EARLY DIAGNOSIS AND TREATMENT OF CERVICAL TISSUE ABNORMALITIES

CREATING A SINGLE INSTRUMENT COLLECTION TOOL FOR PAP SMEARS

By

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STATEMENT BY THE AUTHOR

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APPROVAL BY PROJECT DIRECTOR

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Date

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I would like to acknowledge Judith A Berg, PhD, RNC, WHNP, for her unconditional support, guidance, patience and gentleness. I would like to thank Kenneth Hatch, MD for his inspiration and friendship. I wish to thank my father and step-mother, whose love and support has nurtured me through-out this quest. Not to forget the girls in the study group, for their loving comments, laughter, hats and the cherished lobster dinner. But mostly, to the memory of my mother, who often believed in me more than I did myself.

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ABSTRACT

The purpose of this clinical project is to invent a new Pap smear collection instrument and describe beginning research that is intended to establish an increased endothelial cell yield with intact nuclei that will lead to increased sensitivity and specificity of Pap smears with the use of this new instrument.

CHAPTER 1

Introduction

The purpose of this clinical project was to create a new Pap smear collection instrument, describe it, and design a research study as a beginning step toward establishing sensitivity and specificity of Pap smears with the use of this new instrument. In this chapter, the background, clinical problem, and significance are presented.

Background

Cervical cancer is now the second most frequent cause of death from cancer in women world wide. Cervical cancer screening programs help to lessen the incidence of cervical cancer; however, 50% of invasive cervical cancers arise in women screened with existing cytological methods (Hart, Williams, Thelwell, Fiander, Brown, Borysiewicz, & Gelder, 2001). There are nearly one million precancerous conditions of the cervix in varying grades detected annually due to the human Papilloma virus (HPV) cytomorphologic changes (Cotran, Kumar, & Collins, 1999). No other form of cancer has seen such extensive effects of prevention, early diagnosis, and curative therapy on mortality rate than cancer of the cervix. Since its introduction in the middle

of the last century, cervical cytologic screening using Pap smears has significantly reduced the incidence of cervical cancer in populations where this screening program has been widely implemented. In sharp contrast to this reduced mortality, the detection frequency of early cancers and precancerous conditions is high.

If women are screened regularly, less threatening precancerous lesions, such as Low Grade Squamous Intraepithelial Lesions (LSIL), are more readily detected and effectively treated, thus preventing progression to High Grade Squamous Intraepithelial Lesions (HSIL) and invasive cancer. Many of these precancerous lesions exist non-invasively for up to 20 years. During this time they shed abnormal cells that can be detected on Pap smears (Cotran, Kumar & Collins, 1999).

Problem Statement

Timely detection and treatment of cancer precursors prevents morbidity and mortality caused by cervical cancer. Despite widespread use with resultant reduction in invasive cervical cancer, it is recognized that Pap smears lack sufficient sensitivity. The reported frequency of false negative cytology results vary widely and are attributable to sub-optimal sampling, collection of exfoliative cervical

cells with intact nuclei, and inadequate slide preparation (DeMay, 1996). To off set these problems, data collection instruments (Cytobrush and Cytobroom) were developed. Although these better assured the presence of representative endocervical cells, the problem of inadequate slide preparation prevailed. This problem was addressed by the creation of a new liquid-based/thin-layer preparation which was intended to improve the quality and adequacy of the Pap smears; improve Pap smear interpretation; and facilitate new-generation DNA human Papilloma virus testing methods. Liquid-based cytology (Thin Prep) permits the specimen to be placed directly into a vial of preservative for immediate fixation of endothelial cells. This bypasses the slide and air dry technique which has been fraught with problems.

Sampling of cervical cells to be used with liquid-based cytology is most commonly done as a two-step procedure: exocervical cell collection with a wooden or plastic spatula and endocervical cell collection with a cytobrush or Cytobroom. This procedure requires the clinician to juggle two instruments without assistance or obtain assistance from a nurse or other staff member. Although it is estimated that the two instruments allow collection of

an adequate sample in conjunction with liquid-based cytology (Nuovo, Melnekow, & Howell, 2001), anecdotal information suggests that a one-step or one instrument procedure would ease clinician burden without compromising sensitivity and specificity of Pap smears. Such an instrument is not currently available.

Significance

Several improvements have occurred (endocervical sampling instruments, Thin Prep) to bolster sensitivity and specificity of the Pap test. Yet more improvement is needed in order to provide ease of screening in conjunction with greater sensitivity and specificity. Together these can maintain a woman's confidence in the testing, an essential component of this health promotion activity.

Significance to Nursing

Better cervical cancer detection plus ease of screening are important to nurses. Nurses are charged with educating women about the need for Pap smear screening, and they must also educate women about the sensitivity and specificity of current technology. Data about new technology is a necessary ingredient to education about the purpose and advantages of Pap smear screening that nurses provide to women. As well, in clinic settings, many nurses must assist

clinicians actually performing the tests, as two-step procedures commonly require assistance. These impacts on nurses' time management. Ease of screening, as suggested by a one-step procedure with liquid-based cytology, could positively influence time management by allowing clinicians to perform Pap smears without assistance.

In clinical practice nurse practitioners screen, diagnose and treat cervical cancer and its precursors, and they are reimbursed by on a fee for service basis from Medicare, private insurance, self pay, health maintained organizations and Medicaid for these services. New technology that is less time consuming and reported to have a lower chance of clinician error can ultimately be less costly. For example, decreased need for repeat Pap smears due to problems associated with artifact, decreased cell yield, or clinician error could be cost effective. A one-step sampling instrument used with Thin Prep promises to provide these advantages.

Nursing science can benefit from the successful development of a one-step Pap smear collection instrument as this evidence based process bridges the science practice domains. Research that has direct implications for practice is valued by all nurses.

Summary

The purpose of this clinical project was to create a new Pap smear collection instrument, describe it and to design an appropriate research study intended to establish sensitivity and specificity data on Pap smears conducted with this new instrument in conjunction with Thin Prep. This chapter introduced the problems currently related to Pap smear screening and suggested that a one-step sampling instrument utilized with Thin Prep could have significance to women by increasing their confidence in results obtained from Pap smears. It could significantly reduce the costs of repeat tests and reduce the time needed for nurses to assist clinicians with screening. It could have significance to nurses and nurses in advanced practice by simplifying data collection.

In Chapter Two, the theoretical framework for this clinical project is presented. As well, pertinent literature was reviewed and critiqued as background for the project.

Chapter 2

Critique of the Literature on Liquid-Based Cytology

Theoretical Framework

In this chapter the theoretical frame work is presented. Followed by a review and critique of the pertinent literature related to liquid-based cytology and current instruments for collection of Pap smears.

Summarization of Health Promotion Model

Nola J. Pender proposed the theoretical model, The Health Promotion Model (HPM), which was used as the basis for this clinical project.

The Health Promotion Model (HPM) is an attempt to illustrate the multidimensional nature of persons interacting with their interpersonal and physical environments as they pursue health (Pender, Murdaugh, & Parsons. 2002). This model uses assumptions and theoretical propositions as an attempt help explain the complex interactions between people and their environment.

The HPM is based on the following assumptions, which reflect both nursing and behavioral science perspectives:
1. Persons seek to create conditions of living through which they can express their unique health potential.
2. Persons have the capacity for reflective self-awareness, including assessment of their own competencies.

3. Persons value growth in directions viewed as positive and attempts to achieve a personally acceptable balance between change and stability.
4. Individuals seek to actively regulate their own behavior.
5. Individuals in all their biopsychosocial complexity interact with the environment, progressively transforming the environment and being transformed over time.
6. Health professionals constitute a part of the interpersonal environment, which exerts influence on persons throughout their lifespan.
7. Self-initiated reconfiguration of person-environment interactive patterns is essential to behavior change.

Theoretical statements derived from the model provide a basis for investigative work on health behaviors. The HPM is based on the following theoretical propositions:

1. Prior behavior and inherited and acquired characteristics influence beliefs, affect, and enactment of health-promoting behavior.
2. Persons commit to engaging in behaviors from which they anticipate deriving personally valued benefits.
3. Perceived barriers can constrain commitment to action, a mediator of behavior as well as actual behavior.
4. Perceived competence or self-efficacy to execute a given behavior increases the likelihood of commitment to action and actual performance of the behavior.
5. Greater perceived self-efficacy results in fewer perceived barriers to a specific health behavior.
6. Positive affect toward a behavior results in greater perceived self-efficacy, which can in turn, result in increased positive affect.
7. When positive emotions or affect are associated with a behavior, the probability of commitment and action is increased.
8. Persons are more likely to commit to and engage in health-promoting behaviors when significant others model the behavior, expect the behavior to occur, and provide assistance and support to enable the behavior.

9. Families, peers, and health care providers are important sources of interpersonal influence that can increase or decrease commitment to and engagement in health-promoting behavior.
10. Situational influences in the external environment can increase or decrease commitment to or participation in health-promoting behavior.
11. The greater the commitments to a specific plan of action, the more likely health-promoting behaviors are to be maintained over time.
12. Commitment to a plan of action is less likely to result in the desired behavior when competing demands over which persons have little control require immediate attention.
13. Commitment to a plan of action is less likely to result in the desired behavior when other actions are more attractive and thus preferred over the target behavior.
14. Persons can modify cognitions, affect, and the interpersonal and physical environment to create incentives for health actions (http://www.nursing.umich.edu/faculty 2002).

Along with assumptions and theoretical propositions, the HPM theorizes about the relationships among individual characters and experiences, behavior-specific cognitions and affect, and behavioral outcomes. In Pender's model individual characteristics and experiences include the effect on prior related behavior and personal biological, psychological, and sociocultural factors (Friedman, 1998). See Appendix A.

Prior related behavior is proposed as having both direct and indirect effects on the likelihood of engaging in health-promoting behavior. The direct effect of past behavior on current health promoting behavior may be due to

habit formation, promoting one to continue the same behavior with little attention to the specific detail of why it is habitual. Each time the behavior is repeated habitual strength is reinforced.

Indirect effects on health promoting behavior can be viewed as either a positive or negative outcome. If the desired short-term benefits are experienced early in the course of the behavior, the behavior is more likely to be repeated (Pender, Murdaugh, & Parsons. 2002).

Personal factors have been categorized as biological, psychological and sociocultural. Biological factors include, but are not limited to, age, body mass index, gender, menstrual history, gynecologic history. Psychological factors refer to variables such as self-esteem, self-motivation and perceived health status. Sociocultural factors include variables such as race, ethnicity education, and socioeconomic status.
The core of the Health Promotion Model emphasizes the importance of behavior-specific cognitions and affect as the primary motivators of behavior. Behavior-specific cognitions and affect that are hypothesized to be directly related to health promoting actions included positive perceptions of the anticipated expected outcome, minimal

barriers to action, feeling efficacious and skilled, positive feeling about the health behavior, presence of family and peer social support, positive role models and availability of environmental contexts that are compatible, safe, and interesting (Pender, 1996). See Appendix B

The six behavior-specific cognitions and affects considered of major motivational significance in encouraging an individual to engage in health-promoting behaviors have been identified as: perceived benefits of action, perceived barriers to action, perceived self-efficacy, activity-related affect, interpersonal influences, and situational influences (Pender, 1996).

Perceived Barriers to Action

Anticipated barriers have been repeatedly shown in empirical studies to effect intentions to engage in a particular behavior and the actual exaction of the behavior (Pender, 1996).

In relation to health promoting behaviors, barriers may be real or imagined and consist of perceptions concerning unavailable, inconvenience, experience, difficulty or time-consuming nature of a particular barrier. Most barriers are

viewed as blocks or hurdles that usually arouse ways of avoiding a certain behavior.

Perceived Self-Efficacy

As defined, perceived self-efficacy is being influenced by activity-related affect. The more positive the effect, the greater the perception of self-efficacy. Self-efficacy motivates health promoting behavior directly by efficacy expectations and indirectly by affecting perceived barriers and determining level of commitment or persistence in pursuing a plan of action. Of the HPM studies reviewed, 86% provided support for the importance of self-efficacy as a determinant of health-promoting behavior Pender, Murdaugh, & Parsons, 2002).

Activity Related Affect

Activity related affect consists of three components: emotional arousal to the act itself (act related, the self acting (self related), or the environment in which the action takes place (context related). Behaviors associated with a positive affect are likely to be repeated, whereas behaviors associated with a negative affect are likely to be avoided.

Because this is a recent addition of activity related affect to the HPM, few studies have explored the

contribution to the model. Further studies as needed to determine the importance of activity related affect in regards to the HPM.

Interpersonal Influences

The HPM refers to interpersonal influences as cognitions concerning the behaviors, beliefs or attitudes of others. Theses cognitions may or may not correspond with reality. Primary sources of influence are family, peers, and health care providers. Interpersonal influences also include norms or expectations of significant others, social support, instrumental and emotional encouragement, and modeling, learning through observation. The interpersonal influences are proposed as affecting health promoting behavior directly as well as indirectly through social pressures or encouragement to commit to a plan of action. In studies based on the HPM, 57% provided empirical support for the importance of interpersonal influences as determinants of health promoting behavior (Pender, Murdaugh, & Parsons 2002).

Situational Influences

Situational influences have direct and indirect influences on health behavior. Direct influence can come from situations in the environment with cues to action. For

example, a "no smoking" environment creates demands for nonsmoking behaviors. Indirect influences can come from regulations from employers, such as mandatory ear protection. Both situations enforce a commitment to health promotion action.

Of the HPM studies reviewed, 56% reported situational influences as significant predictors of health promoting behavior (Pender, Murdaugh, & Parsons 2002).

Commitment to a Plan of Action

Commitment to a plan of action triggers a behavior change. According to the HPM, commitment to a plan of action implies the underlying cognitive process: (1) commitment to follow through a specific action at a given time and place and with specified persons or alone, irrespective of competing preferences; and (2) identification of definitive strategies or eliciting, carrying out, and reinforcing the behavior (Pender, Murdaugh, & Parsons 2002).

Behavioral Outcome

Behavioral outcomes are proposed to be influenced by a person's sense of commitment to a plan of action with identified specific strategies, and the capacity of the person to repress competing demands and preferences.

Health-promoting behavior is the action outcome in the model. Pender emphasizes that health-promoting behavior is ultimately directed toward attaining positive health outcomes for the client that should result in a positive health experience throughout that person's lifetime (Friedman, 1998) See Appendix C.

This model is a rational decision-making model that incorporates assumptions and theoretical propositions. These assumptions reflect both nursing and behavioral science perspectives. The assumptions emphasize the active role of the client in shaping and maintaining health behaviors and in modifying the environmental context for health behaviors. Theoretical propositions are statements resulting from the model that provide a foundation for investigative work on health behaviors.

HPM related to this project will focus on increasing the sensitivity of Pap Smears by implementing a new data collection instrument that will increase specificity and sensitivity. By increasing the sensitivity and specificity, women be will trust the results with more certainty. This is expected to bolster (compliance with Pap smear screening/health promoting behavior) and decrease perceived

barriers resulting in increased likelihood of the health promoting behavior.

According to Pender's model, health promoting behaviors are influenced by individual characteristics and prior-related behavior. These, in turn, have an effect on elements that can lead to health promoting behaviors or discourage them. These can be considered interceding variables, as they are not represented as having a direct effect on health promoting behaviors. However, according to the model, actual health promoting behaviors can feedback to affect perceived benefits, barriers, perceived self-efficacy, and other interpersonal influences. Other interceding variables or intervening steps noted are competing demands and commitment to a plan of action. Together these elements create an explanatory model of health promoting behaviors. One can see that the model is not intended to be linear. Rather, there are complex feedback mechanisms that demonstrate health promoting behaviors are complex with individual variations abundant.

Health Promotion Model as Applied to this Clinical Project

The purpose of this project was to develop a new Pap smear data collection instrument. From the view point of Pender's Health Promotion Model, this project focuses on

decreasing barriers to Pap smear screening by increasing women's confidence in the results of this screening test. Improving clinician ease in obtaining cervical material for Pap smear screening in conjunction with liquid-based cytology specimen preservation is expected to improve Pap smears and also time saving for repeat samples when pap smears are inadequate, thus increasing sensitivity and specificity. These serve to increase women's confidence in Pap smear results which is expected to decrease barriers and increase benefits. This, in turn, is expected to affect the behavioral outcome which is the health promoting behavior of obtaining Pap smear screen. Pender's model as adapted for this clinical project can be seen in Appendix D.

Literature Review

Literature is presented in this section that is pertinent to the clinical problem. Areas covered are liquid-based cytology and collection instruments for Pap smears.

Knowledge of the Clinical Problem

The widespread use of cervical cancer screening (Pap smears) has markedly decreased the incidence and mortality of the disease in the United States. Unfortunately, only

50% of women with the diagnosis of invasive cervical cancer have ever had a Pap smear test, and 10% have not had Pap smear screening done in the five years preceding their diagnosis (Cohn, & Herzog, 2001). This implies that not all women avail themselves of this screening. Approaches to improve Pap smear screening include identification of unscreened populations at risk and improvements in the detection of dysplasias or precursors to cervical cancer, HSIL, with the implementation of new technology.
Current clinical practice is in the midst of a controversy about the use of conventionally prepared Pap smear slides verses the use of liquid-based cytology. Studies have found that up to 40% of conventionally prepared slides cannot be interpreted because of some sort of debris on the Pap smear slide. While the percentage of problems with slides prepared from specimens stored in liquid-based preparations approaches zero (Byrnes, 1998).

The United States Food and Drug Administration recently approved the use of liquid-based preparations of cervical cells to minimize the risk of errors in interpretations of conventional Papanicolaou test. Cervical Samples are collected in the usual fashion with a spatula and endocervical brush and are transferred directly into the

fixative solution rather than dispersing the cells on a microscope slide previous to fixation. The liquid is then passed through an 8 micromilimeter filter and transferred to a slide as a monolayer containing approximately 40,000 cells. This slide is then processed like a conventional Papanicolaou test. Because samples are fixed immediately after collection, there are fewer artifacts in cellular morphology. The ability to interpret the slide is also improved because of less artifactual material such as blood and mucus obscuring the epithelial cells (Cohen & Herzog, 2001).

Data-Based Articles

It is estimated that approximately 52 million Papanicolaou tests are performed annually in the United States, at a cost of $20 to $40 per Pap smear slide. Recent data from the Agency for Health Care Policy and Research (AHCPR) suggest that despite the ability of cytological screening to detect dysplasias and HSIL, the conventional Pap test is less sensitive than it was generally believed to be (Cohn and Herzog). The cost for liquid-based cytology, (Thin Prep) can be higher at approximately $40-$60 with the aim to minimize both the sampling and detection errors.

It is estimated that errors in sampling and interpretation account for 30% of the cases of squamous cell cancer in women who are screened, and errors in follow-up and triage account for another 10%. Thus, of the approximately 10,320 cases of invasive squamous cell cancers of the cervix expected to be diagnosed during 2001, 3,096 could have been prevented with a more sensitive cervical cancer screening technique (Cohn, and Herzog, 2001).

Difficulties with Pap smear interpretation have been widely publicized and this adverse publicity can influence women's confidence in Pap smear screening. Lack of confidence in screening could be considered a barrier to the health promoting behavior of obtaining Pap smear screening. Alternatively, to increase confidence in the results of a screening test could bolster the perceived benefit of obtaining a Pap smear.

Liquid-based cytology is gaining in popularity due to its increased sensitivity and specificity. Cohn and Herzog, 2001; Dunton, 2000; Hatch, 2000 and Papillo and Zarka, 1998, compared 7,933 patients who were screened with liquid-based cytology with 16,261 of patients screened with conventional Pap smears. He concluded that liquid-based

cytology demonstrated a significantly increased detection of low grade squamous intraepithelial lesions, LSIL and HSIL, which were confirmed by histologic investigation. These authors also confirmed an increase in specimen accuracy when compared with conventional Pap smears. Papillo and Zarka (1998) found a 1.7% increased rate of normal smears, a 27% decreased rate of atypical smears, and a 52% increased rate of dysplastic smears with the use of liquid-based cytology. There were 32% fewer benign cervical biopsies when liquid-based cytology was used as a primary screening tool, which supports it as a more sensitive test.

The above authors cited limitations in the studies by lack of routine histologic confirmation of abnormalities suggested by cytology and the use of historic controls to determine rates of dysplasia detected by conventional cytology.

Critique of the Literature on Current Instruments for the Collection of Pap Smears

Knowledge of the Clinical Problem

Current clinical practice today favors using the cytology brush along with the Aylesbury spatula. This method became popular after it was shown by cytology that the cotton tip swab did not exfoliate columnar endocervical

cells or squamous metaplastic cells. Because 85-90% of cervical carcinomas originate at the squamo-columnar junction, it is essential to sample this region adequately. The presence of columnar endocervical cells and squamous metaplastic cells is accepted as evidence that the squamo-columnar junction has been adequately sampled (Dehbashi, Honarvar, & Montazer, 2002).

In 1994-1995, 4.5 million cervical smears were examined in England; over 350,000 (7.9%) were deemed inadequate because the proper sampling device, the spatula not the extended tip spatula, was not utilized and the transformation zone, also known as the squamo-columnar junction, this is the area of the cervix where the exocervix transforms into the endocervix, was missed (Sasieni, 1996). The transformation zone must be adequately sampled for identification of precancerous squamous lesions because adenocarcinomas are likely to originate further up the endocervical canal. Thus there should be particular interest in the ability of sampling devices to pick up these glandular lesions (Sasieni, 1996).

Anecdotal reports by clinicians who collect Pap smear specimens suggest that current collection tools are not ideal. The two step process that utilizes the cytobrush

along with the spatula can be cumbersome and time consuming. The current Cytobroom is not long enough or rigid enough to reach the transformation zone. Frequently the broom tip falls off and must be retrieved with dressing forceps. When this occurs cellular material is lost and can result in an inadequate sample. Therefore, more and better controlled studies are needed that use a standardized instrument for the collection of Pap smears with liquid-based cytology.

Data Based-Articles

The availability of data based articles comparing the three collection types is limited. A few studies that were done in the early and mid 1990s focused on instruments for Pap specimen collection.

Neinstein, Church, and Akiyoshi (1992) assess the use of the Ayres spatula with cytobrush combination and the Cervix-Brush to compare the quality of the Pap smear and slide effects associated with these two collection tools. They evaluated 165 Pap Smears, of which 84 (51%) were cytobrush/spatula specimens, and 81 (49%) were from Cervix-Brush specimens. Both collections tools used alone were equally successful in detecting squamous cells, however, the cytobrush/Ayres spatula combination was significantly

better in picking up endocervical cells than the Cervix-Brush ($p < 0.01$). There were no significant differences between the two techniques in degree of bleeding and pain in adolescents where the endocervix is more exposed in adolescents. The conclusion was that the combination of the cytobrush and spatula appears to be superior to the Cervix- carrying out, and reinforcing the behavior (Pender, Murdaugh, & Parsons 2002).

Behavioral Outcome

Behavioral outcomes are proposed to be influenced by a person's sense of commitment to a plan of action with identified specific strategies, and the capacity of the person to repress competing demands and preferences. Health-promoting behavior is the action outcome in the model. Pender emphasizes that health-promoting behavior is ultimately directed toward attaining positive health outcomes for the client that should result in a positive health experience throughout that person's lifetime (Friedman, 1998) See Appendix C.

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In 1994-1995, 4.5 million cervical smears were examined in England; over 350,000 (7.9%) were deemed inadequate because the proper sampling device, the spatula not the extended tip spatula, was not utilized and the transformation zone, also known as the squamo-columnar junction, this is the area of the cervix where the exocervix

transforms into the endocervix, was missed (Sasieni, 1996). The transformation zone must be adequately sampled for identification of precancerous squamous lesions because adenocarcinomas are likely to originate further up the endocervical canal. Thus there should be particular interest in the ability of sampling devices to pick up these glandular lesions (Sasieni, 1996).

Anecdotal reports by clinicians who collect Pap smear specimens suggest that current collection tools are not ideal. The two step process that utilizes the cytobrush along with the spatula can be cumbersome and time consuming. The current Cytobroom is not long enough or rigid enough to reach the transformation zone. Frequently the broom tip falls off and must be retrieved with dressing forceps. When this occurs cellular material is lost and can result in an inadequate sample. Therefore, more and better controlled studies are needed that use a standardized instrument for the collection of Pap smears with liquid-based cytology.

Data based-articles

The availability of data based articles comparing the three collection types is limited. A few studies that were done in the early and mid 1990s focused on instruments for Pap specimen collection.

Neinstein, Church, and Akiyoshi (1992) assess the use of the Ayres spatula with cytobrush combination and the Cervix-Brush to compare the quality of the Pap smear and slide effects associated with these two collection tools. They evaluated 165 Pap Smears, of which 84 (51%) were cytobrush/spatula specimens, and 81 (49%) were from Cervix-Brush specimens. Both collections tools used alone were equally successful in detecting squamous cells, however, the cytobrush/Ayres spatula combination was significantly better in picking up endocervical cells than the Cervix-Brush ($\underline{p} < 0.01$). There were no significant differences between the two techniques in degree of bleeding and pain in adolescents where the endocervix is more exposed in adolescents. The conclusion was that the combination of the cytobrush and spatula appears to be superior to the Cervix-Brush alone in producing adequate Pap smears.

The objective of two studies done in Britain was to compare the adequacy of cervical cytology sampling with two sampling instruments commonly used in primary care—namely, the Aylesbury spatula and the Cervex Brush. This was a pair-matched, population-based, randomized controlled trial. Over 15,882 cervical smears were taken from women aged 20-64 years as part of the national cervical screening program.

The participating centers were allocated to sample with either the Cervex Brush or the Aylesbury spatula. All smears were retained in their original study arm for analysis. The mean ages of women in the Cervex-Brush and Aylesbury spatula arms were 36.0 and 35.5 years. The mean number of smears contributed by each centre was 185 and the intracluster correlation coefficient 0.008. Outcome measurement included inadequate smear rate. Inadequate smears between the groups were compared using the odds ratio. A Mantel-Haenszel statistic, adapted for the group randomized design, was used to test the significance of the odds ratio and 95% confidence intervals were constructed (Dey, P., Collins, S., Desai, M. & Woodman, C. 1996). There were no differences between the instruments in the adequacy of cytological sampling. Inadequate smear rates varied between nil and 18.7% in the centers allocated the Cervex Brush and between 1.2% and 17.4% in centers allocated the Aylesbury spatula (Dey, Collins, Desai, & Woodman, 1996). The wide variations portrayed by these data suggest atrophy or clinician error.

Some studies showed smears taken with the Cervex-Brush were more likely to contain cytological abnormalities. However, the difference between the Cervex-Brush and the combination of spatula and cytobrush on cytological

abnormalities approached significance (p=.05).The results of this study do not support the routine use of the Cervex-Brush to reduce the rates of inadequate Pap smear rates in this cervical cytology screening program.

In 1997, another study was conducted comparing the adequacy of cervical smears using the Aylesbury spatula plus cytology brush with the Cervex Broom in Thin Prep. Both data collection methods were used on each participant, and results were compared. To offset potential collection bias, women were assigned to two groups: In Group I (n=81), the first smear was taken with the Cervix Broom; in Group 2 (n=97), the first smear was taken with the Aylesbury spatula followed by the cytology brush (Sparrow, Fauck, & Gupta, 1997). Both techniques were equal in detecting significant abnormalities. When the Cervex Broom was used first, fewer smears were contaminated with blood; however, when blood was present, there were no significant differences between the two groups. Conclusions drawn from this study focused on the advantage of simple one-step collection procedures afforded by the Cervex broom (Sparrow, Fauck, Gupta, 1997). Missing from these data are reports from clinicians about problems with the Cervex Broom falling apart or breaking. When this occurs, extra steps must be taken to retrieve the broom

filaments. Then, another device must be utilized to collect the Pap smear specimen.

Use of a standard Dacron/cotton swab plus cervical spatula and cytobrush plus spatula for Pap smear collection has been studied (Dehbashi, Honarvar, & Montazar, 2002). The columnar cell yield was significantly greater in the cytobrush group than in the cotton swab group ($p < .01$). From this study, it was concluded that use of the cytobrush for cell material collection improved detection of abnormalities of columnar epithelium of the endocervix. Germain, Heaton, Erikson, Henry, Nash, and O'Connor,(2002) reported that the combination of spatula and cytobrush is superior for detecting true positive dysplasia, however, Stillson, Kight, and Elswick (2002), reported the cytobrush did not increase detection of cytological atypia. These oppositional findings indicate that the science of Pap smear instrument use needs further development. They may also indicate the essential component of the data collector. Differences cannot necessarily be solely attributed to the instruments themselves. Perhaps the user of the instrument is where focus should lie. Clinician's error might be reduced with a simpler and one-step data collection method.

Frequency of cytological abnormalities (atypical squamous cells of undetermined significance [ascus], LSIL, HSIL and carcinoma insitu) detection was higher in specimens collected with the cytobrush plus spatula compared to Cervex Broom alone. The difference was not significant but demonstrated a trend. The lack of statistical significance was attributed to small sample size (Dehbashi, Honarvar, & Montazar, 2002).

Not addressed by research but identified by clinicians, is the potential for cell injury by the cytobrush. Although this instrument is known to exfoliate endocervical cells from columnar epithelium and the transformation zone, anecdotal reports from clinicians suggest that fewer of these cells are intact. Intact cells are necessary for Pap smear interpretation. It may be that a Cervex Broom type device free of the present difficulties noted (instrument falls apart; leaves filaments in cervical canal) could address the issue of intact, thus readable, endocervical cells.

Summary

Pender's Health Promotion Model was used as the theoretical framework for this study. According to this model, perceived barriers and benefits to Pap smear screening can influence the behavioral outcome of obtaining Pap smear screening. To bolster women's confidence in Pap smear test results, use of liquid-based cytology in conjunction with a specimen collection instrument known to adequately sample both the exocervix and endocervical canal is essential.

Current literature supports the use of liquid-based cytology as opposed to conventional slide preparation of Pap smears. It is believed that the studies support the use of liquid-based cytology compared to the conventional Pap smear technology by increasing the sensitivity and specificity of cervical cancer screening and the detection of HSIL.

The use of the ctyo-brush along with the Ayers spatula is reported as superior to use of the Cervix Broom, ctyo-brush or spatula alone for exfoliating endothelial cells. However, clinicians have difficulty managing two separate data collection instruments, and literature reports of statistical significance between the Cervex Broom alone and cytobrush plus spatula suggest the latter method is

superior. Therefore, a new instrument is needed that has the benefits of the two-step process but also the ease of a one-step process. As well, the new instrument must meet the essential criteria of exfoliating endocervical cells in sufficient numbers with intact nuclei.

The next chapter describes a new Pap smear collection instrument that is expected to have the accuracy of the cytobrush plus spatula method and the ease of the Cervex Broom alone. Following a description of this new device, research studies are designed that are intended to provide beginning data on effectiveness.

CHAPTER 3

Development of A Collection Tool

In this chapter a new Pap smear collection instrument will be described. The purpose is to determine the effectiveness of the Wilson Broom (WB) as a single step collection method for obtaining Pap smear specimen material. To establish effectiveness and comparison data with a known method (cytobrush plus spatula) for Pap smear testing, studies must be designed and conducted. In this chapter, two research studies are proposed that would yield these beginning data.

Introduction

Despite its effectiveness as a public health intervention, it is recognized that the Pap smear is imperfectly sensitive and that effective screening is only achieved through repeated testing. 14-33% of women who have cervical cancer had a false negative Pap smear at the time of screening. In other words, these women screened negative for cervical cancer from previous Pap smears. Such failures can be attributed to sampling errors from instrumentation or clinicians: abnormal area of cervix was not sampled adequately, or abnormal cells were obtained yet not identified as abnormal (Hartman, Nanda, Hall, & Myers 2001).

Advances in cytologic screening and implementation of a new single step collection instrument (used with liquid-based cytology fixative) that adequately samples the transformation zone would improve detection of HSIL by reducing false-negatives, and decreasing misclassification. Increasing sensitivity and specificity data is the goal for cancer screening.

The aim of this project was to simplify and improve the collection method for Pap smear screening by designing a new single-step Pap smear collection instrument that will exfoliate endothelial cells from the columnar epithelial layer of the transformation zone. Providing information on transformation zone sampling has value in improving overall specimen quality and encourages efforts to optimize sample collection (JAMA. 2002).

Instrument Design

The Wilson Broom for Pap smear collection is comprised of a plastic adaptor that is 20 cm in length, 1 1/2 cm wide at the top broom end and 1cm wide at the base. The handle and base are made of polypropylene. The top, or data collection end, is made of soft plastic fibers attached to the polypropylene base. Extending between the soft plastic broom fibers is a rounded brush (long end) comprised of

microfilaments that extends 1/2 cm past the broom ends. See Appendix F for a schematic representation of the Wilson Broom. The instrument design accommodates material collection from the exocervix and the endocervix simultaneously. Cost of the device is not yet established, but it is expected that mass production will make the cost competitive.

Use of the Wilson Broom is a single step. The broom is inserted into the endocervical canal and rotated 180°. This affords sample material collection from the exocervix while sampling the endocervix. Should the transformation zone lie on the exocervix, broom filaments from the lateral aspects sweep the area. Should the transformation zone lie in the endocervical canal (not visible to the examiner), broom filaments attached close to the device handle that are in the cervical canal sweep the area. The long end of the broom is inserted into the endocervix with enough pressure to maintain contact with the epithelium but not induce bleeding. The broom is then rotated 180° in a clockwise direction. As the tool is slowly withdrawn from the endocervical canal the brush "sweeps" and fans across the exocervix for another 180° turn. The entire broom end of the instrument is placed in liquid-based cytology and swished 10

times to dislodge adequate amounts of the cervical material into the liquid fixative. Actual slide preparation for reading by a cytologist is conducted by laboratory personnel. Resultant slides are expected to contain sufficient quantities of cervical cells with intact nuclei for detection of abnormalities.

The Wilson Broom is designed to stay in contact with the endocervical canal and exocervix and to exfoliate an adequate number of endothelial cells. This will ensure a quality sample that will increase accuracy of Pap smear screening and encourage use of this health promotion behavior by women due to increased detection of HSIL, LSIL and CIN. Since the procedure uses one instrument only, it is expected to ease clinician burden and decrease errors that occur from a two instrument process such as dropping of the instrument due to juggling more than one at a time). This device will ensure adequacy of cervical cells and a clearer slide that is prepared by laboratory personnel. Air drying is never a problem with liquid-based cytology.

In order to discover the effectiveness of the Wilson Broom for Pap smear collection, research must be conducted. Two studies will be proposed as a beginning. In the first study, the instrument is pilot tested on 20 women. In the

second study, the Wilson Broom is compared to the combination of cytobrush plus spatula at obtaining adequate specimen and detecting cervical abnormalities.

Pilot Test of the Wilson Broom

The purpose of this study is to pilot test the Wilson Broom, a new cervical data collection instrument designed as a single-instrument device for Pap smear data collection. Following are the specific aims:

Aim #1. To describe the ability of the Wilson Broom to obtain an adequate sample for Pap smear testing.

Aim #2. To describe clinician response to use of the Wilson Broom for Pap smear sampling.

Study Design

A descriptive design will be utilized for this pilot study to detect the usefulness of the Wilson Broom in clinical practice. For this study, the Wilson Broom (WB) is used in conjunction with liquid-based cytology.

Patient Population

Twenty women who present to Clinic A at University Medical Center on 6/1/03 for an interim visit not related to cervical pathology will be approached to enroll in this pilot study. Five clinicians who work in Clinic A will be invited to participate. Signed consent forms from both women

participants and clinicians will be obtained. Inclusion criteria for women participants are female gender, age > 18 years, and no prior history of Pap smear abnormality. These criteria are necessary, because females < 18 years have a higher degree of menstrual cycle variation that might lead to specimen collection difficulties. Women with prior histories of abnormal Pap smear results require specimen collection with evidence-based methods. Since we are pilot testing a new instrument with unknown reliability and specificity, it is mandatory that we pilot the instrument on women without suspected cervical disease. Women will be excluded from this pilot study if they have not had a Pap smear within one year. This criterium is necessary as participants cannot rely on this Pap smear as their screening. English language proficiency is a requirement, as informed consent procedures are conducted in English. Women who are currently menstruating will be excluded as menses have historically interfered with Pap smear interpretation.

Inclusion criteria for clinicians are professional practice as a nurse practitioner, physician assistant, physician providing clinical services at Clinic A.

Instruments

Demographic Data: Demographic data on women participants and clinicians will be collected using the Women's Health Questionnaire developed by Woods, Lentz, Mitchell, Taylor, and Lee (1986). It is a self-administered survey of a women's health history. Only the demographic section will be utilized in this study. It includes 14 questions relating to education, marital status, current employment, household composition (who participant lives with), and total household income.

Pap smear Test: Women who agree to participate will have their Pap smear cervical material collected with the Wilson Broom. Cervical material will be placed in liquid-based cytology and submitted to the laboratory for cytologic interpretation.

Clinician Evaluation: A questionnaire has been developed for use with this study. It is a 6-item instrument with Likert Scale responses that range from Strongly Disagree (1) to Strongly Agree (5). Scores can range from 6 to 30 with higher scores indicating a higher evaluation of the Wilson Broom.

Data Analysis

Demographic data will be analyzed for the two groups separately using descriptive statistics and measures of

central tendency. Pap smear results will be analyzed by categorizing tests as adequate and inadequate. Results will be reported as number (#) adequate (that is, presence of endocervical cells with intact nuclei) divided by the total number of tests. The same calculation will be conducted to determine the number (#) inadequate tests/total number (#) of tests conducted. For the purposes of this study, the Number (#) adequate tests/total number (#) tests must be ≥.90 or 18 out of 20 tests. These analyses will answer specific aim #1.

Specific Aim #2 will be answered by totaling participant responses on the Wilson Broom Evaluation and reporting the mean total score. The mean total score can range from 6 to 30. An acceptable total mean score for the purposes of this study is >20. This would indicate that clinicians agree with ease of use and a general positive evaluation of the instrument.

Validity

Validity refers to whether or not the study measured what the researcher wanted to measure. The two types of validity that research designs should address are internal and external validity. Internal validity is whether the

independent variable really made the difference or the change in the dependent variable. Since this study has a nonexperimental design, there are no independent or dependent variables. Therefore many of the internal validity concerns are not of interest here. External validity deals with possible problems of generalizability of the findings to other populations or conditions.

Internal Validity

Internal validity issues related to research design are history, maturation, testing, instrumentation, mortality, and selection bias. The present proposed study is cross-sectional and descriptive. Therefore, issues of history, maturation, testing, and mortality do not apply. However, instrumentation and selection bias may be threats to validity in this proposed study.

Instrumentation poses a threat to internal validity in the proposed study, as more than one clinician will be doing the Pap smears. To reduce this threat, the principal investigator will train each clinician on the use of the Wilson Broom. The training will consist of demonstration and back demonstration to be certain that each clinician fully understands how to use it.

Selection bias is a potential threat to internal validity in this proposed study, as only one clinical site is to be utilized. However, to reduce this threat, every woman who meets the inclusion criteria will be asked if she is willing to participate. Age of participants who decline to participate will be noted and reported as a way to profile refusers. This will aid understanding of participants and their characteristics and allow readers to know whom results can be generalized to.

External Validity

External validity involves generalizing the findings to other persons in others places at other times. Threats to external validity include selection effects, reactive effects, and measurement effects. The only threat to external validity in this proposed descriptive study is the selection effect.

Selection effects refer to the generalizability of the results to other populations. Random selection of participants is the best way to maximize generalizability, but this is not possible in the proposed study. However to minimize the threat of selection effects, this study will include all women who meet the inclusion criteria at a single clinic on a designated day until the sample size (20)

is met. As well, the sample will be described on its demographic characteristics so that others can understand who the results can be generalized to.

Comparison of the Wilson Broom and Cytobrush plus Spatula Methods of Pap Smear Collection

In this second study, the Wilson Broom will be compared to the combination of cytobrush plus spatula at obtaining adequate specimen and detecting cervical abnormalities. Following are the specific aims:

Aim #1. To describe the ability of the Wilson Broom to obtain an adequate sample for Pap smear testing compared to the cytobrush plus spatula.

Aim #2. To describe the ability of the Wilson Broom compared to the cytobrush plus spatula for the detection of cervical tissue abnormalities.

Study Design Number Two

A two group descriptive design will be utilized to determine the comparative effectiveness of the Wilson Broom and the cytobrush plus spatula at obtaining adequate Pap smear samples and detecting cervical tissue abnormalities. Outcome measures will include the number of adequate and inadequate Pap smears per group plus the number of normal and abnormal Pap smears per group. Since the cytobrush plus

spatula collection method is the current standard, any abnormal findings will be considered as true abnormal findings. Failure of the Wilson Broom method to detect the same finding will be reported. Should the Wilson Broom method detect an abnormality not found by the cytobrush plus spatula, a repeat Pap smear will be advised. This too will be reported.

Sample

All women who present to Clinic A at University Medical Centers on 6/20/3 for Pap smear screening will be approached to enroll in this study until a total of 40 participants is obtained. Five clinicians who work in Clinic A will be invited to participate. Signed consent forms from both women participants and clinicians will be obtained. Once informed consent has been concluded, participants will be randomized to one of two groups by the toss of a coin. This procedure (and all informed consent procedures) will be conducted by the principal investigator. All participants in Group A will have their Pap smears collected in the order of Wilson Broom followed by the cytobrush plus spatula. Both specimens will be added to liquid-based cytology. Participants in Group B will have their Pap smears collected in the order of cytobrush plus spatula followed by the Wilson Broom. This

will minimize the risk that order of specimen collection will influence results.

Inclusion criteria for women participants are female gender, age > 18 years, and no prior history of Pap smear abnormality. These criteria are necessary, because females <18 years of age have a higher degree of menstrual cycle variation that might lead to specimen collection difficulties. Women who are currently menstruating will be excluded as menses have historically interfered with smear interpretation. In addition women who are pregnant or who have undergone hysterectomy will be excluded. Unlike the previous proposed study, women can be included who need Pap smear screening based upon time (>one year since last Pap smear) or prior history of Pap smear abnormality. Women who present for repeat Pap smears can also be included. This is possible as the cytobrush plus spatula collection instruments have known sensitivity and specificity and are the usual Pap smear collection method. English language proficiency is a requirement, as informed consent procedures are conducted in English.

Inclusion criteria for clinicians are professional practice as a nurse practitioner, physician assistant,

physician and currently providing clinical services at Clinic A.

Instruments

Demographic Data: Demographic data on women participants and clinicians will be collected using the Women's Health Questionnaire developed by Woods, Lentz, Mitchell, Taylor, and Lee (1986). It is a self-administered survey of a women's health history. Only the demographic section will be utilized in this study. It includes 14 questions relating to education, marital status, current employment, household composition (who participant lives with), and total household income.

Pap Smear Test: Women who agree to participate will have their Pap smear cervical material collected with the Wilson Broom and the cytobrush plus the spatula alternatively collecting endothelial cells from both the exocervix and the endocervical canal. Cervical material will be placed in liquid-based cytology and submitted to the laboratory for cytologic interpretation.

Data Analysis

Demographic data will be analyzed for the two groups separately using descriptive statistics and measures of central tendency. Pap smear results will be analyzed by

categorizing tests from the WB instrument in comparison with the conventional Pap smear as adequate and inadequate. Results will be reported as # adequate (that is, presence of endocervical cells with intact nuclei) divided by the total number of tests per group. The same calculation will be conducted to determine the # inadequate tests/total # of tests conducted. For the purposes of this study, the # adequate tests/total # tests must be 18 out of 20. These analyses will answer specific aim #1.

Specific aim #2 will be answered by calculating the total number of Pap smears divided by the total number of abnormal results per group. Since the cytobrush plus spatula collection method is the current standard, any abnormal findings will be considered as true abnormal findings. Failure of the Wilson Broom method to detect the same finding will be reported and considered as evidence that it has less sensitivity and specificity that the traditional cytobrush plus spatula method. Should the Wilson Broom method detect an abnormality not found by the cytobrush plus spatula, a repeat Pap smear will be advised. This also will be reported.

Validity

Internal and external validity issues can cause threats in this descriptive study. They will be discussed separately.

Internal Validity

Internal Validity is the approximate truth about inferences regarding cause-effect or causal relationships. Internal validity assess the effects of social programs (Pap smear screening) or interventions (invention of a new Pap smear collection instrument) that would be able to conclude that the program or treatment made a difference - it improved sensitivity and specificity. Since the current study is a nonexperimental design, there are no independent and dependent variables, and there is no attempt to establish causality. Therefore, many of the threats to internal and external validity found in studies with experimental designs do not exist.

Internal validity issues related to research design are history, maturation, testing, instrumentation, mortality, and selection bias. The present proposed study is cross-sectional and descriptive. Therefore, issues of history, maturation, testing, and mortality do not apply. However,

instrumentation and selection bias may be threats to validity in this proposed study.

Instrumentation poses a threat to internal validity in the proposed study, as more than one clinician will be doing the Pap smears. To reduce this threat, the principal investigator will train each clinician on the use of the Wilson Broom and re-train them on the use of the cytobrush plus spatula. The training will consist of demonstration and back demonstration to be certain that each clinician fully understands how to use both methods.

Another instrumentation threat is that the first method used might provide the most adequate and readable specimen. To reduce this threat, participants will be randomized to groups. Group A will have their Pap smears done in the order of the Wilson Broom followed by the cytobrush plus spatula. Group B will reverse the order.

Selection bias is a potential threat to internal validity in this proposed study, as only one clinical site is to be utilized. However, to reduce this threat, every woman who meets the inclusion criteria will be asked if she is willing to participate. Age of participants who decline to participate will be noted and reported as a way to profile refusers. This will aid understanding of

participants and their characteristics and allow readers to know who results can be generalized to.

External Validity

External validity involves generalizing the findings to other persons in others places at other times. Threats to external validity include selection effects, reactive effects, and measurement effects. The only threat to external validity in this proposed descriptive study is selection effects.

Selection effects refer to the generalizability of the results to other populations. Random selection of participants is the best way to maximize generalizability, but this is not possible in the proposed study. However to minimize the threat of selection effects, this study will include all women who meet the inclusion criteria at a single clinic on a designated day until the sample size (20) is met. As well, the sample will be described on its demographic characteristics so that others can understand who the results can be generalized to.

CHAPTER 4

Evaluation

In this chapter, the clinical project will be discussed in terms of potential outcomes. In addition, the plan for development and marketing will be provided. Implications for nursing science, practice, and for women's health will be proposed.

Potential Project Outcomes

Possible Results

One possible result would be that the Wilson Broom is equal to the results of the cytobrush plus spatula in obtaining an adequate Pap smear specimen and detection of cervical tissue abnormalities in both the pilot test and comparison.

Another result is that the Wilson Broom is highly superior in obtaining adequate Pap smears and detection of cervical tissue abnormalities in comparison to the cytobrush plus spatula.

The next possible result would be that the Wilson Broom was less than satisfactory in obtaining adequate Pap smears and in detection of cervical tissue abnormalities in comparison to the cytobrush plus spatula, although this

maybe difficult to detect. However, if the Wilson Broom was less than satisfactory in comparison to the cytobrush plus spatula the Pap results could be compared to actual coloposcopic findings.

Preferred by Clinicians

The Wilson Broom will be preferred by clinicians because of the ease of a one-step Pap smear instrument along with the increased sensitivity and specificity that will occur with the help of liquid based cytology. The increase in Pap smear screening could lead to pressure by clinicians to have the manufacture adopt and test market the instrument and this could mean quicker to market time.

Plan for Marketing and Development

The Wilson Broom will be marketed to medical instrument product development companies that specialize in Obstetrical and Gynecological instruments. Prior to any discussions concerning the design, implementation or marketing on the Wilson Broom, a product disclaimer will be signed. This will ensure that the Wilson Broom will not be copied if an agreement is not met with that company. Many medical instrument companies will help obtain the patent licensure for the inventor.

Implications for Nursing Science

Nurses today have so many doors open to them not only in research, but also in patient care, administration, business and free enterprise. Nurses that can harvest their creative genius and invent new technology that is useful in clinical practice and in research will add to the value of nurses as inventors and increase our marketability and professionalism.

Nursing science will benefit from nurses that conduct studies that relate directly to clinical practice. New technology that is less time consuming and that is reported to have a lower chance of clinician error can ultimately be cost effective. Nursing science can benefit from the successful development of new technology. Research that has direct implications for practice is valued by all nurses.

Nurses are expanding and broadening the scope of research activities by nurses. Nurses have great ideas, are very creative, inventive and have the first hand day to day experience for making a procedure simpler with equal or better results.

Implications for Practice

Nurses are charged with educating women about the importance of Pap smear screening, and they must also

educate women about the sensitivity and specificity of current technology. Data about new technology is a necessary ingredient to increase women's confidence in Pap smear screen and reliability of results. The initial education may be more time involved, however, with increased knowledge and confidence levels in the new Pap smear technology, women will be more compliant and in the long run, it will be less time consuming. In a clinic setting, a one step Pap smear collection instrument will decrease staffing and increase utilization of a nurse's time.

Implications for Women's Health

The implications for women's health are over the top. With the Wilson Broom women's confidence levels will rise due to the increase in sensitivity and specificity and the reliability of results women will be inclined to take better care of there health. They will know that this tool was invented by a woman, tested on women and endorsed by women. The increase in sensitivity will make reflex testing for HPV easier. Education for women will be from a knowledge base of increased reliability, ease of testing and greater accuracy of result.

Nurses as Entrepreneurs

With so much opportunity for nurses today it is the next natural step to be entrepreneurs. Nurses understand what needs to be done to complete day to day tasks. With their knowledge base, experience, skills and rich education nurses should harness their inventiveness to create simpler methods, techniques and tools with equal or greater results.

Relationship to the Theoretical Framework

The HPM related to this project has focused on the increasing sensitivity of Pap smears by implementing a new data collection instrument that will increase specificity and sensitivity. By increasing the sensitivity and specificity women will trust the results with more certainty. This will bolster compliance with Pap smear screening and increase health promoting behavior and decrease perceived barriers resulting in the likelihood of the health promoting behavior.

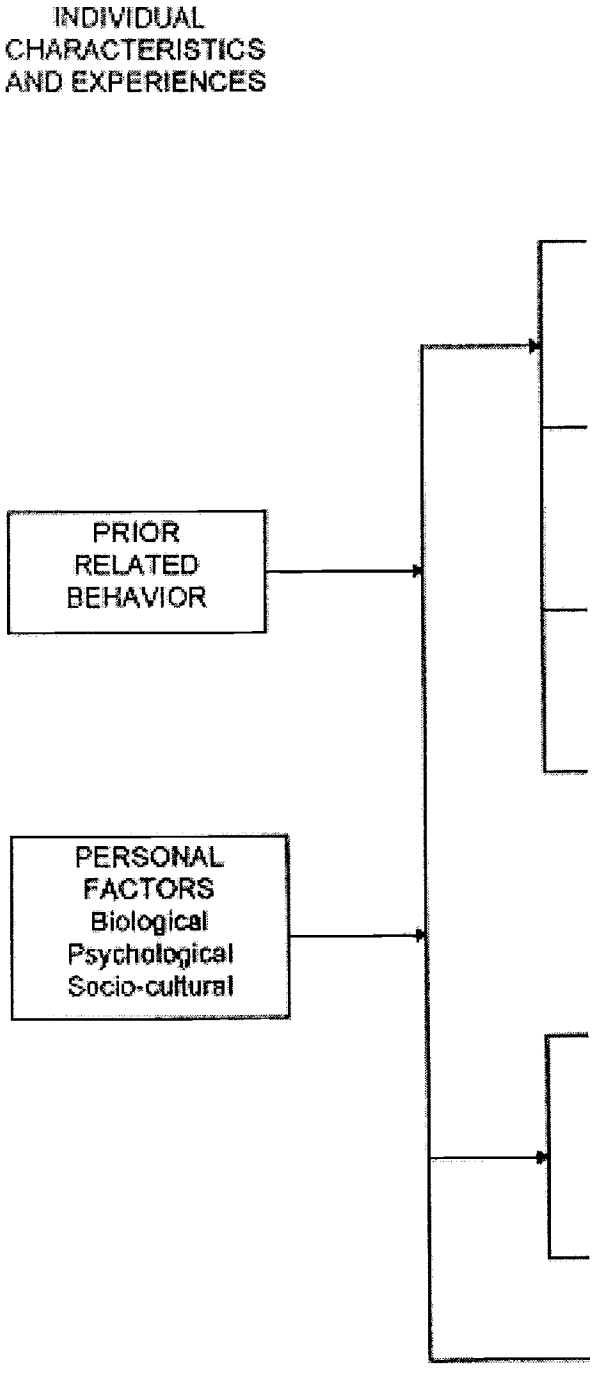
Chapter 5

Project Conclusion

Within the body of this project, cervical cancer disease was introduced, the current instruments for Pap smear screening were described, problems related to Pap smear screening and collection were discussed and creation of a new Pap smear collection instrument, the Wilson Broom was introduced. Beginning research was described to test this single instrument Pap smear collection tool. The Wilson Broom will allow clinicians the ease of a single instrument for the collection of cervical samples. The Wilson Broom will exfoliate endothelial cells with intact nuclei that will allow the cytologist to view the abnormal cells more clearly, therefore permitting prompt intervention and treatment LSIL, HSIL, CIN and differentiate between reactive and dysplastic cellular changes within the nuclei of the endothelial cells. Ultimately this single step collection instrument will improve cervical cancer screening by increasing women's confidence in results and will improve detection and early intervention for detection of dysplasia and cervical cancer, thus impacting the individual, family and community by impeding the process of this curable disease.

Appendix A

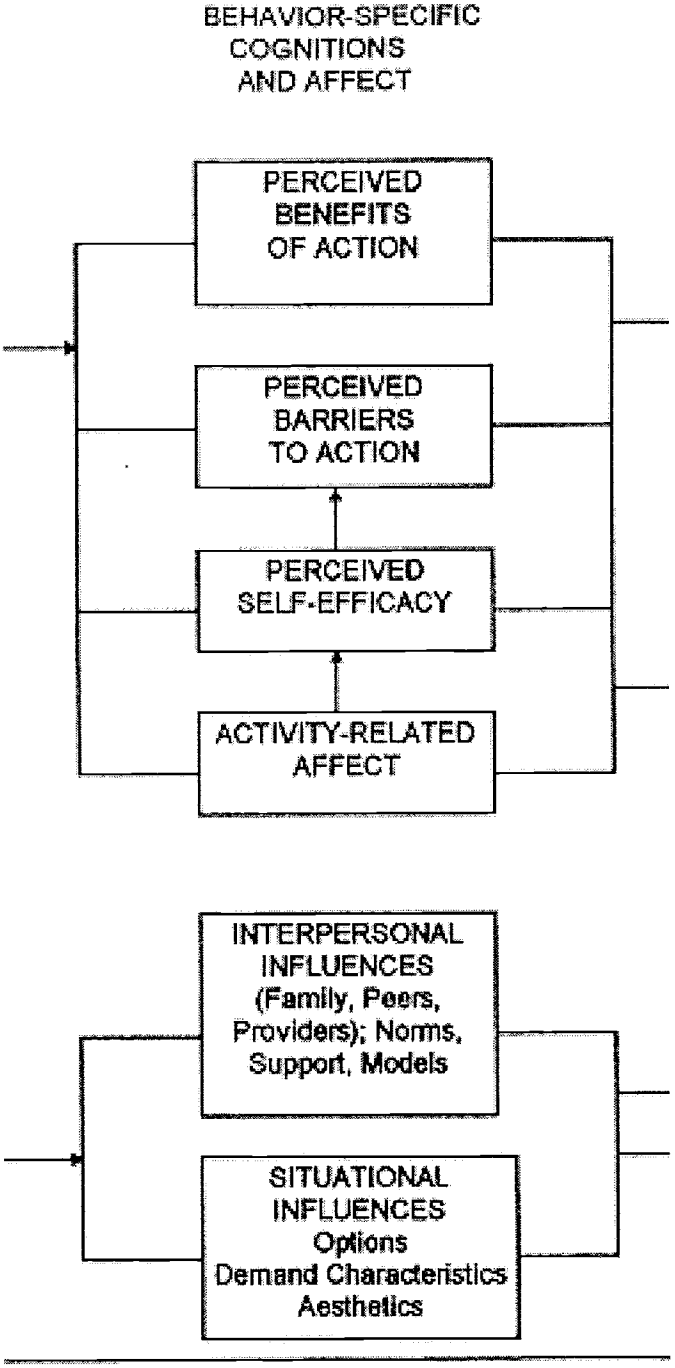
HPM Individual Characteristics and Experiences



Revised Health Promotion Model

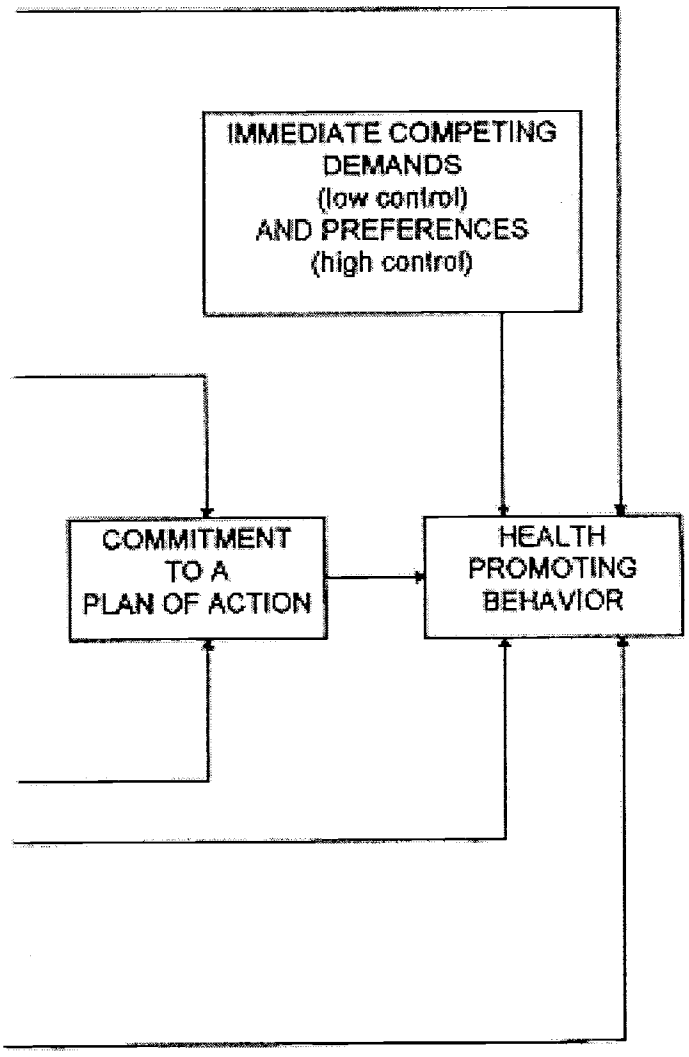
Appendix B

Behavior-Specific Cognitions and Affect



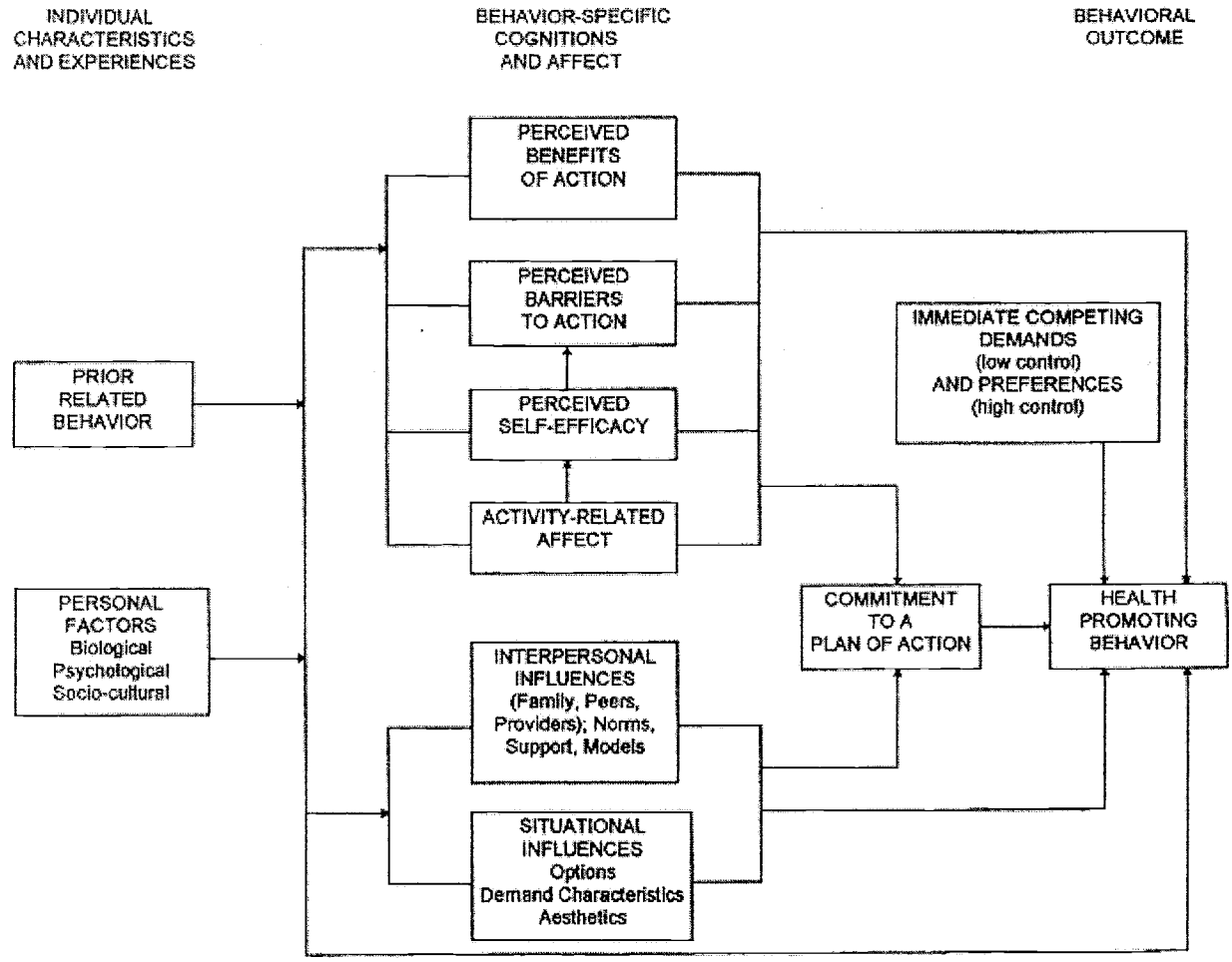
Appendix C

Behavioral Outcome



Appendix D

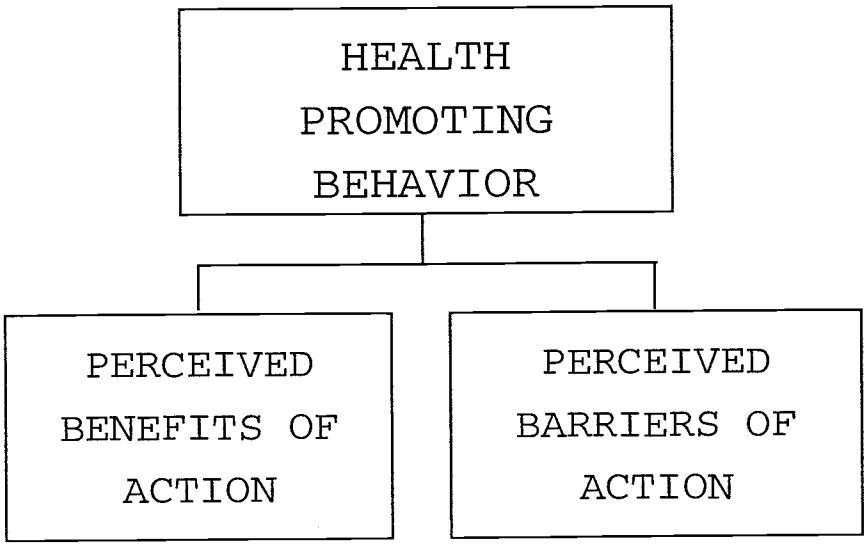
Health Promotion Model



Revised Health Promotion Model

Appendix E

HPM Applied to this Project



Appendix F

Wilson Broom Evaluation

Directions: Please answer the following questions by circling the one best answer that describes your response to the Wilson Broom for Pap smear data collection. Your responses range from "strongly agree" to "strongly disagree". Thank you very much for participating in this study.

KEY
5 = Strongly Agree
4 = Agree
3 = Neutral
2 = Disagree
1 = Strongly Disagree

1. The Wilson Broom is easy to handle.

1. 2. 3. 4. 5.

2. The Wilson Broom appears to collect cervical material for Pap smear adequately.

1. 2. 3. 4. 5.

3. I had no difficulty collecting cervical material using the Wilson Broom.

1. 2. 3. 4. 5.

4. The Wilson Broom remained intact during the sampling procedure.

1. 2. 3. 4. 5.

5. The Wilson Broom takes less of my time than the cytobrush plus spatula method.

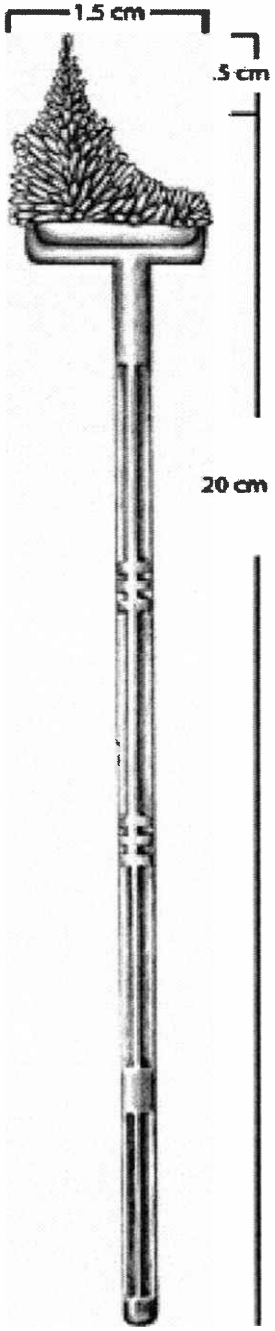
1. 2. 3. 4. 5.

6. I like the Wilson Broom.

1. 2. 3. 4. 5.

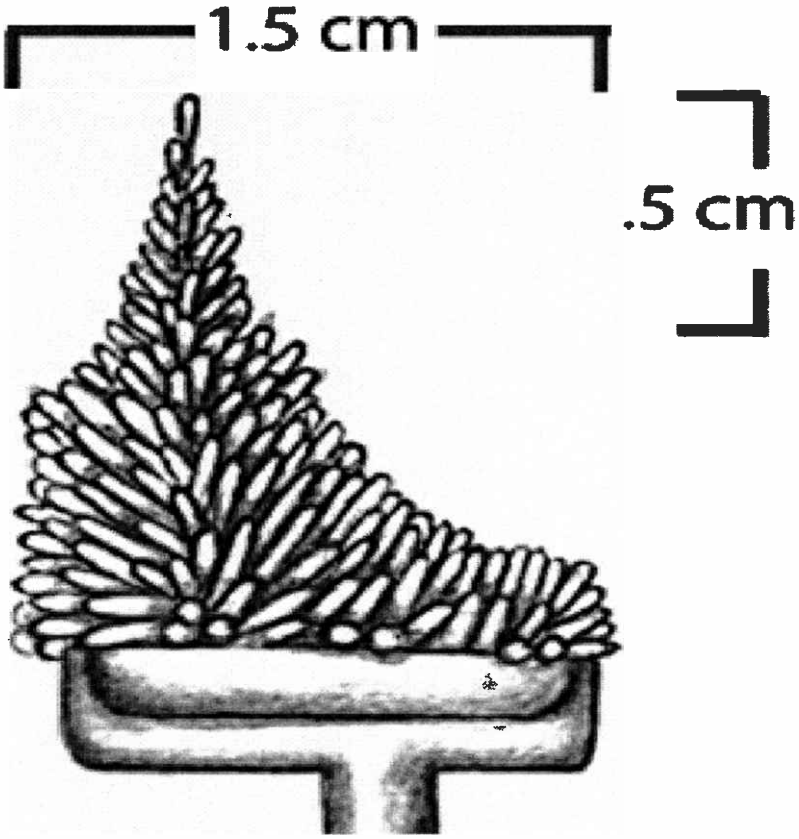
Appendix G

The Wilson Broom



Appendix H

The Wilson Broom Top



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