

**A Case for Process Improvement In Medicine:
The Re-Engineering of Diagnostic Practices to Improve
Patient Care and System Economics With A Medical Device
as Case Study**

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Introduction

In the old producer/consumer paradigm that dominated much of the 20th century, it was up to purchasers to make the most out of suppliers' products. Goods and services were produced based upon the *perceived* needs of the end user, with little formalized interaction. In the mid-1980s, however, a few forward-thinking producers together with their customers began to explore a different approach. They analyzed the impact of improvements in their products on the ultimate end-users of the products. The potential rewards of such an approach were immediately evident. Making use of the opportunity that a new technology offers to redesign (or 're-engineer') an entire business process along the whole "value chain" from initial supplier to end-user clearly offers economic benefits. These benefits are measurable for both suppliers and end-users and include increased efficiency, increased effectiveness and enhanced revenues.

This process has been particularly evident in the telecommunications industry, where equipment manufacturers such as Cisco, Lucent, and Nortel work directly with telephone companies to integrate the latest technology into the varying architecture of local networks for demanding end-users.

There are now signs that re-engineering is beginning to take hold in the healthcare industry, due in large part to industry cost containment pressure. This new approach is characterized by the involvement of all parties along the healthcare value chain: product developers, patients, hospitals, physicians and payers. Moreover, the key determinant of the decision to purchase a product can now be, and increasingly is, the total value of the product and its measurable benefits over time to an entire health care system, not just to one or two parts of it.

Change and the Health Care Delivery System

Historically, re-engineering has not been applied systematically in health care for the simple reason that much of the system is resistant to change. Some of this resistance is intentional, such as the lengthy FDA approval process for pharmaceuticals and medical devices. Other aspects of the resistance are institutional. For example, many medical practitioners are loathe to abandon "tried-and-true" techniques for unfamiliar new techniques that may require capital purchases and training. The fact that the purchasers of the technology (hospitals) are not the end-users (physicians) or the beneficiaries (patients) also contributes to resistance to change.

Despite this resistance, things are beginning to change. Pressures from payers to keep costs down are forcing health care practitioners and system managers to question accepted processes and protocols in search of more efficient methods. Tremendous opportunities exist for pharmaceutical companies, medical device manufacturers, managed care companies and other suppliers to cooperate in developing technologies and solutions that can reduce costs, streamline operations and improve patient care. Indeed, hospitals are beginning to realize that they cannot afford to be so internally focused and that answers to the problems they face may come from the outside.

Case Study: New Approach to Assessment of Post-Menopausal Bleeding

The evolution of ultrasound devices and their use by OB/GYNs is an excellent case example of the benefits that emerge from application of re-engineering in healthcare. In particular, a hand-held ultrasound device that was developed with extensive collaboration with the healthcare community demonstrates the enhanced value that can result from re-designing an accepted protocol.

Background: Evolving Ultrasound Technology

Ultrasound became clinically available in the 1960s, and is now considered an indispensable component of modern medical care. It is widely used by many specialties, having been pioneered in obstetrics and promptly adapted to cardiology. Trying to imagine OB/GYN or cardiology practices without access to ultrasound is like trying to imagine orthopedics without X-rays or a neurologist without a CT Scan. Safe, non-invasive, quick, inexpensive, and revealing, ultrasound is an ideal diagnostic technology.

One of the most important recent advances in use of ultrasound for OB/GYN applications is the development of sophisticated transvaginal probes that provide excellent images of pelvic organs. One physician writes “transvaginal sonography is probably the most important advance in obstetrics and gynecology over the past ten years.”¹ The procedure is cited as being “95% accurate” in detecting the location, size and, consistency of pelvic tumors.²

Transvaginal ultrasound is particularly useful in determining the cause(s) of irregular bleeding in post-menopausal women. Irregular bleeding is a common and frightening occurrence in post-menopausal women that, in the large majority of cases, stems from benign causes. In a small minority, however, irregular bleeding indicates the onset of uterine cancer and, therefore, prompt assessment is essential. Transvaginal ultrasound’s nearly infallible ability in trained hands to rule out cancer has been repeatedly confirmed. A thirty-five-study meta-analysis³ showed that investigators using unenhanced transvaginal ultrasound were able to rule out cancer in nearly 90% of more than 5,000 women studied with a confidence level of 95%.

This accuracy is, of course, extremely beneficial. Women who have cancer can be referred quickly for a confirmatory diagnosis and proceed to appropriate treatment. For women whose irregular bleeding is not a symptom of cancer, ultrasound as a diagnostic tool relieves their anxiety about possible cancer and puts them on the path to treatment for whatever underlying medical problem they do have.

¹ Timor-Tritsch I, Office use of transvaginal ultrasound: ostriches in the sand? *Ultrasound Obstet. Gynecol* 1993; 3:157-159.

² Carter J, Fowler J, et al. How Accurate Is the Pelvic Examination as Compared to Transvaginal Sonography? *Journal of Reproductive Medicine* 1994; 39:32-34.

³ Smith-Bindman R, Kerlikowske K, Felstein VA et al. Endovaginal ultrasound to exclude endometrial cancer and other endometrial abnormalities. *JAMA* 1998;280:1510-1516.

Thanks to recent advances in miniaturization of circuitry, the benefits of transvaginal ultrasound can now become far more widespread.⁴ In fact, transvaginal ultrasound can now be performed at the point-of-care with a hand held device. This hand held device, such as the SonoSite 180, can easily be moved from patient-to-patient. For the first time a practicing gynecologist can have high quality ultrasound available for use on a routine basis at the point-of-care — a development that promises to enhance patient care dramatically. The potential impact on the practice of gynecological medicine is enormous.

Application of the Technology

Up to twenty percent of office visits to gynecologists are due to irregular bleeding in post-menopausal women,⁵ which can be symptomatic of many things, including cancer. As noted above, the patient is fine in the large majority of cases, and requires no treatment after proper diagnostic procedures confirm that cancer is not present. Consequently, as in many medical indications, the art of diagnosis involves detecting the *relatively few cases* in which action is needed, while ruling out illness in other patients and sending them home reassured.

The standard diagnostic assessment process for irregular post-menopausal bleeding has a number of significant shortcomings. Diagnosis often requires several different time-consuming and expensive procedures. Further, patients typically must wait several anxiety-filled days for reassurance that the cause of their bleeding is benign. Briefly, the current diagnostic process includes the following steps in this order:

- bimanual pelvic exam,
- blind intracavitary biopsy,
- standard ultrasound (not point-of-care)

Typically, gynecologists begin with bimanual pelvic exam as the initial diagnostic assessment for irregular post-menopausal bleeding. Note, however, that the bimanual exam is inconclusive in as many as one-quarter of the 50 million pelvic exams performed annually in the U.S. for this purpose.⁶

Consequently, physicians typically recommend Pipelle biopsy or ultrasound, and frequently both. In the case of biopsies, the results of the examination of tissue sample by a pathologist are available only after 2 to 3 days. Further, biopsies have been shown to be 'non-diagnostic' at least 28 percent of the time.⁷ In the case of ultrasound, the patient is typically sent to a near or distant 'ultrasound suite' at which a radiologist or

⁴ SonoSite Corporation, Bothell, Washington. SonoSite was spun off from one of the leading manufacturers of digital ultrasound (ATL) and has released its under 6 lb. hand-carried product for beta tests as of May 1999.

⁵ Goldstein SR, Zeltser I, Horan CK, Snyder JR, Schwartz LB. Ultrasonography based triage for perimenopausal patients with abnormal uterine bleeding. *Am J Obstet Gynecol* 1997;177:102-8.

⁶ Bergman S, Doyle P, Stahl M. Handheld Ultrasound Systems, Inc., Spin-off from ATL Ultrasound, Inc. In: *The Spin-off Report*. New York: Hunstrete Corporation. 1998:1-13.

⁷ Weber A, M.D., Belinson J, M.D., et al. Vaginal ultrasonography versus endometrial biopsy in women with post-menopausal bleeding. *Am J Obstet Gynecol* 1997; 177:924-929.

sonographer makes an unenhanced image of the uterine lining, often obtained through the abdomen.

Upon a return visit—and after several days of anxious waiting for the patient—the gynecologist informs the patient of the results of the biopsy, which is usually atrophic, and/or the outcome of the ultrasound exam, which may or may not have imaged the entire uterine cavity. If bleeding continues without a clear cause, the physician will then typically perform further procedures.

While this sequence of diagnostic tests is common in determining the cause of irregular post-menopausal bleeding, there is no standard approach in general use for women at any age. The tests outlined above are typically performed in some combination and their results *assembled* for diagnosis. Further, because of the difficulty of diagnosing benign causes of irregular bleeding, persistent or recurrent bleeding often leads to repetitive biopsies and progressively more invasive procedures.

Both biopsy and standard ultrasound are necessary and useful procedures. Yet, the way in which both are currently applied to assess irregular post-menopausal bleeding is inefficient for the physician, inconvenient for the patient and costly for the payer. The multi-step procedure is expensive and time consuming, as well as traumatic for the patient.

A New Way: Value Benefits Associated with Point-of-Care Ultrasound

The adoption of point-of-care transvaginal ultrasound has clearly demonstrated that it reduces the time and costs associated with diagnostic evaluation of post-menopausal bleeding and creates enhanced value for patients, physicians, hospitals and payers.

While the Pipelle biopsy (describe above) is one of the current standard tools for diagnosing irregular post-menopausal bleeding, it is neither particularly efficacious nor cost-effective. In fact, compared to transvaginal ultrasound (TVS), Pipelle biopsy has a much lower sensitivity for all causes of bleeding — 44% vs. 82% in one study.⁸ A survey of more than ten studies comparing biopsy to TVS concluded that between 30% and 50% of all biopsies could have been avoided.⁹ The biopsies are also more costly, involving a procedure, tissue processing and analysis of results. In low risk patient groups, biopsies cost \$205,000 per additional year of life saved.¹⁰ Finally, since biopsy results are inconclusive in as many as 28% of cases, an ultrasound is then required.¹¹

According to a point-to-point comparison study, when TVS was administered at the point-of-care, TVS proved to be considerably less expensive per patient than Pipelle

⁸ Van den Bosch T, Vandendael A, Van Schoubroeck D, Wranz PA, Lombard DJ. Combining vaginal ultrasonography and office endometrial sampling in the diagnosis of endometrial disease in post-menopausal women. *Obstet Gynecol* 1995; 85:349-52.

⁹ Parsons & Londono page 8

¹⁰ Feldman S, Berkowitz R, Tosteson A. Cost-Effectiveness of Strategies to Evaluate Post-menopausal Bleeding. *Obstetrics & Gynecology* 1993; 81: 968-975.

¹¹ Weber A, M.D., Belinson J, M.D., et al. Vaginal ultrasonography versus endometrial biopsy in women with post-menopausal bleeding. *Am J Obstet Gynecol* 1997; 177:924-929.

biopsy.¹² This cost reduction only reflects the direct and immediate cost differences between the two procedures and does not explore other potential economic implications of the two approaches.

Patients Presented with PostMenopausal Bleeding		
From Physicians Cost/Reimbursement Perspective		
	Weighted Average Cost/Patient	
	Non Facility	Facility
Pipelle Biopsy Protocol	\$384.24	\$318.88
TVS Diagnosis	\$277.11	\$240.16
Difference \$	\$107.13	\$78.72
Difference %	27.9%	24.7%

The Benefit Stream

Indeed, point-of-care ultrasound offers a number of important qualitative and quantitative benefits, enhancing both patient care and the economics of diagnosis and patient management. Recent analyses have shown that physician time, radiologist time, sonographer time and testing costs can all be reduced with the use of a point-of-care ultrasound device. Transaction and transmission costs as well as patient time are reduced even more, while instrument and operator costs are increased just slightly if at all.

Further, if ultrasound can be performed at the point-of-care, then in a large majority of cases of irregular post-menopausal bleeding, patient concerns about cancer can be dismissed and physician and payer resources can be concentrated on those patients at greater risk.

To further illustrate this, a study using two SonoSite 180 units was conducted at a large, West Coast teaching hospital. The SonoSite 180s were used in the hospital's emergency room and interventional suites, eliminating the need for the hospital to continually transport its cart-based unit from its Ultrasound Imaging Center.

¹² Ibid.

In this analysis, the cost of the SonoSite units was \$X. Billable scans were estimated at \$150.00 each based on average CPT codes. Using these calculations, and weighing in additional scans conducted by the cart-based unit at the Ultrasound Imaging Center, the overall value of adding two units demonstrated an increase in operating income (revenue - costs) of \$193,411 per year. In financial terms, this amounts to an increase in Net Present Value of the “cash flow” (discounted at 12% per year) of \$711,304 over a five year period. This result, of course, accounts for the investment of \$X per SonoSite unit depreciated over three years and then replaced with new units for the next two-year period.

Financial Impact to Hospital Imaging Center

Revenue/Cost	Year 1 - 5	Total
<i>Current</i>		
<u>Revenue</u>	1,331,850	6,659,250
<u>Costs</u>	693,870	3,469,352
<u>Revenue - Costs</u>	637,980	3,189,898
<i>Proposed</i>		
<u>Revenue</u>	1,611,600	8,058,000
<u>Costs</u>	780,210	3,880,250
<u>Revenue - Costs</u>	831,390	4,177,750
Increase in Operating Income	193,411	987,853

Point-of-care ultrasound also offers numerous other benefits in a hospital setting — many with potential cost saving implications not captured in the economic analysis described above.

Additional Value Benefits to Hospital

- Better and more predictable scheduling
- Less transaction time spent by the Physicians
- Less coordination of patient move time spent by nurses, clinicians and administrators
- Less possibility of machine breakage or “accidents” from moving large ultrasound units
- Fewer call-in payments for sonographers when doctors, nurses or already on-site technicians can perform the scan
- Elimination or minimization of “on call payments” to sonographers if ER doctors/nurses or x-ray technicians are trained on the instrument (note our information indicates that x-ray technicians are on site 24 hours each day every day)
- Less waiting trauma for patients
- Less time spent in ER thereby increasing patient service and ER crowding
- Enhanced diagnostic ability in ER since the decision to use Ultrasound for “routine” OB/GYN or abdominal trauma problems would be unconstrained by the requirement to wait for a machine to be brought to the unit.
- More efficient process in the intervention unit since there would be no waiting and set up time for needed Ultrasound.

In fact, point-of-care ultrasound adds value in both hospital and clinical practice settings. In hospitals, patient movements are reduced and simplified by having point-of-care machines available to physicians in emergency rooms, Labor and Delivery Suites, on wards, and in outpatient treatment rooms. In hospital and clinic settings and in a gynecology practice costs will decrease due to the disappearance of trips to imaging centers and a reduced number of biopsies. The overall cost savings will certainly be in large multiples of the simple comparison of costs mentioned on the previous page.¹³

Point-of-care ultrasound also provides easy and convenient medical record keeping. Like X-rays, patient ultrasound scans can become part of medical records, allowing physicians to establish baseline values for pelvic organs and record changes over time. Because the scans are digital, archiving will become easy as the connectivity abilities of the point-of-care machines are enhanced. Remote transmission of images will become commonplace within the next five years and scans can be shared with distant experts for consultation in real time or on a delayed review basis. Further, the collection, examination, and archiving of such scans by physicians providing care will dovetail with the emphasis of many health plans on maintaining health and ‘wellness’ rather than simply treating disease.

Fortunately, with the recent advances in ultrasound technology described earlier, use of TVS at the point of care can now become widespread. SonoSite’s digital, hand-held

¹³ Weber A, M.D., Belinson J, M.D., et al. Vaginal ultrasonography versus endometrial biopsy in women with post-menopausal bleeding. Am J Obstet Gynecol 1997; 177:924-929.

device, which offers comparable image quality to all existing rolling and stationary devices, is already available. This device is plug and/or battery-operated and small enough (eight pounds or less) to be hand-carried or wall mounted. The system can be used on a heretofore unreachable scale, even in remote areas where there is no electricity. Moreover, the system can be moved to an accident site or bedside with little effort and can begin digitally scanning with no more than a 30-second warm up time. The relatively low cost per system (between \$12,000-\$20,000, depending on features needed) ensures that purchasers and payers will seriously consider TVS units.

Additional Applications of This Technology

Clearly, the value benefits demonstrated by the SonoSite 180 could also be achieved in other areas where ultrasound plays a significant role in diagnostic assessment, including cardiology. In fact, Sonosite has recently begun delivering the SonoHeart device to physicians and hospitals across the U.S. and cardiologists welcome the device's portability, low cost and ease of use at the point of care.

SonoHeart hand-carried echocardiography enables physicians to instantly assess and document left ventricular function, chamber size, source of murmurs, wall thickness, valve regurgitation, cardiomyopathies and more. Performing focused echocardiography during an exam can also allow physicians to rule out the need for a more time intensive and costly full echocardiography exam that may not be needed.

"The strength of this system is that its portability expands our ability to perform quality examinations of patients at the bedside or even in the office," said Natessa Pandian, M.D., associate professor of medicine & radiology, Tufts University School of Medicine, and director, Cardiovascular Imaging & Hemodynamic Laboratory, New England Medical Center, Boston. "An evaluation with the *SonoHeart* system allows us to quickly confirm or exclude some of the major cardiac abnormalities."

"Preliminary studies at Scripps Mercy with traditional ultrasound equipment have shown that a brief, focused cardiac exam can reveal potentially significant cardiac findings that were missed on an initial clinical evaluation using only auscultation," said Bruce Kimura, M.D., director, Non-invasive Imaging, Scripps Mercy San Diego, San Diego, Calif. "The portability, low cost and ease of use of the *SonoHeart* system potentially could make focused exams on the heart more accessible and convenient to perform."

Conclusion

The move to contain costs in the healthcare industry can have the added effect of enhancing value for hospitals, patients, and physicians by forcing the re-thinking of many current protocols.

The change in process improvement thinking conducted for the launch of the SonoSite 180 clearly demonstrates that point-of-care ultrasound allows (1) physicians to arrive more quickly at accurate diagnoses; (2) patients whose conditions are not threatening to be reassured sooner; (3) patients with more serious conditions to be assessed promptly and proceed to appropriate treatment; and (4) payers to reduce outlays on biopsies and secondary ultrasound. It will indeed soon become the “gold standard of office practice” to offer transvaginal ultrasound as an adjunct to the bimanual pelvic exam.¹⁴

By working with the purchasers of their equipment in early process improvement testing, SonoSite was able to design powerful new use models. These models will not only aid in the selling of its devices, but will help create better care for patients and savings for care providers.

Note, however, that the new technological device is not sufficient to realize these benefits. New technology provides such pervasive improvement in qualitative and quantitative healthcare measure only when it is coupled with a reconsideration of the process in which the device is a part, even an important part. Without such reconsideration, producers and purchasers run the risk of using a dramatically different device as if it were only a marginal development – thereby losing a real opportunity to create value throughout the process chain. Such technologically-driven process improvement will characterize the healthcare field for the next decades.

¹⁴Timor-Tritsch I, Office use of transvaginal ultrasound: ostriches in the sand? *Ultrasound Obstet. Gynecol* 1993; 3:157-159.