The innovative bundling of teleradiology, telepathology, and teleoncology services

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Teleradiology, telepathology, and teleoncology are important applications of telemedicine. Recent advances in these fields include a preponderance of radiology PACS (Picture Archiving and Communications System) users, the implementation of around-the-clock teleradiology services at many hospitals, and the invention of the first ultrarapid whole-slide digital scanner based on the array microscope. These advances have led to the development of a new health-care-delivery clinical pathway called the ultrarapid breast care process (URBC), which has been commercialized as the UltraClinics® process. This process bundles telemammography, telepathology, and teleoncology services and has reduced the time it takes for a woman to obtain diagnostic and therapeutic breast-care planning services from several weeks to a single day. This paper describes the UltraClinics process in detail and presents the vision of a network of same-day telemedicine-enabled UltraClinics facilities, staffed by a virtual group practice of teleradiologists, telepathologists, and teleoncologists.

INTRODUCTION

Telemedicine is the delivery of physician services using telecommunications and, often, video-imaging technology. In the United States, its most common applications are teleradiology, telepsychiatry, teledermatology, and telepathology. Over 60 other applications have been identified, but most of them are used on a more limited basis. *Telehealth* is a broader term and includes non-physician health-care services, such as telenursing and telepharmacy.[1,2]

The health-care landscape in the United States is in a state of flux. In 1996, over 40 million people lacked health insurance coverage.[3] Emergency rooms and urgent care facilities are often overflowing with patients. The vertical integration of some health services and the bundling of others, given this environment, are desirable, but are hampered by insurance reimbursement issues.[4]

The health-care industry is intrinsically slow to embrace innovations. The wide deployment of telemedicine and telehealth services as a way of addressing specific health-care issues in the United States has been no exception to this trend. Despite this, some organizations have effectively used telehealth as an engine for innovation.[5,6]

In the following subsections, we briefly review the telemedicine applications of teleradiology, telepathology, and teleoncology.

Teleradiology

Teleradiology uses information technology (IT) to store digital radiographic images and to transmit them for interpretation to the consulting site. An example of teleradiology is telemammography, which uses images acquired by means of full-field digital devices. The efficacy of teleradiology has been validated in the scientific literature.[7] Specific quality control requirements have been developed by the American College of Radiology and are used as guidelines for diagnostic efficacy and reimbursement from third-party payers.[8]

In mammography, quality assurance and control is insured by the Mammography Quality Standards Act (MQSA). The popularity of Picture Archiving and Communications Systems (PACS) has revolutionized radiology. Films are no longer used in the majority of practices. Patients emerge from appointments with a CD instead of a film packet, and if the CD is misplaced, the original image data can be recovered from the system storage server. While the original image data are preserved, digital images can be manipulated by the reviewer to correct brightness and contrast. When questions arise, the images can be electronically transmitted for virtual review anywhere in the world where a DICOM (Digital Imaging and Communications in Medicine) reader exists. For patients, the digital procedure is quicker and less painful and exposes them to less radiation than its analog predecessor. Radiologists affiliated with the Arizona Telemedicine Program (ATP) have diagnosed over 250,000 teleradiology cases, including 65,000 digital telemammography cases, originating from a large number of urban and rural health-care facilities.

Telepathology

Telepathology is the practice of pathology at a distance though the use of video microscopy at one location, a telecommunications link, and a pathologist's workstation at another location.[9–13] Although video microscopy was used in a few demonstration projects in the 1960s and 1970s, sustained development of the field began in the mid-1980s.[11,12]

Table 1 shows an updated classification of telepathology systems. Unlike radiology systems, telepathology systems have not been standardized based on the DICOM standards. Some laboratories still use telepathology systems that were purchased many years ago but continue to satisfy their clinical requirements. Nonetheless, these older telepathology systems might not satisfy the specifications of a large distributed network of clinical facilities in which tissue biopsies are processed simultaneously at multiple locations.

In the table, "dynamic" refers to the real-time imaging component of the system. "Hybrid" means a combination of dynamic and store-and-forward imaging. A *virtual slide* is a digitized whole slide, typically stored on a server and accessible by an Internet browser.

The first two competing telepathology technologies emerged independently in the mid-1980s: robotic (also known as dynamic) telepathology, which uses a remotely controllable motorized microscope, and static-image (also known as store-and-forward) telepathology, which uses computer image capture boards as its enabling technology.[13–15] To date, 12 classes of telepathology systems have been described in the pathology literature.[12]

The routine clinical use of telepathology is not new. In 1989, Nordrum and Eide combined dynamic and static-image telepathology components into a single hybrid telepathology system.[16] They implemented their system at two small hospitals about 400 kilometers away from their university hospital. The authors and their colleagues served as the telepathologists and rendered diagnoses on intraoperative frozen-section cases in real time.[17] Their system is still operational today.

Formal studies have validated the diagnostic accuracy of telepathology. Halliday et al. documented the diagnostic accuracy of static-image telepathology as used in an international telepathology second-opinion service.[18] The contributing hospitals were in Arizona, Mexico, and China.[19] Dunn et al., at a Department of Veterans Affairs Medical Center, carried out a telepathology diagnostic accuracy study and demonstrated a diagnostic

Table 1 Classification of telepathology systems

Date/Generation	Class	Symbol	Category	Enabling Technologies
1968–1989 First generation	1A	D-NR	Dynamic nonrobotic	Video microscopy
	1B	D-R	Dynamic robotic	Robotic microscopy
	2A	SF-NR	Store-and-forward nonrobotic	Image grabber boards
	2B	SF-R	Store-and-forward robotic	
1989–2000 Second generation	2C	SFS-R	Store-and-forward stitch robotic	Electronic stitching software
	3A	HDSF-NR	Hybrid dynamic store-and-forward nonrobotic	
	3B	HDSF-R	Hybrid dynamic/store-and-forward robotic	
	4A	VSA	Virtual slide/automatic/non-robotic processor	Whole glass slide digital imaging
	4B	VSI	Virtual slide/interactive (robotic) processor	
2000–2004 Third generation	5A	HVS	Hybrid virtual slide processor	Combined automatic and interactive modes
	5B	RVS	Rapid virtual slide processor	Continuous stage motion
2004– Fourth generation	5C	UVS	Ultrarapid virtual slide processor	Array microscope

accuracy of 98.5 percent for routine surgical pathology cases.[20,21] Since then, Dunn's group has completed over 10,000 telepathology cases, using a Class 3B telepathology system (see Table 1). All of these cases have been re-reviewed by light microscopy. No statistically significant difference was found in the diagnostic accuracy of conventional light microscopy compared with robotic telepathology.

Virtual slide telepathology evolved in the late 1990s.[22] A virtual slide is produced by digitally imaging an entire histopathology glass slide. The very large digital-slide file produced at high microscopic resolution is typically stored on a server and examined by using a browser.[22,23] An *ultrarapid* virtual slide scanner is defined as a virtual slide scanner that can image a standard tissue section (1.5 × 1.5 cm) in less than one minute.[24,25]

Telepathology virtual group practice

The concept of the telepathology virtual group practice has evolved over the past two decades.[12] A brief review of the history of the concept provides some perspective on the development of such practices. ***Figure 1*** shows a diagram from the first public lecture on the concept of a telepathology virtual group practice, delivered in 1987 by the first author of this paper, Dr. Ronald S. Weinstein, at a meeting of the United States and Canadian Academy of Pathology.

In the figure, Telepathology Network #1 illustrates the concept of a telepathology referral network serving multiple hospitals (in this case, eight hospitals, H1 to H8). It was envisioned that pathologists at outlying hospitals would send surgical pathology cases for second opinions by telepathology to a specialty institute serving as a diagnostic hub.

Telepathology Network #2 illustrates a central hub where most, but not all, of the subspecialists are physically located. In the figure, the neuropathologist and the gastrointestinal pathologists are physically located at other hospitals. Such pathology diagnostic networks have indeed been organized in the past five years, although on a limited scale.[12]

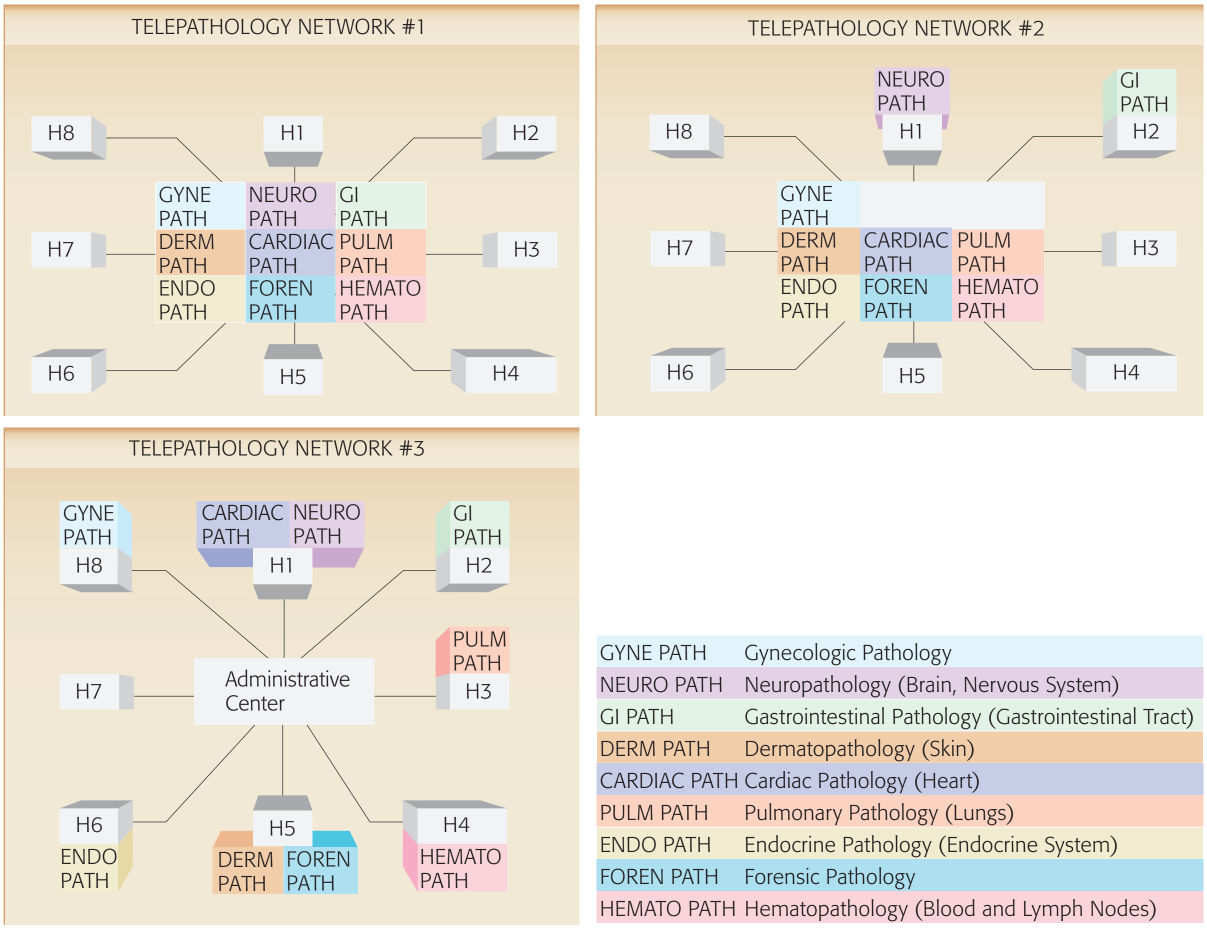

Figure 1
Evolution of the distributed telepathology "virtual" group practice

Telepathology Network #3 is more futuristic and shows the full implementation of a "decentralized virtual group practice" in which a distributed network of pathology subspecialists resides in many different physical locations, shown as H1 to H8. The hub functions as a triage and administrative center where case assignments are made, workflow is monitored, cases and their virtual slide files are archived, and quality assurance and educational programs are managed in an ongoing basis.[12] We now know that a telepathology network of this type could be greatly facilitated by virtual slide telepathology, the implementation of pathology PACS, and grid computing. This representation of pathology subspecialties is by no means inclusive.

Teleoncology

Teleoncology is the term adopted to refer to the use of telehealth technology in the delivery of cancer care, including diagnosis, consultation, pathology, surgery, treatment planning, supportive care, and follow-up services.[26] Teleoncology can assist patients who must travel significant distances to receive comprehensive, specialized cancer care. Allen and Hayes describe rural patients as satisfied with seeing their oncologist by telemedicine and state that patient acceptance is high.[27] Doolittle and Allen, with the Kansas Telemedicine Project, demonstrate that practicing clinical oncology using telemedicine is a useful technique for both direct care and supportive care for the cancer patient.[28] The ATP has diverse experience in providing teleoncology services, including education of providers, patients, and lay health-care workers. Clinical care has included consultations in surgical and medical oncology.

The Arizona Telemedicine Program

In Arizona, the state-wide Arizona Telemedicine Program (ATP) has served as an incubator for innovation in health care.[6,29] Although the program was originally created to deliver badly needed health-care services to underserved populations, the program is simultaneously serving as a test bed for innovation. It has been involved in the development of novel health-care services and in the development of a new medical device that has been recognized as breakthrough technology, and it has created innovative educational programs. The ATP and its members have successfully competed for many extramural grants and contracts that have supported its programs in innovation and technology transfer over the past decade.

University medical centers might not provide the ideal setting for the development of innovative health-care systems, in part because of their mission-defined limited view of the health-care world. Despite this, introducing telemedicine and telehealth programs in university medical centers can broaden the center's perspective by exposing university-based innovators to the practical needs of patients in diverse health-care settings. In our experience, a well-structured telehealth program can become the "eyes and ears" of the university's health-care clinical-research enterprise. This, in turn, provides valuable opportunities for expanding the university's involvement in health-care innovation, especially as it relates to information technology (IT) and medical devices. An understanding of the organization and resources of the ATP helps explain why this particular program, which is headquartered at a research university, has succeeded in creating a well-recognized program in health-care innovation.

The ATP was originally created as a comprehensive telemedicine program, with five core components: a broadband telecommunications network, which later evolved into a large not-for-profit telecommunications collaborative; an "open staff" model for its telehealth service providers, who would be drawn from the staffs of many independent service-provider organizations; regularly scheduled telehealth training programs at nominal cost to Arizona health-care professionals; distance education programs; and an extramurally funded research and assessment program. Although some state governmental leaders initially discouraged the last of these components due to concerns that academics would be distracted from the health-care service element of the mission, the program's early successes led to enthusiasm in the state legislature for the diversification of its activities. The ATP was given a license to become an agent for innovation in the state on the condition that health-care services remain the top priority.

Today, the ATP has a large staff, including many telephysicians representing most medical specialties, telecommunications engineers, biomedical communications specialists, business managers, assessment professionals, a number of researchers drawn from many diverse fields, and strategic planners. The scope of the ATP and its cross linkages to numerous other organizations encourage individuals with a wide variety of skill sets to identify opportunities for health-care innovation. This process is monitored by the state legislature's representatives on the Arizona Telemedicine Council. Working in ad hoc groups, the ATP staff and its partners at dozens of affiliated institutions across the state constantly update the clinical research agenda for the ATP and work on strategic plans for the development and deployment of new health-care delivery-system initiatives.

The ATP business model also fosters innovation. The business model is that of a membership-based application service provider (ASP).[30] An incentive for health-care organizations to become ATP members is the ATP's reputation for being at the forefront of innovation; in some instances, the ATP has been the agent of change for its own institution.[6,29] Often, the ATP serves as a clearing house for innovations and as a magnet for extramural funding for projects involving multiple, otherwise unrelated communities. The ATP also serves as a neutral broker of opportunities for member organizations to participate in technology transfer programs. For Arizona's nonacademic rural and urban health-care institutions, having a role in health-care innovation is a source of both institutional and community pride.

The roster of members of the ATP's ASP includes 55 independent health-care organizations in communities throughout Arizona and neighboring states, as shown in ***Figure 2***. (The sites shown to the right of the Arizona map are located in New Mexico.) This broad base of participants has proven to be an invaluable asset when it comes to matching opportunities to innovate with the health-care objectives of individual organizations. Community health centers and schools as well as

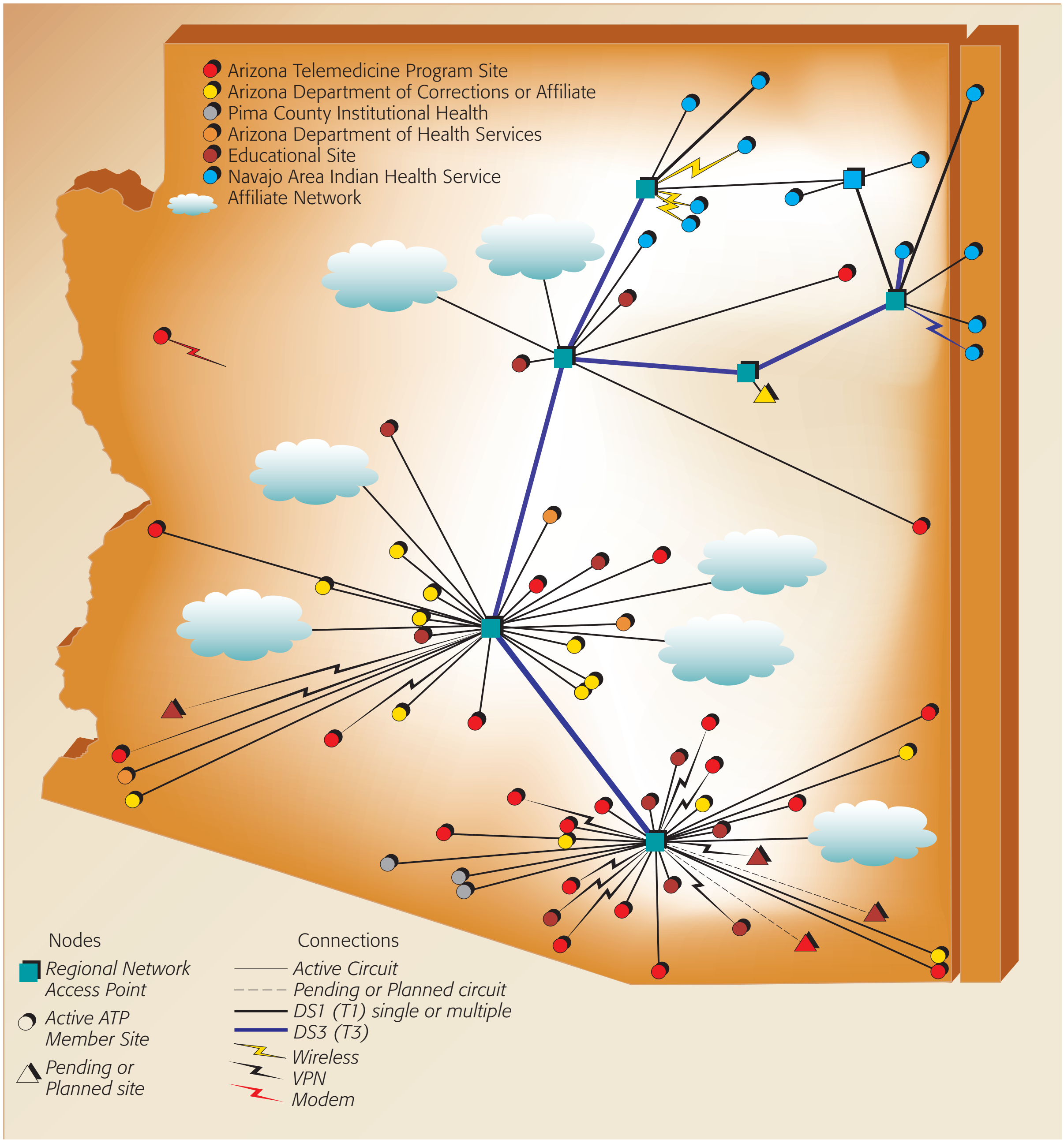

Figure 2
Arizona Telemedicine Network

health-care facilities in both urban and rural communities, on numerous Indian reservations (e.g., the Navajo, Hopi, and Apache nations), and in 10 of Arizona's 11 state prisons participate in the ATP. Currently, the ATP's network links 171 sites in 71 communities ranging in size from 280 people to 1.9 million people. The diversity of the ATP's member communities with respect to their sizes, cultures, locations, and economies provides the ATP with many potential partners for collaborative projects. Since Arizona legislative leaders embraced a policy to support a single multispecialty statewide telemedicine program many years ago, there has been a shared sense of mission with regard to maintaining a significant role for the ATP as a national leader in telehealth innovation.[31]

The ATP's telecommunications network also encourages innovation. The network is a private, not-for-profit, dedicated network that functions as a university-based telecommunications collaborative. The ATP's in-house engineers designed, installed, and now operate the ATP's broadband telecommunications network.[32,33] Access through multiple T1 (1.5 megabits per second [Mbps] or T3 [45 Mbps]) lines is available at most sites. The engineers have expertise in all telecommunications modalities, including broadband wireless. The ATP network facilitates clinical, administrative, and educational telemedicine communications throughout the State of Arizona with the goal of improving access to specialized medical care. ATP layers a privately managed asynchronous-transfer-mode (ATM) network infrastructure on top of its private data communications infrastructure as the basic wide area network transport. Most ATP member sites are directly connected to the network on a single-site-per-connection basis, but increasingly ATP is interconnecting with members at a network-to-network level, allowing an ATP member organization to leverage its existing intranet communications facilities to enable communications with ATP. The ATP network supports both real-time and store-and-forward telemedicine communications. Real-time sessions are facilitated by video conferencing. ATP primarily utilizes the H.323 protocol (for audio and video over packet networks) for real-time video conferencing communications, although the H.320 protocol (for audio and video over switched-circuit networks) is still utilized at some locations. Non-real-time or store-and-forward communications are facilitated through the DICOM protocol or proprietary protocols.

To date, over 400 health-care service providers, including doctors, nurses, clinical psychologists, and physician's assistants, have been involved with cases over the ATP telecommunications network. The ATP is staffed by 150 physician service providers who are employed by many different independent health-care organizations. Telemedicine and telehealth services are provided in a broad range of medical and nursing specialties, and health-care professionals have handled well over 300,000 telemedicine cases to date. Over 90 percent of the cases involve teleradiology, but there have been thousands of teledermatology, telepathology, and telepsychiatry cases as well.

Development of an innovative telehealth service

In this paper, we use the development of an innovative clinical service, an ultrarapid breast care (URBC) service, as an example of a new telehealth-enabled health-care service (developed on a fast track) within a telemedicine program.[24,34] This service is now being commercialized by UltraClinics, Inc., a company created at the University of Arizona and recently approved by the Arizona Board of Regents. In Arizona, the state government encourages university personnel to create for-profit enterprises and has a formal approval process for such entities.

Development of a new health-care delivery system is a complex undertaking. The UltraClinics** development program involved the identification and validation of a clinical need that lent itself to a telehealth solution, the development and implementation of an entirely new technology (ultrarapid whole-glass-slide scanning), the design of a new health-care delivery model, market testing and the writing of a business plan, and the creation and capitalization of a for-profit company.

Breast cancer is the most common cancer diagnosis in women and is the second leading cause of cancer death for women in the United States. It is predicted that over 200,000 new breast cancer cases will be diagnosed in 2006, with over 40,000 estimated deaths.[35] Early detection and prompt entry into breast cancer care are related to prolonged survival.[36] Breast cancer screening includes mammography and clinical breast exams, and is an important component in the breast cancer detection process. Over 48 million mammograms are performed each year. Approximately one million women are found to require a biopsy and the large majority of breast biopsies result in noncancerous (benign) diagnoses. Malignancy is encountered in 1 in 10 women who undergo breast biopsy.[37,38]

The UltraClinics program addresses the problem of highly fragmented breast care services. A woman with an ambiguous mammogram study may have to wait many days, or even weeks, before she receives a definitive diagnosis of cancer or non-cancer based on a tissue biopsy. This fragmentation and delay of services causes extreme anxiety for many patients and can take both a physical and psychological toll on the patient.[39]

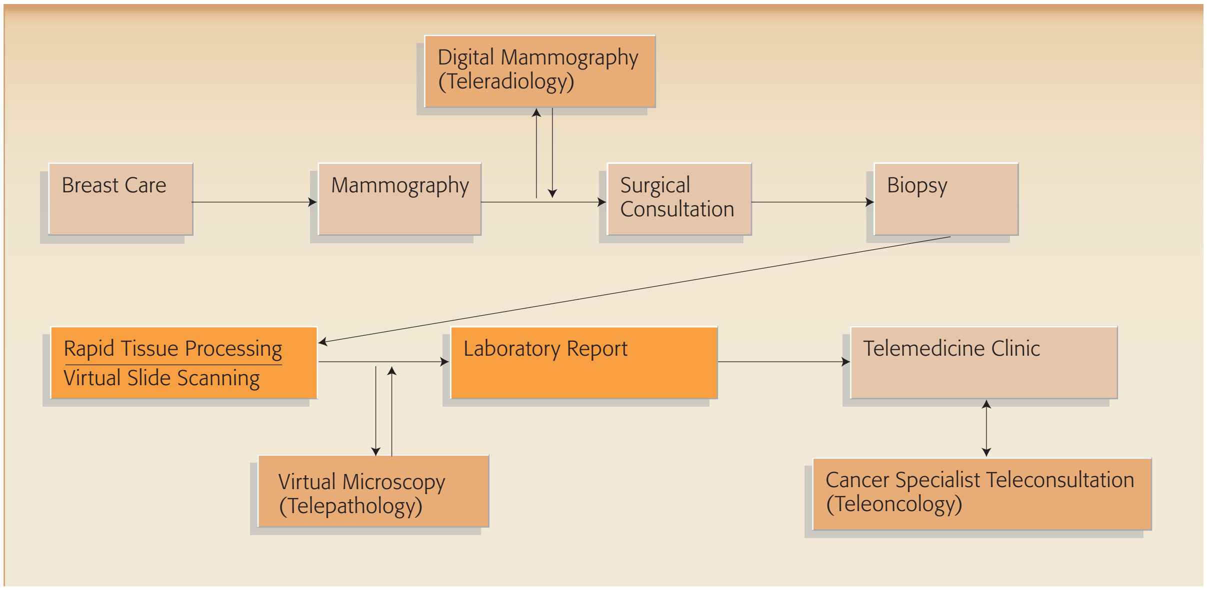

Figure 3
UltraClinics breast care process

Figure 3 shows the process of breast cancer detection from mammography to clinical consultation with the oncologist (i.e., cancer specialist). This process often takes 30 to 35 days with traditional breast care, as shown in ***Table 2***. This table compares the time lines for breast care services at traditional clinics (a typical scenario for many patients) and at URBC clinics (using the UltraClinics process).

Table 2 Time line comparison of traditional and URBC processes

Event	Traditional Breast Care	UltraClinics Process
Digital mammography	Day 1	Day 1
Mammography report	Day 2 to 7	Day 1
Breast tissue biopsy	Day 8	Day 1
Biopsy laboratory report	Day 16	Day 1
Biopsy second opinion	Day 24	Day 1
Appointment with specialist to receive results	Day 30 (surgeon)	Day 1 (oncologist)
Schedule surgery	Day 35	Day 1

The pathway of treatment often begins with an abnormal screening test or breast mass detection, either by a clinical breast exam, self-breast exam, or mammography (see Figure 3). This is followed by a tissue biopsy performed at the mammography center by a radiologist, by a surgeon at a surgical outpatient clinic, or in an operating room. Once the biopsy is performed, the tissue is processed into glass slides, not infrequently in another city or state, and diagnosed by a pathologist who generates the laboratory report. This report is sent to the surgeon or radiologist who performed the biopsy. If the diagnosis is cancer, the patient then schedules an appointment with a medical oncologist for consultation and the development of a customized treatment plan.

The UltraClinics process provides the results of the breast biopsy on the same day that it is performed and enables the patient to have immediate access to a consultation with a woman's cancer specialist.[40] If proven effective, the URBC process could become not only a new health-care delivery system for breast care, but a new standard for cancer care in general.

With the UltraClinics process, telehealth interventions include digital telemammography, virtual slide

Table 3 Comparison of outpatient health-care clinics

Profile	Traditional Clinics	First-Generation Miniclinics	Second-Generation Miniclinics
Health-care problems	Non-complex and complex	Non-complex	Complex
Locations	• Office buildings • Outpatient clinics	• Megamall • Pharmacies	• Imaging centers • Surgicenters
Health-care providers	Primary-care provider specialists	Midlevel providers	Nurses, midlevel providers, and telephysicians
Operations	Point-of-care + off-site labs and imaging	Point of care	"Virtual" point of care
Payors	Variable	• Self-pay plans • Consumer-driven health-care (CDHC) plans • Traditional insurance coverage • Capitated insurance coverage	• Self-pay plans • CDHC plans • Traditional insurance coverage • Capitated insurance coverage

telepathology, and teleoncology, as shown in Figure 3.

ORIGINS OF THE ULTRACLINICS PROCESS

The URBC clinic concept (i.e., the UltraClinics process) is the outgrowth of an innovative breast mammography program initiated as a collaborative effort to bring better health-care services to the Navajo nation in Northern Arizona and the Four Corners region (see Figure 2). In Arizona and neighboring states, a number of the Navajo area health-care service units are consistently at the leading edge of telehealth innovation. In the late 1990s, General Electric (GE) Imaging and Johns Hopkins University developed a mobile digital mammography trailer, which was subsequently deployed in Tuba City, Arizona, on the Navajo reservation, in 2000. The ATP's broadband telecommunications network linked the permanently installed digital mammography trailer to the University of Arizona, 300 miles to the south. To date, over 4000 Navajo women have received final digital mammography reports in an hour or less, without leaving Tuba City. Cases are routinely diagnosed by university radiologists in Tucson using telemammography. The rapid mammography service increases the occurrence of patient follow up on their diagnoses for subsequent breast care and has achieved a high level of both patient and physician satisfaction.

The success of the program led to the idea of bundling radiology, pathology, and oncology services into a single-day comprehensive breast care clinic. Subsequent work showed that it was possible to uncouple laboratory processing of glass slides and pathologists' readouts of the glass slides by using virtual slide telepathology (see Figure 3 and ***Table 3***). In the field of pathology, the physical uncoupling of the histology laboratory where glass histopathology slides are manufactured and the location of the office where the pathologist examines the glass slides under a light microscope and generates a laboratory report, is a significant breakthrough. Having these tasks occur at different sites, or even in different states, opens many opportunities to redesign health-care delivery systems and streamline their activities.

Building on the ATP experience with teleradiology, telepathology, and teleoncology as separate services, the ATP and UltraClinics, Inc. are developing additional components for a comprehensive URBC service. In Tucson, UltraClinics is developing the IT infrastructure for an enterprise-wide medical-image archive system, one element of the UltraClinics health-care system. According to the UltraClinics business plan, a network of UltraClinics-branded same-day breast care clinics, without on-site radiologists, pathologists or oncologists, will have priority access to panels of off-site telephysicians.

The telephysicians will be appropriately credentialed and licensed. The telepathologists will be available on demand to provide primary diagnoses for biopsies and other surgical pathology specimens.

UltraClinics will also provide access to panels of pathology experts for same-day expert-pathologist second opinions. Teleoncologists will be available to discuss clinical pathways and therapeutic options with newly diagnosed breast cancer patients.

TECHNOLOGY

Three laboratory components are essential to the implementation of same-day URBC services: rapid tissue processing, telepathology case diagnoses, and access to panels of off-site telepathologists who are organized into virtual group practices.

Rapid tissue processing, which is integral to the UltraClinics process, has been successfully implemented at a growing number of hospitals and laboratories since the year 2000. Various vendors sell automated microwave-assisted rapid tissue-processing equipment that provides simple, practical, and automated methods for fixing and processing tissue biopsies into paraffin tissue blocks in about one hour. Traditional fixation and embedding procedures often involve overnight processing. Using rapid processing, the quality of hematoxylin-eosin stain paraffin sections is comparable to that obtained following conventional tissue processing. In practical terms, tissue processing that required overnight processing in the past can now be completed before a patient leaves a clinic.

In the future, rapid processing may become the standard of care. Since tissue processing can be completed during a single clinical visit, there is added value to providing a means for diagnosing cases by pathologists as soon as the histopathology glass slides become available in the processing laboratory for evaluation. Previously, the vast majority of pathology cases were signed out the second working day, with laboratory results often reported to patients in a week or more. Now, many of these cases can be examined immediately by off-site telepathologists as soon as the slides are available for viewing. This approach could represent a significant paradigm shift in the practice of pathology in the future.

The development of an ultrarapid virtual slide scanner (Table 1, Class 5C system) was critical to the implementation of a large network of breast UltraClinics facilities, because we anticipated in-sourcing simultaneous telepathology services into a decentralized network of clinics. We realized from the outset of the URBC program that none of the telepathology technologies then available would suffice for the projected workload and throughputs of a large network of UltraClinics facilities (estimated at 500 to 1000 independent facilities).

Taking advantage of technology developed at the Arizona College of Optical Sciences in Tucson (formerly called the Arizona Optical Sciences Center), DMetrix engineers designed and fabricated the world's first ultrarapid virtual slide processor based on array-microscope technology.

The design and specifications of the DMetrix DX-40 ultrarapid virtual slide scanner have been described elsewhere[24,25,40] but are summarized here. At the heart of the system is a small disk-shaped digital imaging device, called a "lenslet array ensemble." This 2.54 cm $\times$ 1.3 cm imaging disk contains a geometric array of 80 tightly packed miniaturized compound light microscopes. The field of view of the disk-shaped imager is the full width of a histopathology glass-slide cover slip, slightly under 20 mm. This enables the device to make a digital image of an entire pathology specimen with a single sweep of the long axis of the glass slide within a minute or two, depending on the area of the tissue sections mounted on the glass slide. The imaging disk, including its attached sensor, is about the size of a stack of five United States quarter coins. The DMetrix optical disk serves as the digital imaging engine of the DMetrix DX-40 ultrarapid virtual slide scanner and accounts for its remarkable throughput.

The DMetrix instrument consists of a parallelogram-shaped 8 $\times$ 10 array of miniaturized microscopes that are arranged in staggered rows. These miniaturized microscopes replace the single-optical-axis light microscope of a legacy whole-slide processor. In the DMetrix instrument, each three-lens miniaturized compound microscope is 1.5 mm in diameter and approximately 9 mm in height, in the optical axis perpendicular to the plane of a tissue section mounted on a glass slide. In order to accomplish this, the device is manufactured as an array of "lenslets". Eighty identical individual aspheric lenses within a single plane are aggregated into an 8 $\times$ 10 lenslet array. In turn, three lenslet arrays, separated by baffle spacers, are stacked into a lenslet array ensemble. Lenses in each layer of the stack, although identical within the layer, have a different shape for each of the three layers. The three layers are precisely aligned to form the 80 miniaturized microscopes. As a result, each three-aspheric-element microscope has a numerical aperture of 0.65 and a diffraction-limited image quality across a field of view that is a significantly greater fraction of the objective's diameter than has been achievable with spheric optics.[40] Individual lenslets can be made from glass or plastic. Using a monolithic material for the fabrication of an individual lenslet array simplifies construction, because all lenses in a given lenslet array are at an identical level in the Z-axis of the device. In addition, assembly of lenslet arrays into a three-tiered lenslet array ensemble is simplified.

The length of the optical pathway of the DMetrix lenslet array ensemble, including its sensor/camera, is approximately 10 mm. The optics of the first DMetrix scanner had a field of view of 18 mm, but it is anticipated that future models will have larger fields of view. The scalable design of the DMetrix lenslet array ensemble allows the field of view of the imaging system to be increased by incrementally adding additional miniaturized microscopes to the lenslet array ensemble.

The DMetrix sensor/camera is mounted directly on top of the lenslet array ensemble. The DMetrix system uses a custom-designed sensor and a specialized digital imaging camera. Image capture is accomplished by using a scientific-grade 24-megapixel CMOS image sensor. Each pixel projects to a 0.47-micron size on the microscope slide. The DMetrix image sensor can sustain a frame rate of 3000 frames per second. This is 100 times faster than what is normally referred to as real-time imaging.

The scanning process is initiated by placing a glass slide on a specially designed slide carrier. As the glass histopathology slide continuously moves through the optical pathway of the lenslet array ensemble at a rate of approximately 3 mm/sec, the ensemble hovers over and changes position along the main axis of the slide. In order to achieve the required slide scanning throughput, the digital imaging system captures over 200,000 images/sec. Each tiny microscope digitizes an image track 225 microns in width. The adjacent tracks are aligned through the use of ultra-precise manufacturing methods for the fabrication of individual lenslet arrays and the assembly of the lenslet array ensembles. Digital images of the tracks are simultaneously sorted into giant image files by massively parallel processing. High-speed image capture and high throughput of slides are achieved by concurrently executing imaging and processing tasks. The DMetrix instrument scans a 1.5 $\times$ 1.5 cm histopathology tissue section in less than a minute, a three- to tenfold improvement over scan rates achieved using single-optical-axis image-capture systems.

The whole-slide digital images are stored on a DMetrix onboard server and can be accessed over a secure Internet connection. Individual images captured with a DMetrix lenslet array ensemble require between 50 MB and 1 GB of storage, after compression. Large numbers of such images can be stored on a RAID (redundant array of independent disks) that is part of the DMetrix DX-40 instrument. Images can be accessed using a Web-based browser or a Microsoft Windows** application installed on the end user's computer. The system includes the capability to deliver image data and metadata to multiple clients.[24,25,40]

Currently, the DMetrix system can serve as the input device for telepathology virtual-group-practice networks, which were described in the previous section.[9,10,12]

IT INFRASTRUCTURE FOR A LARGE ULTRACLINICS SERVICE NETWORK

With UltraClinics operations expanding, it is essential to create a large, scalable IT infrastructure to support a much larger same-day clinic enterprise. A unique command and control system (patent pending), designed specifically to manage a distributed virtual group practice, is under development. The full embodiment of a virtual slide telepathology system recently became commercially available as a packaged system, one that includes a digital imaging engine, mass storage, image management and analysis tools, telecommunications linkages, and high-quality virtual slide viewers. This system will be important for UltraClinics' success. DMetrix, IBM, and Apollo Telemedicine will partner as the system integrators for UltraClinics.

DMetrix has developed a digital-image archiving system called the "Arizona" system. It can accommodate up to 33 terabytes of image data and manage more than 100,000 high-resolution images. Users are able to access image data, acquired with the DMetrix

DX-40 scanner, and metadata through a secure Web site. The Arizona system is designed to be flexible and support multiple use cases, for example, same-day cancer clinic patients or other remote consultations. The Arizona system uses IBM eServer* and xSeries* systems to operate all software and hardware components. IBM Tivoli* Storage Manager is included to automate data backup and archiving and to protect data from hardware failures and other errors. The use of a grid-powered storage system enables information systems to more readily access fixed-content data, including medical images.

CLINICAL EXPERIENCE AND OUTCOMES

An UltraClinics facility has been up and running at University Physicians Hospital in Tucson for over a year. A second facility is in operation, also in Tucson, and has a steady flow of patients. Women can enter UltraClinics facilities either through a surgical clinic or through a breast-imaging center. During the initial offering of the UltraClinics service, over 100 women received expedited breast care.

Diagnosing cases by virtual slide telepathology has been straightforward and efficient. The quality of the ultrarapidly processed biopsy glass slides is excellent and easily equivalent to the glass slides produced by the traditional methodology. In one of the pathology group's laboratories, ultrarapid tissue processing is now used exclusively for all tissue processing, and the quality of the histopathology slides is judged by the technicians and the pathologists to be excellent. The DMetrix ultrarapid virtual slide scanner at University Physicians Hospital works well. Its operation has become routine for laboratory technologists. The DMetrix virtual slide images are of diagnostic quality and are often equivalent to looking through a conventional light microscope. Examination of virtual slides can be easier, because the telepathologist can see a thumbnail image of the whole slide while navigating around the virtual slide at higher magnification in the main screen. The telepathologists have also found that examining virtual slides on a video monitor can be mastered easily. Digitized images can be stored as an educational resource.

Overall, patient satisfaction with UltraClinics same-day breast care is very high, as indicated by patients' remarks on the benefits and relief of receiving rapid results. They are pleased to get their biopsy results the same day and to have immediate access to a cancer specialist by video conferencing. Even when the results are benign, being able to discuss follow-up planning with a breast specialist is helpful and reassuring to the patient. One surgeon noted that patients are more informed, ask appropriate questions, and are generally better prepared when they attend their pre-operation appointment. Patients appreciate the opportunity to begin to forge a relationship with their treating oncologist and remark that they have an understanding of the treatment team approach and of their own individual treatment plan earlier in their cancer journey.

UltraClinics services in Tucson are expanding. Another same-day service is now being developed by UltraClinics for prostate cancer patients. Initial experiences have shown that this is promising, and that men are quite eager to have access to same-day laboratory results. We plan to extend the UltraClinics same-day process to several other disease groups, such as skin cancer, in the foreseeable future.

CONCLUSIONS

In this paper, we showed how a state-wide telemedicine program can serve as an incubator for innovations in health care. The ATP, the University of Arizona, and dozens of their community partners have created an unusually cooperative and productive environment in which next-generation health-care systems can be planned and implemented.

One of the missions of the ATP is to improve the efficiency of health care. Because of the scope of the clinical-research and technology-transfer programs affiliated with the ATP and the University of Arizona, we found that we had the critical mass of interested individuals essential to develop and then commercialize the UltraClinics process. This was all accomplished in an unusually brief period of time: the total time from the conceptualization of the URBC service to its deployment as a commercial service in Arizona was under four years. This is unusual for the creation, validation, and implementation of any complex clinical service, especially one requiring the incorporation of a new technology such as the DMetrix virtual slide scanner.

The rapid development and deployment of UltraClinics facilities benefited from the coexistence of many programs in Tucson: the Arizona Telemedicine Program, the Arizona Cancer Center, the Arizona College of Medicine, the Arizona College of

Optical Sciences, the University of Arizona Women's Health Initiative, and two independent university hospitals six miles apart. The proximity of the organizations and their ongoing working relationships expedite the transfer of innovative technologies into new models of health-care. The presence of these programs in one city, and a number of crucial overlapping interests among the staffs, set the stage for pursuing the collaborations and facilitating the expediting of the innovation process. Many physicians, scientists, and engineers associated with these programs formed teams on a number of interrelated projects. As encouraged by Arizona State economic development policies, faculty members were able to spin off a health-care service company, UltraClinics, Inc., which capitalized, and then commercialized, several key components of the URBC process.[41]

The URBC model can also be viewed from a broader perspective. The URBC health-care delivery model builds on the concept of miniclinics. So-called first-generation miniclinics are walk-in clinics, typically located in megastores or pharmacies. They treat noncomplex diseases such as sore throats and urinary tract infections, are staffed by midlevel providers, and are largely self-contained. Patients with more complex conditions can enter without a referral, but are immediately referred elsewhere, usually at no charge. Such facilities are proliferating at a rapid rate.[4]

UltraClinics's idea was to create what would now be classified as a second-generation miniclinic business model. Such clinics are telehealth-enabled and could manage more complex conditions, such as the diagnosis of breast cancer and initial clinical planning. The initial second-generation miniclinics have been located at a breast imaging center and a surgical center.

Table 3 compares traditional clinics with first and second-generation miniclinics. The latter are based on the UltraClinics business model.

One obstacle that UltraClinics will face is in bundling imaging services, because traditionally pathology and radiology services have existed within separate domains. Although pathology and radiology departments should be linked by a common interest in medical imaging, and those interests may converge as radiology imaging resolution increases to the near microscopic level, pathology and radiology departments differ in other ways: their business models are different; there is surprisingly little cross-training between pathologists and radiologists; contracting for laboratory and radiology services within a single health-care organization is typically separate; pathology departments have a disproportionately large aftermarket in the form of additional laboratory testing once a diagnosis is reached based on the examination of glass slides; and, until recently, laboratories and radiology departments used separate information systems that lacked interoperability. Conversely, the development of middleware to bridge the gap between laboratory and radiology IT systems, the trend toward the deployment of comprehensive hospital information systems, and electronic health record initiatives for patients all bring radiology and pathology IT closer together. Until now, there have been very few economic incentives to bundle pathology and radiology services. However, new incentives could come from the bundling of teleradiology, telepathology, and teleoncology services as described in this paper.

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