Lay Advisors and Navigators Across the Continuum of Cancer Care

Edward E. Partridge, MD
Director, UAB Comprehensive Cancer Center
Professor of Gynecologic Oncology
Evalina B. Spencer Chair in Oncology
Overview

1) Personal journey
2) Cancer disparities – cervical cancer as the prototype
3) UAB experience in reducing/eliminating disparities
4) The future of cancer care delivery
should be added to this list where a substantial number of women are employed. We think that this is a step in the right direction. For example, very few plants require routine interval check-ups, and yet here is an unparalleled opportunity to reduce the mortality rate of carcinoma. Industrial physicians are doing an excellent work in protecting the health and welfare of the nation’s large number of industrial employees. They need the experienced and trained specialist to control and study the problems of women workers, that adequate rules and regulations can be drawn up for their protection and well-being.

1327 Second Street.
1808 Ocean Park Avenue.

REFERENCES

CANCER OF THE UTERUS: THE VAGINAL SMEAR IN ITS DIAGNOSIS*

HERBERT P. TRAUT, M.D.
San Francisco

AND

GEORGE N. PAPANICOLAOU, M.D.
New York

A NEW method for detecting the presence of uterine cancer is based upon the well-established vaginal smear technique. Much use has been made of vaginal smears in the study of the reproductive cycle in laboratory animals, as well as in women. Cells from the various epithelial surfaces of the uterine canal, the cervix and the vagina undergo changes in morphology and staining properties which are sufficiently characteristic to enable one to evaluate much of the normal or abnormal physiological responsibility for the variable cell patterns. It is only necessary to collect the exfoliated cells from the posterior vaginal fornix; spread them upon a clean glass slide, fix them in an alcohol and ether solution, stain them, and they are ready for study under the microscope. In the course of routine studies of human vaginal smears, Papanicolaou discovered that not only were the normal cells shed and hence demonstrable in the vaginal smears, but also many pathological cells could be found, among them those of cancer.

AUTHORS’ STUDIES

To determine the relationship of cancer cells in the vaginal smear to the incidence of malignant disease in the uterus, as demonstrable by clinical methods and the biopsy technique, Papanicolaou and Traut have collaborated in a study covering three years at the Cornell Medical College. Vaginal smears, many thousands, were made and studied, with the result that, in their hands, the method has been demonstrated to have a decided advantage in that it enabled them to detect cancer without even a minor surgical procedure. The preparation of vaginal smears is easy, may be quickly carried out, and can be repeated at frequent intervals whenever desirable.

It is particularly valuable in the diagnosis of very early carcinoma of the cervix and fundus—even before such lesions can be demonstrated by the biopsy method—with the single exception of adenomatous malignancy.

METHODOLOGY

The method, therefore, will be described in some detail in the hope that others may become interested in learning how the malignant cells can be recognized. An adequate description cannot be attempted, however, for lack of space. The interested reader is, therefore, referred to a more complete work which is to be available shortly.

The malignant epithelial cells exfoliate from the surface of neoplastic growths, much as do normal cells. They then float downward into the vaginal fornix, where they accumulate and become mixed with normal cells of epithelial and blood origin, as well as with mucus, bacteria, parasites and cellular debris. The rate of exfoliation of the malignant cells seems to depend upon the rate of growth of the neoplasm and its size. Young, small, and slow-growing lesions, therefore, usually shed only a few cells, whereas a large and rapidly growing lesion will ordinarily contribute relatively rich showers of characteristic cellular elements.

Metastatic scrutiny of the stained smear preparations is an important essential as well, as that such searching may be done by a person trained in the details of this type of cellular diagnosis. An atlas with colored illustrations has been prepared and will shortly be available to aid those interested in learning the method. The details of the staining technique will also be given in all the details necessary to duplicate the color reactions as shown.

DIFFERENTIATION

In brief, the differentiation of the malignant cell from those of benign origins is based upon changes in the size, shape, staining reactions, and the characteristics of the chromatin elements in the nucleus, the nucleoli, and the cytoplasm. Variations in size, with lobulated, crumpled, or elongated nuclei are most suggestive. If, in addition, the chromatin shows fragmentation, granulation, or displacement to one or other pole of the nucleus with one or more nucleoli, the probabilities of malignancy are great. If, in addition, one sees numbers of such cells in close proximity to one another so that the above criteria can be established by accurate comparison, a presumptive diagnosis of malignancy can be made. The word “presumptive” is used advisedly, as we do not feel one should ever use this method as the basis for an absolute diagnosis. Each of
Mortality Rates for All Malignancies (ICD 8: 140-209) per 100,000, Age-Standardized to U.S. 1970 Population: 1950-77
Uterus Cancer (ICD 8:180-182) Mortality Rates per 100,000, Age-Standardized to U.S. 1970 Population: 1950-77
The Transition Years

- University of Alabama 1965-1969
- UA School of Medicine 1969-1973
- OB/GYN Resident 1973-1977
- GYN Oncology Fellow 1977-1979
- Southern GYN Oncology 1979-1990

  Alabama Chapter, American College of Surgeons
  Alabama & Mid-South Division, American Cancer Society

- Director, Division of GYN Oncology 1990-2003

- African Americans
- Whites
- Hispanic/Latina
- American Indian/Alaska Native
- Asian American/Pacific Islander

American Cancer Society, Surveillance Research, 2007
U.S. Colorectal Cancer Mortality 1975-2005

- Black Male
- White Male
- Black Female
- White Female

Rate per 100,000

The Cancer Continuum

Prevention → Early Detection → Treatment → Survivorship → End of Life

UAB Comprehensive Cancer Center experience
lay (non-clinical) health advisors/navigators across the continuum
Mississippi Delta and Alabama Black Belt
## Demographics

<table>
<thead>
<tr>
<th></th>
<th>Per Capita Income</th>
<th>% Poverty</th>
<th>% AA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black Belt</td>
<td>$12,612</td>
<td>34%</td>
<td>64%</td>
</tr>
<tr>
<td>Delta</td>
<td>$12,650</td>
<td>31%</td>
<td>60%</td>
</tr>
</tbody>
</table>
Deep South Network for Cancer Control

NCI Funded
Community Network Partnership Center
2000 – 2015
Edward E. Partridge, MD – Principal Investigator
Claudia M. Hardy, MPA, Program Director
Recruitment, Training, and Maintenance

• 8 weeks - 2 hours/week training
  - Cancer education
  - Core leadership skills

• Graduation ceremony

• Monthly maintenance meetings
Disparities in Mammography Screening Between White and African American Women with Medicare Alabama Black Belt Counties
Cervical Cancer Mortality Impact of Deep South Network for Cancer Control

Pre-DSN (1995-1999)  
129 patients  
DSN county CC rate/non-DSN county CC rate  
(HR = 2.0  95% CL  1.10,3.72)

Post-DSN (2000-2005)  
175 patients  
(HR = 0.54  95% CL  0.35,0.87)

ASCO Abstract
Comparative Community Outreach to Increase Cervical Cancer Screening in Mississippi Delta

Castle P, Partridge E, Scarinci I, et al

Objective – Increase participation in cervical cancer screening in Mississippi Delta

Prev Med 52 (2011)
13.8 to 28.8
11.6 to 13.7
9.9 to 11.5§
9.0 to 9.8
8.1 to 8.9
6.6 to 8.0
3.7 to 6.5*‡
Suppressed

* All races national average: 4.5 per 100,000
§ Black national average: 11.3 per 100,000
‡ White national average: 3.9 per 100,000

* Data have been suppressed to ensure confidentiality and stability of rate estimates.
Comparative Community Outreach to Increase Cervical Cancer Screening in Mississippi Delta

• Door-to-door feasibility study of women without Pap in >3 years

• Offered cost-free choice of clinic based Pap or home self collection with HPV testing

Consenting Women
\((n = 119)\)

- Pap Test – 35.3% \((n = 42)\)
  - Completion – 40.5% \((n = 17)\)

- Self Collection & HPV Testing – 64.7% \((n = 77)\)
  - Completion – 80.5% \((n = 62)\)

\(p = 0.0001\)

*Prev Med 52 (2011)*
Community Health Advisors in Action Program (CHAAP)

Fouad, Ethnicity & Disease, Volume 20, Spring 2010
Objectives

To facilitate access to care and to ensure adherence to diagnostic follow-up of positive breast cancer screening or prescribed treatment for confirmed cancer among low income women
Cancer Patients Barriers

Percent of Participants with Barriers

- Access/Transportation
- Financial/Insurance Issues
- Lack of Information/Education
- Fear/Emotional Issues
- Hospital navigation
- Social Support Issues
- Cultural Beliefs/Attitudes
## Results

### Adherence Outcomes by County

<table>
<thead>
<tr>
<th>County</th>
<th>Number of patients</th>
<th>Scheduled</th>
<th>Attended</th>
<th>Not attended</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dallas and surrounds</td>
<td>21</td>
<td>181</td>
<td>179</td>
<td>1</td>
<td>0.6%</td>
</tr>
<tr>
<td>Jefferson and surrounds</td>
<td>81</td>
<td>514</td>
<td>444</td>
<td>24</td>
<td>4.7%</td>
</tr>
<tr>
<td>Montgomery and surrounds</td>
<td>31</td>
<td>438</td>
<td>424</td>
<td>10</td>
<td>2.3%</td>
</tr>
<tr>
<td>Sumter and surrounds</td>
<td>14</td>
<td>251</td>
<td>239</td>
<td>8</td>
<td>3.2%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>147</strong></td>
<td><strong>1,384</strong></td>
<td><strong>1,286</strong></td>
<td><strong>43</strong></td>
<td><strong>3.1%</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>55</strong></td>
<td><strong>4%</strong></td>
</tr>
</tbody>
</table>
IMPaCT – Improving Minority Participation in Clinical Trial Navigation

Morehouse School of Medicine / Tuskegee University / UAB Comprehensive Cancer Center Partnership

NCI Funded

Edward Partridge – Principal Investigator (2000-2010)

Mona Fouad, MD, MPH – Co-Principal Investigator

African American women trained to discuss clinical trials and to overcome barriers to participate
## Accrual to Clinical Trials: CCSG - 2005

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>US</th>
<th>Alabama</th>
<th>Cancer Cases</th>
<th>Clinical Trial Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>74.3%</td>
<td>70.4%</td>
<td>78.3%</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>12.3%</td>
<td>26.2%</td>
<td>20.3%</td>
<td>11.2%</td>
</tr>
<tr>
<td>Asian</td>
<td>4.4%</td>
<td>1.0%</td>
<td>0.5%</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>15.1%</td>
<td>2.7%</td>
<td>0.7%</td>
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</table>
## Accrual to Clinical Trials: CCSG - 2010

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<td>22.7%</td>
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<tr>
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<td>1.0%</td>
<td>0.5%</td>
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<td>0.7%</td>
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*JOP, in press*
Weight Loss Program
Monica L. Baskin, PhD - PI

2-year cluster-randomized trial among overweight African American women in eight (8) rural counties in Alabama and Mississippi

Behavioral weight loss program adapted from evidence-based behavioral trials\(^1\)\(^2\)\(^3\) and delivered by trained local staff and volunteers.

Study enrolled 409 women (age 30-70)

High rate of retention noted at 6-, 12- and 24-months (99.5%, 98.5%, and 75%, respectively).

\(^1\) Wadden et al., Obes Res. 2004; 12(Suppl 3): 151S-62S;
\(^3\) Brantley et al., Clin Trials. 2008; 5(5):546-56.
Phase 1
(6 months)

- 20 weekly face-to-face group sessions
- Led by regional and local coordinators with help by community-health advisors (CHARPs)
- Goal: 5-10% weight loss
  1. Attending sessions
  2. Keeping track of food and physical activity
  3. Sticking to suggested calories per day
  4. Eating 5 or more fruits and vegetables a day
  5. Getting 150 minutes of physical activity a week

Phase 2
(6 months)

- Face-to-face group sessions twice a month for 3 months, then once a month for 3 months
- Led by local coordinator with help by CHARPs
- Goal: maintaining weight loss or reaching initial 5-10% weight loss
  1. Reviewing key Phase I sessions
  2. Social support
  3. Problem solving

Phase 3
(12 months)

- Monthly motivational phone calls
- Led by CHARPs
- Local coordinator provides CHARP supervision and support
Primary Successes

1. Community-Based Participatory Research (CBPR) methods associated with significant reach and retention of a traditionally “hard-to-reach” target population

2. Findings suggest improvements in health outcomes (weight, waist circumference, blood pressure, triglycerides) that may be clinically meaningful

3. Trained lay health staff and volunteers delivered a translation of a high intensity behavioral intervention, resulting in findings that rival major efficacy clinical trials

Ard, JD et al., Weight loss and improved metabolic outcomes among rural African American women in the Deep South: Six-month outcomes from a community-based randomized trial (under review).
Summary of Experience with Community Health Advisors

1) Promote awareness, change behavior, screening
2) Effectively assist compliance with diagnostic and treatment recommendations
3) Increase minority participation in clinical trials
4) Serve as research assistants
Deep South Cancer Navigation Network

Patient Care Connect
A service of UAB Health System Cancer Community Network

CMS Innovation Challenge Grant
Patient Care Connect

A Lay Navigator Program
Better Health, Better Health Care, Lower Cost

Treatment → Survivorship → End-of-Life
• 12 cancer centers across 5 southeastern states
• ~40 lay (non-clinical) navigators
• 12 nurse site managers
DSCNN Program Overview

Focus
- Diet & Exercise
- Tobacco Control
- Risk Management

Age Appropriate Screening
- Prompt Evaluation
- Accurate Diagnosis
- Accurate Treatment Plan

Complete Treatments
- Coordination of Care
- Stay on Medications

Stay on Medications
- Manage Comorbidities

Regular Surveillance
- Manage Comorbidities
- Physical Activity / Healthy Diet

Advanced Disease Management & Planning

Community Health Advisory (Screening & Awareness)
- Community Navigators (Non-nurse)
- Clinical Trial Navigators (Non-nurse)
- IMCCP Navigators (Non-nurse)
- CMS Patient Navigators (Non-nurse)

First 12 Months
- Evaluation & Treatment Planning

Continuing Phase
- Active Treatment
- Post Tx Follow Up

Last 12 Months
- Survivorship & Surveillance
- Palliative & Hospice

Advanced Disease Navigation
## Estimates for Healthcare Utilization

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Groupa x Time</th>
<th>Time</th>
<th>Groupa</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>β</td>
<td>SE</td>
<td>P-value</td>
</tr>
<tr>
<td>Total Cost to Medicare</td>
<td>-781.29</td>
<td>45.77</td>
<td>&lt;0.00</td>
</tr>
<tr>
<td></td>
<td>(0.92-</td>
<td>&lt;0.00</td>
<td></td>
</tr>
<tr>
<td>Number of ER visits (IRR, CI)</td>
<td>0.94</td>
<td>0.96</td>
<td>01</td>
</tr>
<tr>
<td></td>
<td>(0.90-</td>
<td>&lt;0.00</td>
<td></td>
</tr>
<tr>
<td>Number of Hospitalizations</td>
<td>0.92</td>
<td>0.94</td>
<td>01</td>
</tr>
<tr>
<td>(IRR, CI)</td>
<td>(0.86-</td>
<td>&lt;0.00</td>
<td></td>
</tr>
<tr>
<td>Number of ICU visits (IRR, CI)</td>
<td>0.90</td>
<td>0.94</td>
<td>01</td>
</tr>
</tbody>
</table>

*Navigated vs. Non-Navigated
Model adjusted for calendar time
SE=standard error; IRR=incidence rate ratio; CI=confidence interval

Cost and Healthcare Utilization After Program implementation

Cost and Healthcare Utilization After Program implementation

Cost and Healthcare Utilization After Program implementation

Cost and Healthcare Utilization After Program implementation

Trends in Medicare Costs per Quarter by Race and Navigation Status

![Graph showing trends in Medicare costs per quarter by race and navigation status. The graph includes lines for African American navigated group, African American comparison group, White navigated group, and White comparison group. The y-axis represents mean per quarter costs, ranging from $0 to $16,000, and the x-axis represents quarters from 1 to 8. The lines indicate a decreasing trend over time.]
Trends in Hospitalizations per 1,000 Beneficiaries per Quarter by Race and Navigation Status
Trends in ER Visits per 1,000 Beneficiaries per Quarter by Race and Navigation Status
Differences in End-of-Life Utilization, Quality, and Cost between Decedent UAB Program Participants and Comparison Group Participants

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Adjusted Difference [90% Confidence Interval]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalizations (Likelihood per 1,000 Patients)</td>
<td>-30 [-53, -8]**</td>
</tr>
<tr>
<td>ED Visits (Likelihood per 1,000 Patients)</td>
<td>-34 [-54, -15]***</td>
</tr>
<tr>
<td>Hospice Care in the Last Two Weeks of Life ±</td>
<td>85 [63, 108]***</td>
</tr>
<tr>
<td>Chemotherapy in the Last Two Weeks of Life</td>
<td>-22 [-78, 35]</td>
</tr>
<tr>
<td>30-Day Total Cost of Care per Patient ($)</td>
<td>-$2,733 [-$3,701, -$1,766]***</td>
</tr>
<tr>
<td>90-Day Total Cost of Care per Patient ($)</td>
<td>-$5,824 [-$7,180, -$4,469]***</td>
</tr>
<tr>
<td>180-Day Total Cost of Care per Patient ($)</td>
<td>-$8,093 [-$9,927, -$6,258]***</td>
</tr>
</tbody>
</table>

Aggregate Impact

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Adjusted Difference [90% Confidence Interval]</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-Day Total Cost of Care per Patient ($)</td>
<td>-$6,007,134 [-$8,134,798, -$3,881,668]***</td>
</tr>
<tr>
<td>90-Day Total Cost of Care per Patient ($)</td>
<td>-$12,801,152 [-$15,781,640, -$9,822,862]***</td>
</tr>
<tr>
<td>180-Day Total Cost of Care per Patient ($)</td>
<td>-$17,788,414 [-$21,819,546, -$13,755,084]***</td>
</tr>
</tbody>
</table>
Medicare Access and CHIP Reauthorization Act (MACRA)

- MIPS - Merit-based Payment System
- APMs - Alternative Payment Models
  - ACOs, Patient center medical homes
  - Bundled payments
Value Based Payment Models

Oncology Payment Model

CMS

ASCO

1) Payment increased
   CMS – during chemotherapy
   ASCO – across continuum

2) Decreased utilization downstream (shared risk)

3) Quality measures
Summary

Lay Navigators/Community Advisors (volunteer/paid) can assist nation (and the world) in achieving cancer health equity.
Important Concepts

• Create trust
• Eliminate bias
• Share power