be reviewed during the implementation process.

11) **Marketing** - educate referring physicians about the procedure. May also create custom marketing materials including a press release and potentially create a case study after a few months of service are completed. Consider regular news items to keep providers abreast of the latest changes in radiology, including virtual colonoscopy.

12) **Evaluation** - feedback from the physicians on their level of satisfaction with the report quality, from patients regarding satisfaction, quality assurance committees regarding level of service, administration regarding workflow effectiveness.

Key Milestones:

There are 5 key points at which the project will be reviewed during development.

- 1) Needs assessment completion - available facility (space, equipment); staff capability (training requirements, workflow changes, billing codes & process).
- 2) Initial set up and training completion— setting startup date, schedule of training and installation as needed.
- 3) Implementation of facility and workflow processes, Installation, setup and testing completion
- 4) First patient

- 5) One year summary – results of the Support and Evaluation for the first year would be assessed, including comparison to the 3 and 6 month interval evaluations.

Project Management Plan

Project Manager – responsible for overall development and implementation of the project. This includes meeting detail and milestone targets, ensuring appropriate levels of completion in each detail task prior to proceeding, and overall quality of the project at the end of the first year of service.

Program Manager – responsible for all aspects of marketing, provider outreach, literature development and printing, social networking, advertising budgeting and buys. This individual serves as VC's Goodwill Ambassador, educator, and cheerleader.

Information Technology Director – responsible to ensuring appropriate hardware and software installation and technical setup. Ensure appropriate storage of images, availability to the radiologist via hospital network, VPN or transmitted imaging. Also ensure accurate transfer to portable media as needed. Assure radiology staff has sufficient technical knowledge to trouble shoot to an appropriate level based on Information Technology Department standards.

Radiological Technician Director – responsible to ensure appropriate clinical setup, development of policies and procedures for clinical implementation, and assuring adequate training for staff. Assist in developing appropriate communications between departments, assuring appropriate documentation of radiology procedures and results, and ensure overall adherence to quality standards as established by the process and subsequent evaluations.

Radiologist (or Liaison) – assist in ensuring adequate training and credentialing for medical staff, ensure that radiology policies and procedures will create a quality process, ensure appropriate medical guidelines ethically and scientifically.

Administrative/Business Office Liaison – responsible to ensure appropriate policies and procedures for communication between departments, adequate billing information is attainable from the process, and assist in ensuring appropriate medical staff credentialing. Assist in generating a quality plan and setting bench marks for quality and business success.

Medical Records Liaison – responsible to ensure that appropriate policies and procedures are developed for documentation and record keeping regarding radiology results and communication of those results to the ordering provider.

Cost Estimates and Funding

One of the benefits of using the new VC procedure, besides all those mentioned above is that the startup costs are relatively low. Hospitals and practices can use their existing CT scanners to gather the raw data. Then, special software reads and interprets that data on a special workstation. Since the software does most the heavy lifting, reading the results will no longer have to be done by a GI specialist, but can instead be read by a radiologist, CT technician, or PCP, which saves money and time.

When estimating overall costs, it is safe to assume that the CT scanner is a sunk cost², and will not factor into the overall purchase price. You can add incidental charges for equipment uptime and maintenance costs if you desire, but they are not germane to the cost of the VC purchase.

The two main components to cost are the software, and the workstation. The average cost of VC software is around \$30,000 in initial purchase, with around a \$100 license per user of the system each month.^{3 4} The cost of the workstation ranges significantly from between \$24,000 up to \$115,000. It is possible that an organization could make the purchase for as little as \$55,000.

Marketing costs can be estimated at between \$5,000 and \$10,000⁵ with portions of that sum being devoted to printed materials and promotional expenses involved in physician outreach. Radio advertising can be considered to augment direct promotion if necessary and social networking costs are expected to be minimal.

There are also training costs associated with the installation of a new system. We will need to send some key personnel to training the expected costs of which are between \$5,000 and \$15,000 for training and employee time. This brings our total costs up to \$70,000 at a minimum.

With the increase received from the new procedure of \$300 per patient, it would take only 230 patients to pay this initial investment back off. That is less than a year of only one patient a day. With startup costs so low, an organization can easily construct a system such as this and evaluate its feasibility with very little capital risk.

Alternatives considered

Remaining with the sole use of conventional colonoscopy or sigmoidoscopy or fecal blood testing and not incorporating virtual colonoscopy is an option to be considered. By analyzing the cost benefit of implementing VC, it shows that this method will improve screening with a relative low cost compared to the missed opportunity of not screening

² Wikipedia, Sunk Cost, http://en.wikipedia.org/wiki/Sunk_cost

³ <http://www.hbs.edu/units/tom/conferences/docs/Virtual%20Colonoscopy%20Software%20Service.pdf>

⁴ http://www.imagingeconomics.com/issues/articles/2001-12_09.asp

⁵ Healthcare Success, Establishing a Marketing Budget, <http://www.healthcaresuccess.com/articles/establish-your-marketing-budget.html>

a patient early compared to treatment of cancer once the disease has evolved. A study by Vogelaar in *Cancer* found that increasing screening by 70% will decrease deaths from colon cancer by 50% by 2020.⁶ By incorporating computed tomography colonography as an alternative for patients, increased screening can be accomplished.

Opposing Arguments and Responses

Implementing and incorporating a virtual colonoscopy can provide benefits to all stakeholders from patients through administration. However, there are as with any new project some opposing views. Following is the discussion of these views.

The patient will need a second procedure to biopsy any abnormalities found with VC.

-This is true, however, the benefit in VC is that it is less invasive, requires no sedation, shorter procedure. These benefits will attract patients that were opposed to the traditional method. This patient is one that would be screen that might not have otherwise been screened. It is a life saved. The argument is that the patient would have to go through 2 procedures if abnormalities were found, but if the patient is informed of this prior to the procedure then the patient is fully aware that this is a possibility.

The VC may miss small polyps due to decreased detail that is viewable.

-The small polyps that it may miss in general have a low malignancy rate. Nonreporting of small lesions was found to be the most effective and safe screening option. Removal of the small or diminutive lesions will increase costs and complications in comparison with the gain in clinical efficacy.⁷

Lack of acceptance by payers for reimbursement.

- As acceptance and recognition of VC as an alternative to the traditional screening mechanisms, insurers may include VC as an option for screening of colon cancer. Until then, patients may decide that the increased benefit of VC is well worth the out-of-pocket cost of the procedure.

Conclusion:

Virtual colonoscopy is a patient-centric solution for timely screening for colorectal cancers. It is convenient, non-threatening, accurate, and cost-effective. Offering this service will reflect positively on our organization and provide cutting edge technology in service of top quality care and patient satisfaction. It will increase our patient population, increase customer loyalty, and promote wellness and preventive care while forging more cooperative relations with our primary care community.

⁶ Vogelaar I. How much can current interventions reduce colorectal cancer mortality in the U.S.? *Cancer*. 2006; 107:1624-1633

⁷ Pickhardt PJ, Hassan C, Laghi A, et al. Cost-effectiveness of colorectal cancer screening with computed tomography colonography. The impact of not reporting diminutive lesions. *Cancer*. 2007; 109:2213-2221.

Performing virtual colonoscopy is a win-win plan with limited financial risk and significant upside potential. It is truly an idea whose time has come.