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Blake Gibson, The University of Arizona
Erika Bracamonte, The University of Arizona
Elizabeth Anne Krupinski, Emory University
Margaret M. Briehl, The University of Arizona
Gail P. Barker, The University of Arizona
John B. Weinstein, Bard College
Ronald S. Weinstein, The University of Arizona

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A “Pathology Explanation Clinic (PEC)” for Patient-Centered Laboratory Medicine Test Results

Blake Gibson, MD1, Erika Bracamonte, MD1, Elizabeth A. Krupinski, PhD2,3, Margaret M. Briehl, PhD1, Gail P. Barker, MBA, PhD2,4, John B. Weinstein, PhD5, and Ronald S. Weinstein, MD1,2,4

Abstract
This concept paper addresses communication issues arising between physicians and their patients. To facilitate the communication of essential diagnostic pathology information to patients, and address their questions and concerns, we propose that “Pathology Explanation Clinics” be created. The Pathology Explanation Clinics would provide a channel for direct communications between pathologists and patients. Pathologists would receive special training as “Certified Pathologist Navigators” in preparation for this role. The goal of Pathology Explanation Clinics would be to help fill gaps in communication of information contained in laboratory reports to patients, further explain its relevance, and improve patient understanding of the meaning of such information and its impact on their health and health-care choices. Effort would be made to ensure that Certified Pathologist Navigators work within the overall coordination of care by the health-care team.

Keywords
communication, laboratory medicine, patient-centered care, Second Flexner Century, surgical pathology

Introduction
This is the fifth in our series of Second Flexner Century papers on innovations in medical education and health-care delivery systems, published in Academic Pathology.1-4 Surgical pathology dates back to the early 20th century, but the major advances in immunohistochemistry, laboratory medicine, molecular diagnostics, pathology informatics, and personalized medicine have occurred in the last 40 years. However, in the words of Dr Edward O. Uthman, a “paraffin curtain” has been constructed between the pathologist and the patient, referring to the fixation of many surgical pathologists on rendering diagnoses on paraffin histopathology slides.5 Uthman was regretting that surgical pathologists rarely interact directly with patients. This does not mesh well with the emerging model of “patient-centered care” in which patients become integral to decision-making processes as members of their own individual health-care teams. Nor need Uthman’s “paraffin curtain” metaphor apply exclusively to surgical pathology. Direct communication between patients and pathologists...

1 Department of Pathology, College of Medicine–Tucson, The University of Arizona, Tucson, AZ, USA
2 Arizona Telemedicine Program, The University of Arizona, Tucson, AZ, USA
3 Department of Radiology and Imaging Sciences, Emory University, Atlanta, GA, USA
4 Mel and Enid Zuckerman College of Public Health, University of Arizona, Tucson, AZ, USA
5 Bard Early Colleges, Bard College, Annandale-on-Hudson, NY, USA

Corresponding Author:
Ronald S. Weinstein, Department of Pathology, College of Medicine, University of Arizona, Tucson, AZ, USA.
Email: rweinstein@telemedicine.arizona.edu
regarding the full spectrum of laboratory medicine test results is all too infrequent.

In this concept paper, aimed at expanding the role of pathologists in patient-centered care, we are proposing the broadening of the definition of “laboratory medicine,” making the term inclusive of all aspects of anatomic pathology, including surgical pathology in addition to what is currently defined as “laboratory medicine.” We envision the creation of Pathology Explanation Clinics (PECs) where discussing laboratory medicine test results with patients would involve “one-stop-shopping” including the integration of test results for the patients’ immediate consideration and appropriate conversations between patients and pathologists, along with relevant and necessary clarifications. We acknowledge that many practicing pathologists would require additional training in order to assume this role.

As clients of pathology services, physicians ordering diagnostic tests for their patients must grapple with the rapidly evolving diagnostic and therapeutic advances. They must continually realign, along with these advances in laboratory diagnostic technologies and medical imaging services, what they discuss with their patients. Newer models for health-care delivery could actually complicate a physician’s efforts to effectively communicate with the patient. Interdisciplinary care is now normative in the management of complex medical diseases, such as cancer. Individual members of teams, such as advanced practice nurses, might be unprepared to answer important questions about laboratory results coming from the patient within their own interdisciplinary care team.7,8 Electronic health records (EHRs) can add yet another layer of complexity to patient management. Increasingly, EHRs give patients direct access to their personal laboratory reports. Patients can bring up laboratory test results on their computers, including surgical pathology reports, and then contact laboratories directly to discuss their own test interpretations with a pathologist. However, they rarely do so. This concept article proposes an innovative approach to engaging pathologists in “patient-centered laboratory medicine.”9

Pathologist-to-Patient Communication Interventions

Since the year 2000, commentaries supporting direct pathologist-to-patient interactions have appeared sporadically in the literature.10,11 Currently, some patients seek out other trusted physicians for help in delineating, and deciding on, their health-care choices. In one study, women with breast cancer often consulted their primary care provider on a specialist’s diagnoses and treatment recommendations.12 By participating in such discussions, pathologists could contribute valuable information to the patient about their laboratory reports, their diagnoses, how they were made, and the pathologist’s level of certainty in the diagnoses rendered. Potentially, knowing that information could help patients feel more confident accepting, and adhering to, their team’s treatment recommendations.

Recently, pilot pathologist-to-patient interventions have been described.13,14

With respect to the question of sharing laboratory reports directly with patients, in studying patients’ personal understanding of their surgical pathology reports, Mossanen et al showed that “pathology reports are written at reading levels above the average reading capability of most Americans.”15 They found that “deleting descriptive pathologic terms and replacing complex medical terminology with lay terms resulted in improved readability for some urologic oncology reports but complicated the readability for others.”15 Another report by the same group was aimed at reworking urinary bladder surgical pathology reports so that patients could better understand them. The result was a significant improvement in patients’ ability to identify the stage and grade of their cancer and understand the clinical implications.16

Having personally observed the benefits of direct pathologist-to-patient communication in his own busy surgical pathology practice, Juan Rosai, MD, a leader in the surgical pathology field, organized an international meeting of pathology thought leaders at the lakeside resort community of Sirmione, in Northern Italy, from May 2 to 4, 2008 (Figure 1 and Table 1). The challenge from the sponsoring organization, Milestone Medical Technologies, a laboratory equipment company headquartered in nearby Bergamo, Italy, was to “identify and address a major surgical pathology issue.”17 At the opening session, the attendees agreed that direct communication between patients and pathologists was a serious need. An outgrowth of the “Sirmione Group” meeting was the creation of an online patient resource, by Jonathan I. Epstein, MD, at Johns Hopkins Medical School in Baltimore, a member of the
Communicating the Results of Surgical Pathology Reports to Patients

The communication of laboratory results directly to patients by experts will have its share of challenges, even in the new patient-centered care environment. In order to facilitate this level of pathologist-to-patient communication, we propose creating a specific category of specially trained laboratory test results-communicators, the so-called “Certified Pathologist Navigators (CPNs)” (see below). Clearly, not all pathologists would be interested in interacting directly with patients, nor would clinicians necessarily wish to share such responsibilities with pathologists. Those pathologists who are interested in being CPNs could opt into such programs and then train for the certification.

We envision that creation of this niche opportunity would include special training, extensive marketing of the concept on the part of organized pathology, and the proactive addressing of legal and regulatory issues that might emerge along the way. As for the participating pathologists, the training would be in such areas as interpersonal communication, cultural sensitivity, clinical medicine, standard and advanced therapeutics, statistics, precision medicine, population health, medical economics, and methodology for assessing patient health literacy.

Creation of Pathology Explanation Clinics

We propose that this practice model be called the “PEC.” For purposes of this introductory concept paper, we shall focus the discussion on how the PEC could be used for discussing a surgical pathology report with a patient, recognizing that this is one of a list of potential clinical applications. Another might be the discussion of results of genomic testing. In the surgical pathology example, a patient with a previous biopsy and its surgical pathology report would be provided with a handout, or the hyperlink to a website, that describes the PEC program. It offers instructions for an appointment at either a virtual PEC or a physical PEC location. The handout would explain the potential benefits and limitations of communicating directly with a pathologist. Alternatively, patients could learn about the

Table 1. Invitees at the Sirmione Group Meeting, May 2 to 4, 2008.

<table>
<thead>
<tr>
<th>Member</th>
<th>Institution</th>
<th>City/State/Country</th>
</tr>
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<tbody>
<tr>
<td>Juan Rosai, MD (Chair)</td>
<td>Centro Diagnostico Italiano</td>
<td>Milan, Italy</td>
</tr>
<tr>
<td>Manfred Dietel, MD</td>
<td>Institute of Pathology</td>
<td>Berlin, Germany</td>
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<td>Charité</td>
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<tr>
<td></td>
<td>Humboldt University of Medicine</td>
<td></td>
</tr>
<tr>
<td>Jonathan I. Epstein, MD</td>
<td>The Johns Hopkins Medical Institutions</td>
<td>Baltimore, Maryland</td>
</tr>
<tr>
<td>Robert J. Kurman, MD</td>
<td>The Johns Hopkins Medical Institutions</td>
<td>Baltimore, Maryland</td>
</tr>
<tr>
<td>Elizabeth A. Montgomery, MD</td>
<td>University of Porto</td>
<td>Porto, Portugal</td>
</tr>
<tr>
<td>Simões, MD</td>
<td>The University of Arizona</td>
<td>Tucson, Arizona</td>
</tr>
<tr>
<td>Francisco Visinoni (ad hoc member)</td>
<td>Milestone Medical Technologies</td>
<td>Bergamo, Italy</td>
</tr>
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Meeting in Sirmione, Italy.

Sirmione Group. With the encouragement of the Sirmione Group, Epstein created a website entitled, “The FAQ (Frequently Asked Question) Initiative: Understanding Your Surgical Pathology Report.”18 The FAQs were developed by the Association of Directors of Anatomic and Surgical Pathology and have been endorsed by the College of American Pathologists. This Internet site is still active. It is maintained by the American Cancer Society as a public service for patients with cancer and their caregivers.18

Recently, The University of Arizona College of Medicine’s Department of Pathology followed up on the original Sirmione Group initiative, with the objective of further expanding direct pathologist-to-patient communication and increasing patient access to pathologist expertise. The Arizona group, inspired by the work of the Sirmione Group, but proceeding independently, compiled the set of “pathologist-to-patient” action items outlined in this concept paper (Table 2). Our intent is to seek input from, and partnerships with, pathology professional organizations, with the hope that the concept of a PEC can be validated through patient-centered outcomes research and then taken to scale in health-care delivery systems. Attention should also be given to advocating for specific pathologist-to-patient communication intervention billing codes (see Appendix B).

Table 2. Pathologist-to-Patient Action Items to Enhance Access to Pathologist Expertise.

<table>
<thead>
<tr>
<th>Activity</th>
<th>References</th>
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<tbody>
<tr>
<td>A. Identify a need&lt;sup&gt;y&lt;/sup&gt;</td>
<td>17,18</td>
</tr>
<tr>
<td>B. Create ACS “online/FAQ” website&lt;sup&gt;o&lt;/sup&gt;&lt;sup&gt;1&lt;/sup&gt;</td>
<td>17,18</td>
</tr>
<tr>
<td>C. Examine pathologist–surgeon–oncologist communication&lt;sup&gt;z&lt;/sup&gt;</td>
<td>4,8</td>
</tr>
<tr>
<td>D. Explore pathologist–patient engagement and solutions&lt;sup&gt;z&lt;/sup&gt;</td>
<td>10,11,13,14</td>
</tr>
<tr>
<td>E. CPN training and certification programs&lt;sup&gt;z&lt;/sup&gt;</td>
<td>-</td>
</tr>
<tr>
<td>F. Pilot program implementations&lt;sup&gt;z&lt;/sup&gt;&lt;sup&gt;y&lt;/sup&gt;</td>
<td>30,31</td>
</tr>
<tr>
<td>G. Validate with patient-centered outcomes research&lt;sup&gt;z&lt;/sup&gt;&lt;sup&gt;y&lt;/sup&gt;</td>
<td>28,29</td>
</tr>
<tr>
<td>H. Billing code reform&lt;sup&gt;z&lt;/sup&gt;&lt;sup&gt;,z&lt;/sup&gt;&lt;sup&gt;,§&lt;/sup&gt;</td>
<td>24,25,26</td>
</tr>
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Abbreviations: ACS, American Cancer Society; FAQ, frequently asked questions.

<sup>y</sup>The Sirmione Group.
<sup>o</sup>Johns Hopkins Medical Institutions.
<sup>1</sup>The University of Arizona College of Medicine-Tucson.
<sup>2</sup>Appendix B: Funding for patient-centered outcomes research.
<sup>3</sup>Appendix A: Pathologist payment models.
PEC from an oncologist, oncolgic surgeon, or their primary care provider or by word of mouth from a friend or family member. Initially, the PEC might be held one day a week, as are many subspecialty clinics in academic medical centers. For a PEC held at an academic medical center, glass histopathology slides or whole-slide images (WSI) would be retrieved for the pathology resident on service to examine, much as is done for tumor board conferences. Each PEC office will be equipped with a large video monitor for demonstrating the patient’s WSI (Figure 2). This is included to provide patients with a frame of reference for the discussions, fully understanding that patients do not have previous experience with histopathology. Patients will also be provided with web-based instructional materials suitable for independent study.

Individual appointments would be 15 minutes to an hour in length, depending on the complexity of the case, the health literacy level of the patient, and level of interest of the patient in a discussion of their disease. We previously implemented some elements of the “PECs” in our “rapid breast care” clinics in Arizona.\(^{20}\)

For PEC sessions held at teaching hospitals, a resident pathologist or fellow would initially meet with patients and assess their interests, their understanding of common medical terminology, and then score their prior use of computers and the Internet for addressing personal health matters. The pathology case discussion would begin with a brief orientation on histopathology and WSI. The preselected WSI representing the biopsy from the case would be shared with the patient. Then, the resident would follow a script for talking points including: (1) steps taken to make the diagnosis, (2) whether the diagnosis would be difficult to make and the level of certainty in the diagnosis, (3) the nature of the disease, (4) further testing needed to establish a definitive final diagnosis, and (5) implications of the biopsy results with regard to therapeutic options and prognosis. The discussion of these points, between the resident and the patient, might be videotaped for future reassessment by the staff pathologist. The pathology resident would then bring in an attending staff pathologist to answer any additional questions and ensure that all of the patient’s questions have been answered adequately and accurately. Patient inquiries on treatment options, and their benefits and risks, could be referred to a “treating” physician if they are beyond the scope of expertise of the CPN. In cases where the patient has accompanying molecular diagnostics, those test results also would be explained in the context of the biopsy diagnosis. After the completion of the PEC visit with the patient, the CPN would write a brief EHR progress note summarizing the information covered with the patient and listing the recommendations and action plan.

In another version of a PEC clinic, the subspecialty pathologist CPN would be embedded into on-site clinics (ie, oncology clinics) during regular clinic hours. For example, at the head and neck oncology clinic held weekly at many academic medical centers, the subspecialty head and neck pathologist would be present at the clinic and see patients immediately after their pathology reports are provided to patients by their clinicians. This practice model eliminates the need for a separate PEC appointment, but it does not give patients time to adjust to their new diagnosis. The attendance of patients at the PEC appointment could be done virtually, with the patient, and the pathologist linked into sessions using bidirectional video conferencing. Video-enabled community tumor boards have been reported.\(^{21}\)

### Training Certified Pathology Navigators

At the Department of Pathology at The University of Arizona College of Medicine–Tucson, we are developing a training program for this new category of health worker, the “CPN.” These CPNs will have special competencies for communicating directly with patients, regarding the interpretations and implications of their pathology reports.\(^ {22}\) Initially, the CPNs would be boarded pathologists with additional training, through a certificate program, on communicating directly with patients. For purposes of creating the initial certificate program for the CPNs, we are assuming that the initial targeted interaction between a patient and the CPN will take place after the patient’s primary care physician, oncologist, or surgeon has informed the patient of the results of their surgical pathology biopsy report. This timing is in deference to some patients’ preferences for receiving “bad news” face-to-face with a physician or nurse in a physician’s office, with no additional health professionals in the room.\(^ {23}\)

We are in the process of developing the initial scripts, and visuals, to be followed and described by the CPNs during their appointments with the newly diagnosed patients with cancer.
Commentary and Summary

Patient-centered diagnostic pathology could open certain windows of opportunity for pathologists capable of performing additional communication functions that support direct patient care. The concept described in this paper is the PEC. In this model, pathologists would take responsibility for explaining laboratory findings, and their implications regarding therapies and prognosis, to patients often in greater detail and with the benefits of special expertise beyond that of a primary care provider. An enabling concept involves the creation of a new category of health-care service provider which we are calling “Certified Pathologist Navigators”, or “CPNs.” The CPNs would leverage their combination of patient communication skills and their mastery of diagnostic anatomic pathology and laboratory medicine. The CPNs would collaborate with the patients’ primary care physician in recommending pathways for medical care. Ultimately, this initiative will depend on the demonstration of value of direct pathologist–patient interventions, in terms of patient outcomes and reduced health-care costs, as the health-care market moves from “volume to value” with regard to physician compensation.6

Appendix A

Payment Models for Face-to-Face Pathologist-to-Patient Consultations

At the time this paper is being written, no Medicare Current Procedural Terminology (CPT) code exists for billing a direct consultation between pathologists and patients. We acknowledge that the pathway to obtaining Medicare reimbursement for this service could be long, possibly convoluted, and time-consuming. It involves, at a minimum, pathology organization advocacy at the Centers for Medicare/Medicaid Services level. One option would be to initiate a new CPT code for pathologists to provide information and education directly to patients. A pathologist–patient education consultation, if tied to patient health literacy, could lend added legitimacy to the service. Nevertheless, this could be somewhat challenging as it is not customary for pathologists to interact directly with patients. Pathologist consultations, with the exception of some second opinion requests, have predominantly been conducted with other health-care providers. In fact, it is reasonable to expect that other providers might see a direct pathologist–patient consultation as an intrusion into their domain. In addition, some pathologists, who might select this specialty with the understanding patient interaction would be minimal. Are there sufficient numbers of pathologists who would want to interact with patients on a more consistent basis? These are just some of the challenges in changing the current paradigm. On the other hand, much as primary care practitioners, through professional trade organizations like the American Academy of Family Physicians, successfully advocated for a CPT code to reimburse preventative medicine counseling on tobacco cessation and exercise, the College of American Pathologists and other pathology groups could advocate for a new pathology direct consultation CPT code to be created.

Another option might be to modify current CPT codes to include direct patient consultation. Currently, there are 2 clinical pathology consultation CPT codes, 80500 and 80502. CPT 80500 is a limited consultation that does not include a review of patient’s history and medical records, whereas CPT 80502 is used for comprehensive consultation for a complex diagnostic problem that requires a review of the patient’s history and medical records.24 The patient’s clinician must request the consultation, and the pathologist must render a medical opinion and report the findings. Typically, clinicians request consults for results of a previously performed test that are erroneous or out of the normal range.24 Because CPT 80500 does not require the review of a patient’s medical history and records, this code might not be appropriate for a rigorous or meaningful patient consultation. That leaves CPT 80502 as the most suitable code. The 2017 Medicare Reimbursement for CPT 80502 is US$75.01.25 Much like consultations in the evaluation and management section, this pathology consultation requires the 3 Rs: request from the treating clinician, rendering of a medical opinion by the pathologist, and report of the pathologist’s findings.26 If the requirement of clinician invitation were successfully managed and the interpretation of the 80502 codes could be expanded, PEC could likely satisfy the requirement of rendering medical opinions directly to the patient.

Also, it should be mentioned that another potential payment model already exists for direct pathologist-to-patient communications interventions. A cash payment model would allow pathologists to directly bill patients for their patient consultation services. This model is currently used when patients request a second opinion and insurance companies do not cover the service. Ultimately, it is incumbent on pathologists to demonstrate that patient counseling improves clinical care and patient outcomes in some meaningful way to justify reimbursement.

Appendix B

Potential Sources of Funding for Patient-Centered Outcome Research

Development and implementation of the PEC model would of course require a significant amount of fundamental research and work to validate its utility and impact on patient care and...
outcomes. Efforts to involve patients more in their own care, to increase health literacy, and improve patient outcomes by tailoring medicine to the individual are increasingly being funded by federal (eg, National Institutes of Health, Agency for Healthcare Research and Quality, Department of Defense Medical Research and Materiel Command) and other grant agencies. In particular, the Patient-Centered Outcomes Research Institute (PCORI) is a relatively new, nonprofit, nongovernmental organization in Washington, DC. Funding for the PCORI was authorized by the US Congress in 2010.27,28 It could potentially be tapped for clinical research projects related to the “Patient-Centered Diagnostic Pathology” concept. The PCORI’s mandate is to improve the quality and relevance of information available to help patients, caregivers, insurers, and policy makers render better informed health-care decisions. Focusing the adequacy and suitability of communication at the patient-to-pathologist interface might fall within the PCORI mission. We can envision how funding from any of these agencies might be applicable to the study of issues regarding best practices in helping patients understand the content and ramifications of their laboratory reports. The University of Arizona Department of Pathology, which houses the state-wide multispecialty Arizona Telemedicine Program, has been partially supported by a PCORI grant which funds a study on the use of telehealth to instruct colostomy and urostomy patients on the management of their ostomies.29

Authors’ Note
The Sirmione Group Meeting, May 2 to 4, 2008, was sponsored by Milestone Medical Inc., a laboratory equipment company headquartered in Bergamo, Italy. The company president, Franco Visinoni, participated in the initial session and the closing session of this 5-day meeting.

Declaration of Conflicting Interests
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