ELSEVIER

Contraception

Contraception 67 (2003) 115–132
Original research article

Counseling in the clinical setting to prevent unintended pregnancy: an evidence-based research agenda

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Abstract

Context: Unintended pregnancies account for about half of all pregnancies in the United States and, in 1995, numbered nearly 3 million pregnancies. They pose appreciable medical, emotional, social and financial costs on women, their families and society. The US is not attaining national goals to decrease unintended pregnancies, and little is known about effective means for reducing unintended pregnancy rates in adults or adolescents.

Objective: To examine the evidence about the effectiveness, benefits and harms of counseling in a clinical setting to prevent unintended pregnancy in adults and adolescents and to use the evidence to propose a research agenda.

Data sources: We identified English-language articles from comprehensive searches of the MEDLINE, CINAHL, PsychLit and other databases from 1985 through May 2000; the main clinical search terms included pregnancy (mistimed, unintended, unplanned, unwanted), family planning, contraceptive behavior, counseling, sex counseling, and knowledge, attitudes and behavior. We also used published systematic reviews, hand searching of relevant articles, the second *Guide to Clinical Preventive Services* and extensive peer review to identify important articles not otherwise found and to assure completeness.

Data synthesis: Of 673 abstracts examined, we retained 354 for full article review; of these, we used 74 for the systematic evidence review and abstracted data from 13 articles for evidence tables. Four studies addressed the effectiveness of counseling in a clinical setting in changing knowledge, skills and attitudes about contraception and pregnancy; all had poor internal validity and generalizability and collectively did not provide definitive guidance about effective counseling strategies. Nine studies (three in teenage populations) addressed the relationship of knowledge on contraceptive use and adherence. Knowledge of correct contraceptive methods may be positively associated with appropriate use, but reservations about the method itself, partner support of the method, and women's beliefs about their own fertility are important determinants of method adherence that may attenuate the knowledge effect. Many factors influence contraceptive use and adherence; among them are age, marital status, ambivalence about becoming pregnant, attitudes of partner, side effects, satisfaction with provider and costs; however, the impact of such factors may not be consistent across populations defined by cultural, age or other factors. The studies themselves differed materially in outcome variables, populations and methodologies and did not yield a body of work that can reliably identify specific influences on contraceptive use and adherence. No literature reports on harms of counseling or on the costs or cost-effectiveness of different approaches to counseling about unintended conceptions in the primary care setting.

Conclusion: Virtually no experimental or observational literature reliably answers questions about the effectiveness of counseling in the clinical setting to reduce rates of unintended (unwanted, mistimed) pregnancies in this country. Existing studies suffer from appreciable threats to internal validity and loss to follow-up and are extremely heterogeneous in terms of populations studied and outcomes measured. The quality of the existing research does not provide strong guidance for recommendations about clinical practice but does suggest directions for future investigations. Numerous issues warrant rigorous investigation. © 2003 Elsevier Science Inc. All rights reserved.

Keywords: Unintended pregnancy; Counseling; Contraception

1. Introduction

Nearly half (49.2%) of all pregnancies in the United States are unintended. This percent translates into 3 million unintended pregnancies in 1995, the last year for which data are available [1]. The experience affects large numbers of women; 48% of those ages 15 to 44 years have experienced at least one unintended pregnancy [1]. Experts generally believe that nearly 50% of unintended pregnancies are aborted [2]. The social, medical and economic impact of unintended pregnancies is significant. The Institute of Med-

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doi:10.1016/S0010-7824(02)00472-9

icine (IOM) detailed studies examining the effects of "unintendedness"—i.e., of unwanted and mistimed pregnancies—on children, women, men and families [2]. The IOM report concluded that such pregnancies, especially those that are unwanted, carry appreciable risks, many of which burden the nation's health resources. Such pregnancies are associated with elective abortions, late entry to prenatal care, low birth weight, child abuse and neglect, behavioral problems in the children and lower educational and economic attainment in young mothers. The high social costs of these pregnancies suggest an important prevention opportunity for clinical encounters.

The 1996 edition of the *Guide to Clinical Preventive Services* from the US Preventive Services Task Force (USPSTF) recommended counseling to prevent unintended pregnancy: "Periodic counseling about effective contraceptive methods is recommended for all women and men at risk for unintended pregnancy" [3]. It continued: "Counseling should be based on information from a careful sexual history and should take into account the individual preferences, abilities, and risks of each patient. Sexually active patients should also receive information on measures to prevent sexually transmitted diseases" (p. 749). In *Healthy People 2000*, the federal government indicated that the prevention of unintended pregnancies was a priority for the nation. The national health objective was to "reduce to no more than 30% the proportion of all pregnancies that are unintended" (citing a baseline of 56%) [4]. The *Healthy People 2010* objective has been restated to provide an element of positive direction, but the intent and target remain unchanged. The new objective reads: "Increase the proportion of pregnancies that are intended: Target 70% (baseline 51%)" [5].

Although no specific content or method of counseling has been recommended, the IOM, the USPSTF, and others agree that clinicians should consider counseling their patients to reduce the risk of unintended pregnancy. To identify effective, evidence-based information for clinicians, we systematically reviewed the published literature from the United States that addressed counseling in the clinical setting to prevent unintended pregnancy.

2. Materials and methods

2.1. Key questions

Five key questions guided this review:

1. How effective is counseling in a clinical setting to prevent unintended pregnancy in changing knowledge, skills and attitudes?
2. What are the influences on contraceptive use and adherence (often referred to as compliance)?
3. What is the association between behaviors that support fertility desires and the prevention of unintended conceptions?
4. What are the potential harms of contraception counseling?
5. What is the cost-effectiveness of counseling in the clinical setting to prevent unintended pregnancy?

2.2. Inclusion/exclusion criteria

We used numerous search strategies to identify the English-language literature likely to answer the key questions. To maximize the likelihood of identifying a coherent body of evidence, especially related to recent contraceptive methods, we included only articles that reported data collected in or after 1985. The review was undertaken in 2000 and included literature published in that year. Because cultural, religious and political influences are likely to be important determinants of the impact of counseling about fertility decisions and contraceptive actions, we decided that the generalizability of findings from foreign studies could not be assumed and therefore excluded all studies done outside the United States.

The search strategies aimed to identify all research on counseling approaches in a clinical setting targeted toward the prevention of unintended pregnancy, including abstinence counseling. We tried initially to mount a search strategy for each key question. Because the body of research relative to counseling to prevent unintended pregnancy in a clinical setting is so limited, the results of these searches were either irrelevant or redundant. Often the searches found large number of articles on abortion and prenatal care, neither of which was the focus of the review. Eventually, we decided to do a combined search using the key words *pregnancy*, along with the descriptors *unwanted* or *mistimed* or *unintended* or *unplanned* alone and in combination with the terms *contraceptive behavior*, *counseling* and *family planning*. Once relevant articles were identified using this search strategy, it was later determined during the article review process which, if any, key question a specific article addressed.

The formal MEDLINE searches did not identify some highly relevant articles. When we probed, we found that these articles were indexed as "pregnancy" with no further refinement in coding that would lead us to a new strategy. Thus, we supplemented MEDLINE searches with citations from relevant articles, book bibliographies and recommendations from experts in the field. We also searched the Cochrane Collaboration database, PsychLit and the Cumulative Index for Nursing and Allied Health Literature (CINAHL).

Two of the authors independently reviewed the titles and abstracts of the articles identified by the literature searches and excluded ones that they agreed did not meet eligibility criteria. Abstracts on editorials and opinion pieces, case studies, literature reviews and community-based interventions were designated as "background." Abstracts that suggested experimental and cohort designs, cross-sectional data or qualitative methodology were advanced for full article

review. If the reviewers disagreed about designation of an article during the abstract review, the article was reviewed in full again by both authors.

2.3. Literature preparation and synthesis of systematic evidence review

We ultimately reviewed 673 abstracts, keeping approximately half (n = 354) for full article review. After full review, we retained 74 articles for use in the systematic evidence review as either background and context material or for the evidence tables. All studies that met our inclusion criteria (published after 1984; set in a US clinical setting; cohort, experimental or cross-sectional in design), irrespective of quality, were abstracted and put into the evidence tables. One study [6] was entered into two different tables because of its relevance to two of the key questions. We included studies that did not feature an experimental design but addressed a key question through cohort and cross-sectional designs (e.g., influences on contraceptive use and adherence). We subsequently eliminated 10 studies from the tables because their methodologies were evaluated as too flawed to contribute to answering the key questions [7–16]. Thirteen articles were uncovered that described the results of experimental or cohort designs and these are included in the evidence tables. The evidence tables are organized according to the five key questions. Articles are placed in alphabetical order in the table that most closely aligns with the study's intent and/or findings.

3. Results

3.1. How effective is counseling in changing knowledge, skills and attitudes?

Four studies conducted a decade ago investigated different subpopulations of individuals at risk of conception. These are described in detail in Table 1. The first study listed, conducted by Adams and colleagues, compared adolescent mothers who experienced a subsequent pregnancy to those who did not and found no significant difference in the contraceptive knowledge scores between the two groups [17]. Although this study has various weaknesses (very small sample, a large percentage of the sample lost to follow-up, and an unvalidated questionnaire), it suggested that the theoretical framework of knowledge, attitudes and skills may not be the only or even the key determinant in successful contraceptive use.

Danielson and colleagues, in the only randomized controlled trial (RCT) we found, investigated the impact of a reproductive health program on sexual behavior among 1,195 men 15 to 18 years of age receiving care from a West Coast health maintenance organization (HMO) [6]. The program involved a "highly explicit" half-hour slide-tape program followed by a personal health consultation by specially trained nonphysician providers. On the basis of self-report, the association between the intervention and use of effective contraception was statistically significant among the young men who were sexually active at follow-up [odds ratio: (OR) 1.51; $p < 0.05$]; the finding was even stronger among young men who had not been sexually active at baseline (OR: 2.53; $p < 0.01$). Knowledge about sexually transmitted diseases and the fertility cycle was also significantly different in the intervention group ($p < 0.001$ and $p < 0.01$).

Namerow and colleagues tried to determine if individually designed pregnancy prevention plans designed to address likely problems in using a chosen method affected contraceptive use and pregnancy rates [18]. Of 914 women enrolled in the study from a New York City family-planning clinic, 502 received traditional family-planning counseling (education and method choice); 412 received counseling that included the enhanced contingency planning (additional attention to possible problems that might arise with the method such as side effects, pressure to discontinue, difficulty in obtaining the method, etc.). Although both patients and staff evaluated the contingency planning approach favorably, the two groups did not differ significantly in the outcomes measured (clinic follow-up; contraceptive continuation or adherence). The lone exception was that, at 6 months, previously pregnant patients receiving contingency planning were significantly less likely than their traditionally counseled counterparts to have become pregnant again ($p < 0.05$); the difference disappeared by 12 months.

Winter and Breckenmaker evaluated special protocols for the care of teenage family-planning patients in six nonmetropolitan family-planning clinics [19]. Adolescents in the experimental group who received in-depth counseling were more likely to continue to use a method of contraception at 6 ($p < 0.01$) and 12 months ($p < 0.05$) after exposure, less likely to report difficulty in dealing with problems with the method ($p < 0.01$), and more likely to continue using the method despite problems ($p = 0.01$); they also had higher knowledge acquisition from educational programs provided in all the clinics. Comparability of the two populations is difficult to determine, and loss to follow-up was very high: only 39.1% of patients from experimental sites and 37.8% from control sites attended their 12-month follow-up visit.

We judged these four studies, collectively, to have been poorly designed (low internal and external validity) and to have offered little comparable information. We concluded, therefore, that no robust evidence exists to determine effective counseling approaches for changing knowledge, attitudes or behaviors.

3.2. What influences contraceptive use and adherence?

Numerous factors influence knowledge about contraception [7,18–21] and adherence with or continuation of contraception [22–28]. Tables 2A–C presents study design and

Table 1
Effect of counseling in a clinical setting on knowledge, skills and attitudes change

Source: Author, Year	Study population	Enrollment and definition of groups	Design/ time frame	Methods and measures	Results	Conclusions	Quality considerations
Adams et al., 1990 [17] Study objective: Identify differences between teens enrolled in a comprehensive clinic who had a repeat pregnancy within 2 yrs of first pregnancy and those did not	Females, 12–19 yrs IQ >85 75% AA	79 women enrolled in larger study of pregnant teens who received individual and group interventions in comprehensive program for pregnant teens 43 (54%) of these teens were located 2 yrs after enrolling in the program	2-yr cohort study with retrospective analysis	Methods: Self-administered questionnaire given at baseline and 2 years after delivery Retrospective analysis comparing survey results between the subjects who had second pregnancies and those that did not Measures: Locus of control Contraceptive knowledge School attendance Graduation from high school Support from teen's mother	23 (53%) of located teens had a 2nd pregnancy during the 2-yr period These teens did not differ significantly from the nonrepeaters by demographics (race, age, education), contraceptive knowledge scores, contraceptive use, locus of control scores, maternal support or program activities (including prenatal attendance or SW visits)	Authors and Reviewers: The reasons for repeat pregnancies in teens are complex, multifactorial and very difficult to measure.	Self-report Small sample size Large percent lost to follow-up (selection bias). Retrospective questionnaire not previously validated. Generalizability: urban teens only
Danielson et al., 1990 [6] Study objective: Impact of a reproductive health program on sexual behavior	Males 15–18 yrs 91% white 5% AA 4% Asian 44% with college-educated parents	2,602 eligible males 2,444 reached by phone 1,449 enrolled 971(67%) completed Inclusion: Boys who received care at HMO in Portland, Oregon and Vancouver Washington between 6/85 and 11/86	Randomized controlled trial with 1-yr follow-up	Methods: Slide presentation followed by reproductive health consultation with FNP, PA or RN Questionnaire given to intervention and control groups at baseline and 1 yr later Measures: Sexual activity Sexual knowledge "Sexual impatience"	In total group: 37% of subjects were sexually active at baseline; 53% were 1 yr later No difference was seen in increase of sexual activity in intervention vs. control group At 1-yr follow-up, the intervention group was statistically different by: likelihood of having partner using OCPs if sexually active (OR = 1.66); likelihood of being "sexually impatient" (OR = 0.64); knowledge score of protection for STDs (OR = 1.98); and knowledge score about fertility cycle (OR = 1.37).	Authors: Reproductive counseling session in primary care setting can have potential impact on knowledge about STDs fertility cycles and perhaps on use of OCPs in female partners and may decrease "sexual impatience." Counseling does not increase sexual activity. Reviewers: This evidence suggests that counseling may affect knowledge but unclear if it changes behavior.	Self-report of outcomes Possible selection bias: many parents or subjects refused study Little information given comparing intervention and control groups. Generalizability: HMO setting; higher income; mostly white No intention-to-treat analysis

Continued

Table 1
Continued

Source: author, year	Study population	Enrollment and definition of groups	Design/ time frame	Methods and measures	Results	Conclusions	Quality considerations
Namerow et al., 1989 [18] Study objective: Determine if an individually designed pregnancy prevention plan including contingency planning affected contraceptive use and pregnancy outcomes	Females, 33% < 20 yrs 5.2% white 40.8% AA 49.8% Hispanic 4.2% other 51% on public assistance 55.8% completed > 12 grade	823 new and returning patients to hospital FP clinic in NYC who requested contraception between 3/85 and 10/85 502 in traditional counseling groups 412 in contingency planning counseling group 73% of total completed study	12-month longitudinal cohort study.	Methods: Women were assigned to counselors based on availability; some got counselors trained in contingency planning and others did not. All got face-to face interview at baseline with phone interview at 6 and 12 months. Measures: Correct use of method Use of plan in contingency-counseled patients Demographic data Reproductive histories Pregnancy rate	The group who received contingency planning as part of their counseling showed a statistically significant increase in effective pill use in the first 6 mos ($p < 0.05$). This effect disappeared after 12 mos. At 6 mos the rates of unintended pregnancy were lower in study participants who had previously been pregnant if they received the contingency counseling ($p < 0.05$). This effect disappeared at 12 mos.	Authors: There may be some benefit to including contingency counseling in contraceptive education session in FP clinics. Reviewers: This study may inform clinicians on need to counsel about contingency planning, but the weak design and little provided information lessened the strength of conclusions.	Self-report Nonrandomized Large potential selection bias Counselors who provided the contingency planning were different people than those providing the traditional counseling There was no script and the skills of the counselors varied Difficult to replicate 12-mo data scarce due to poor follow-up rates. Generalizability: No age info given but good race variability, urban setting.
Winter and Breckenmaker, 1991 [19] Study objective: Evaluate the use of a unique educational intervention focusing on psychosocial needs, and its effect on contraceptive use and pregnancy prevention in teens	Females, < 18 yrs 98% white No other info provided	1,256 teens were enrolled from 6 FP clinics in urban area. 518 received the experimental counseling intervention. 39% of the clients returned in 1 year.	1-yr longitudinal cohort study	Methods: Site-specific intervention Experimental group received education in a 1-on-1 setting using visual aids, 2 separate appts, longer visits with specially trained staff, participation of males and others encouraged. Counseling emphasized recognizing peer pressure, parental communication, and confidentiality.	Results were analyzed at baseline, 6 and 12 mos. Significant differences in knowledge improvement occurred in the experimental group between baseline and 6 mos ($p = 0.015$) and significant differences in use of original contraceptive method occurred between the experimental group and controls at 6 mos and 12 mos ($p < 0.01$).	Authors: Tailoring family-planning services to special needs may have benefits (including increased contraceptive use and decreased pregnancy rates).	Large number of patients dropped out (limiting follow-up). The interventions were site-specific, introducing a possible selection bias by choice of clinic site and variation from site to site.

Continued

Table 1
Continued

Source: author, year	Study population	Enrollment and definition of groups	Design/ time frame	Methods and measures	Results	Conclusions	Quality considerations
		738 received usual FP clinic care (control group). 37.8% of these subjects returned in 1 year		Control group received "usual care" (not described further). Self-administered questionnaires given to both groups at baseline, 6 mos and 12 mos. Measures: Knowledge Patient satisfaction Method use No-show or continuity rates Rates of unintended pregnancy	Of those women in either group who reported side effects or problems with their method, those in the experimental group were more likely to continue use of method ($p < 0.05$). There was a trend toward significant difference in pregnancy rates between groups at 12 mos ($p < 0.10$). Educators spent an extra 20 minutes with each teen in the experimental group (increasing the personnel time).	Reviewers: Costs (including provider time) increase with this intervention and measured benefit was small.	Difficult to pinpoint what in this intervention worked (description of intervention not detailed)—would be difficult to replicate. Generalizability: Little demographic data given

AA = African American; FNP = family nurse practitioner; PA = physician assistant; RN = registered nurse; SW = social worker; OCP = contraceptive pill; STD(s) = sexually transmitted disease; FP = family planning; HMO = health maintenance organization; NYC = New York City.

results information for nine investigations pertaining to these issues done between the late 1980s and late 1990s.

3.2.1. Relationship of knowledge to contraceptive use and adherence

The only RCT reviewed [6] suggested that attention to men may affect contraceptive practice and that the educational intervention may have served to move sexually active young men toward increasingly effective contraceptive practice. Although the impact of the intervention was modest and not measured beyond 1 year, patient education emphasis on sexuality may have had a restraining rather than encouraging effect on the sample's sexual behavior.

Jaccard et al. set out to determine if knowledge about contraceptive use translates into accurate behaviors in diaphragm habits [20]. In their work, 111 women who participated in a larger study on the components of effective fertility regulation and who were starting, continuing or restarting the diaphragm were interviewed at enrollment and in two follow-up periods, each about 4 months apart. Subjects had to identify the diaphragm as their major method of birth control during the entire 8 months of the study. Knowledge about what a woman should do to use a diaphragm correctly was relatively high and persistent during the entire study; however, knowledge of correct behavior did not necessarily translate into correct use: The study found three motivational factors which the authors believe family-planning practitioners should consider in their counseling: reservations about the method to be used, partner support of the method and beliefs about own fertility were important determinants of method adherence. Although the report provides little information about the subjects and, therefore, limits any generalization, important strengths of the work were analyses for selection bias, retention bias and retesting bias. The researchers concluded that the biases were minimal.

Oakley and Bogue reported that general knowledge about contraception predicts positive condom use behaviors [21]. Their intervention included randomly assigning (based on clinic session) women who were attending health department family-planning clinics to usual care (the control group) or one of four intervention groups: usual care plus a brochure; usual care, brochure and face-to-face expanded nursing care; all of the above plus a telephone interaction approximately 6 weeks after the initial clinic visit; or all of the above with a clinic visit at 6 weeks rather than the telephone interaction. Using multiple linear regression, they found that more effective condom use was reported by women who did not have a history of an induced abortion, were not using condoms only because they were starting oral contraceptive pill regimens, had more knowledge about birth control in general, and had more communication with their partner in relation to sex, birth control and use of birth

Table 2A
Influences on knowledge about contraception

Source: author, year	Study population	Enrollment and definition of groups	Design/ time frame	Measures and methods	Results	Conclusions	Quality considerations
Danielson et al., 1990 [6] Study objective: Impact of a reproductive health program on sexual behavior	Males, 15–18 yrs 91% white 5% AA 4% Asian 44% with college-educated parents	2,602 eligible males 2,444 reached by phone 1,449 enrolled 971(67%) completed Inclusion: Boys who received care at HMO on Portland, Oregon and Vancouver, Washington between 6/85 and 11/86	Randomized controlled trial with 1 yr follow-up	Methods: Slide presentation followed by reproductive health consultation with FNP, PA or RN. A questionnaire was given to intervention and control groups at baseline and 1 yr later Measures: Sexual activity Sexual knowledge "Sexual impatience"	In total group: 37% of subjects were sexually active at baseline—53% were 1 yr later No difference in increase of sexual activity was observed in intervention vs. control group At 1 yr of follow-up the intervention group was statistically different by: likelihood of having partner using OCPs if sexually active (OR = 1.66); likelihood of being "sexually impatient" (OR = 0.64); knowledge score of protection for STDs (OR = 1.98); and knowledge score about fertility cycle (OR = 1.37).	Authors: Reproductive counseling session in primary care setting can have potential impact on knowledge about STDs, fertility cycles and perhaps on use of OCPs in female partners and may decrease "sexual impatience." Counseling does not increase sexual activity. Reviewers: This evidence suggests that counseling may impact knowledge but unclear if it changes behavior.	Self-report of outcomes Possible selection bias: Many parents or subjects refused study Little information given comparing intervention and control groups Generalizability: HMO setting, higher income; mostly white No intention-to-treat analysis
Jaccard et al., 1996 [20] Study objective: Determine if knowledge about contraceptive use translates into accurate behavior, and if not—what influences behavior?	Females, 14–46 yrs No race or income data provided	375 diaphragm users identified from a larger study group; 298 enrolled 111 (37%) completed study Inclusion: Clients in 1 of 10 FP clinics in NYC enrolled in larger study—all used diaphragm as main source of contraception during entire study period.	8-mos longitudinal cohort study	Methods: 2-hr interview and written questionnaires (read aloud if necessary) repeated at 4 and 8 mos. Measures: Contraceptive accuracy Attitudes toward contraceptives Attitudes toward becoming pregnant Perceived susceptibility to pregnancy and partner's attitudes toward contraception Pregnancy	No significant correlation was seen between knowledge and contraceptive accuracy. Motivation factors (attitudes toward contraceptives and becoming pregnant, perceived risk of pregnancy, partner's perceptions of methods) influence accurate use of methods ($p < 0.05$ for correlations and $p < 0.01$ for these factors in a multiple regression analysis).	Authors: Contraceptive knowledge does not predict contraceptive use. Motivational influences on client and partner are of equal importance. Reviewers: The findings suggest that knowledge is necessary but not sufficient for effective contraceptive behavior	Self-report Selection bias (subjects volunteered for study) Multiple measures and scoring systems were used to quantify attitudes and beliefs. Generalizability: No race info given

Continued

Table 2A
Continued

Source: author, year	Study population	Enrollment and definition of groups	Design/ time frame	Measures and methods	Results	Conclusions	Quality considerations
Oakley and Bogue, 1995 [21] Methods described only in Oakley et al., 1989 [23] Study objective: Analyze the determinants of quality condom use after first FP clinic visit	Female of reproductive age (no specifics given) 89% white	1,819 women seen for first visit at a HD FP clinic in Michigan between 2/87 and 4/89 1,311 completed outcome interviews 360 identified as condom users Subgroups included: Condom/pill users (158) Condom only (24) Other condom users (178) Follow-up rate not given	12-mos longitudinal cohort study	Methods: Subjects were part of a larger study where they were randomized into one of five groups: (a) usual care, (b) usual care plus brochure, (c) same as (b) plus face-to-face expanded nursing care (following components of self-care counseling model), (d) same as (c) plus a 6-week follow-up phone call, (e) same as (d) but without the nursing intervention Self-administered questionnaire given initially with a phone survey in 6–12 mos (average 8 mos) Measures: Behaviors associated with effective condom use Attitudes about sex, contraception and pregnancy Communication with partners and family support	Of the 1,247 women who reported sexual activity in last year 29% were condom users (13% condom/pill users, 2% condom only, and 14% occasional condom users). Of these, only 1% engaged in all 5 quality condom use behaviors Statistically significant predictors of quality condom use were the following: History of prior abortion ($p = 0.011$); Receiving a nursing intervention ($p = 0.004$); Using condoms exclusively ($p = 0.031$); Having more than average contraceptive knowledge ($p = 0.001$); Having more frequent partner communication about sex and contraception ($p = 0.001$) Variables that did not predict quality use included (not significant): age, marital status, race, income, attitudes about sex and contraceptives, contraceptive self-care ability, family support, number of partners, and importance of not becoming pregnant	Authors: Pill users are at risk for poor-quality condom use; general knowledge about contraception predicts positive condom use behaviors; partner communication is important to quality condom use; an education intervention improved condom use behaviors Reviewers: The study suggests that education through counseling (along with other personal factors) influences effective condom use	Self-report Nursing intervention described only in another published study Generalizability: Largely white population with little demographic info given

AA = African American; FNP = family nurse practitioner; PA = physician assistant; RN = registered nurse; STDs = sexually transmitted disease; FP = family planning; NYC = New York City; HMO = health maintenance organization; HD = health department.

control. Attitudes about birth control and the reported importance of avoiding conception did not predict better condom use. When combined into one group, the women in the intervention groups did have more effective condom use than those in the control group. However, when each intervention group was analyzed independently, no specific intervention modality affected condom use, making conclusions regarding ideal counseling interventions impossible.

3.2.2. Influences on adherence and continuation of contraceptives

Adherence issues have been suggested as a major contributor for unintended pregnancies in women who conceive while having a contraceptive method available to them [1]. Several studies have examined influences on the consistent or inconsistent use of contraceptives [22–25]. These studies are described in detail in Evidence Table 2B. Jaccard and colleagues tested a model of individual differences that might moderate attitude-behavior consistency in the use of the diaphragm [20], using data on the 111 women described in the work discussed above [22]. Using a mathematical model to investigate the impact of attitudinal variables, they found that, for a subset of women, attitudes toward the diaphragm and becoming pregnant did not influence behavior. Inconsistency of diaphragm use was best predicted by negative experiences that close friends had in using a diaphragm, low levels of perceived susceptibility to pregnancy, alcohol consumption, concern about becoming too old to

Table 2B
Influences on compliance and continuation of contraception

Source: author, year	Study population	Enrollment and definition of groups	Design/ time frame	Measures and methods	Results	Conclusions	Quality considerations
Jaccard et al., 1990 [22] Study objective: Gain insight into the consistent use of diaphragm	Females, 14–46 yrs Seen at one of 10 FP clinics in NYC No other demo data provided	1,300 screened 375 were diaphragm users initially Inclusion: 111 (30%) of subjects remained in study and identified diaphragm as main method of contraception during entire 8 months of study.	8-mo longitudinal cohort study	Methods: Interviewed at baseline, 4 and 8 mos Measures: Consistency of diaphragm use Perceived susceptibility to pregnancy Attitude toward method (AC) Attitude toward getting pregnant (AP) Relative contraceptive utility (RCU = AC-AP) Contraceptive locus of control Partner measures Sexual interest Life change events Additional moderators	Little correlation was found between RCU measures and consistent diaphragm use. All analyses yielded statistically insignificant results.	Authors and Reviewers: Study was unable to demonstrate that attitudes toward contraception or attitudes toward pregnancy influence consistent use of diaphragm.	Self-report Although study size large to start, only a very small number of diaphragm users identified—may limit findings Questionnaire and measured variables (AC, AP, RCU) never previously validated Generalizability: 10 sites used and wide age range included
Oakley et al., 1997 [23] Study objective: Examine consistency of OCP use and characteristics of women at increased risk of pregnancy during first 3 mos after OCP initiation	Females No other demo info provided	Number eligible not given 103 women initiating OCP use from university student health services and Title-X funded clinics in Michigan and North Carolina in 1993–1994. 89 (86%) completed survey.	3-mo longitudinal cohort study	Methods: Received free pack OCPs with electronic monitoring device and monthly diary card × 3 mos Counseled on effective use of OCPs Completed questionnaire at end of each pill cycle to receive next free pack Measures: Demographic, reproductive and psychosocial info Electronic monitoring day/time OCPs taken from pack Diary report of pills taken, intercourse, and back-up method used	The percentages of women always protected in some way were as follows: mo 1—93%; mo 2—87%; and mo 3—75% The percentages protected by pill alone were as follows: mo 1—85%; mo 2—79%; mo 3—61% Of all women completing survey, 27.2% were at risk for unintended pregnancy at some time during the 3 mos. The characteristics of individuals more likely to be at risk (all $p < 0.05$) included perceived low partner support, being unmarried and not being highly invested in avoiding pregnancy The highest risk occurred in first 7 days after Rx started but risk increased with each month thereafter. Demographic and psychosocial characteristics were not significant.	Authors: Large numbers of women place themselves at risk for pregnancy in the first 3 mos after initiating OCPs. Certain variables may be useful to identify women at risk for inconsistent contraceptive use. Reviewers: Follow-up visits should take place within the first 3 mos after Rx given for OCPs. Certain variables (perceived low partner support) may be useful screens during counseling to identify high-risk clients.	Weakness: Small sample size Unclear if questionnaire previously validated Strengths: Self-report validated with objective electronic devices to measure pill use Generalizability: University and FP clinic sites only No demographic data given

Continued

Table 2B
Continued

Source: author, year	Study population	Enrollment and definition of groups	Design/ time frame	Measures and methods	Results	Conclusions	Quality considerations
Rosenburg and Waugh, 1998 [25] Study objective: Determine reasons for discontinuing oral contraception	Females Mean age 26 yrs Race info not provided	1,657 women enrolled from 271 clinics: 42% Planned Parenthood 56% private, 2% HMO 1,062 (64%) completed 2 mos 887 (54%) completed 6 mos Inclusion: Women initiating or switching oral contraceptives	6-mo longitudinal cohort study	Methods: Self-administered questionnaire at initial clinic visit with follow-up questionnaires mailed at 2 and 6 mos (with cash incentive) Measures: % of women who stopped OCPs in first 2 and 6 mos and reported reasons	Of total sample, 15% stopped OCPs in the first 2 mos and 28% in the first 6 mos Reasons cited included: side effects (37%); wanted to conceive (23%); and too hard to use (14%) Discontinuation rate was significantly different by: 1st time OCP users (32% of them stopped vs. 16% of other) (p values not given) Demographic and psychological measures were not significant	Authors: Most people who stop OCPs do so within the first 2 mos; most switch to a less effective method. Side effects were most common reason cited for stopping method. New OCP starters were more likely to stop. Reviewers: This evidence suggests follow-up appointments within 2 mos for first time OCP users may be useful. Contraceptive counseling should address side effects.	Self-report Rate of follow-up only 55% at 6 mo: Potential selection bias No analysis done of nonparticipants Clinics self-selected to participate in study Unclear if questionnaire previously validated Generalizability: Private and HMO settings only and higher income women
Rosenberg et al., 1998 [24] Study objective: Examine characteristics that affect consistency of contraceptive use (including counseling interactions)	Females Mean age 25 yrs No race info provided 28% <$15,000 per yr 15% >$55,000 per yr 11% < High School education 22% with college or > 62% never married	4,000 physicians invited to participate, 271 agreed 1,555 women from 271 clinics: 42% Planned Parenthood, 56% private, 2% HMO 992 (64%) completed the questionnaire at 2 mos 943 of these met inclusion criteria Inclusion: Women receiving services from these clinics who were initiating or switching oral contraceptives	2-mo longitudinal cohort study	Methods: An initial written enrollment questionnaire given out in clinic with follow-up questionnaires mailed at 2 mos (with cash incentive), and nonresponders contacted by telephone. Measures: Demographics Health Beliefs and Patient-Provider interactions (through the use of the Provider Reactions Assessment) and Method satisfaction	47% of women missed one or more pills per cycle 22% missed 2 or more. Predictors of missed pill behaviors: Lack of established routine for pill taking (OR = 3.6) Reading or understanding only part of the pill package insert (OR = 2.3) Spotting/bleeding (OR = 1.6) Method dissatisfaction was significantly related to: Number of side effects (OR = 9.8 for 7 or more, OR = 6.0 for 4-6, OR = 2.3 for 1-3) Number of beneficial effects (OR = 2.2 for 0-1, OR = 1.6 for 2, OR = 1.6 for 3) Provider–Patient interaction (as measured by the PRA score) (OR = 2.2 for first quartile PRA score, OR = 1.6 for second) Past pill use (OR = 1.3 never used vs. previous use) Taking pill at same time every day (OR = 1.9) Calling provider due to side effects (OR = 1.5) Cost of pills (OR = 1.7 for 4th quartile cost)	Author: Provider–patient interactions in a clinic setting may affect contraceptive use. Establishing specific use behaviors (routines, etc.) may improve OCP use. Reviewers: Clinic interactions (although they are not well defined in this study) affect contraceptive use.	Grade: poor Self-report Potential physician selection bias Short follow-up time Low follow-up rate (64%) may create a selection bias Generalizability: No race info given, but wide variety of providers and settings

FP = family planning; NYC = New York City; AC = attitude toward contraceptive method; AP = attitude toward getting pregnant; RCU = relative contraceptive utility; HMO = health maintenance organization; OCP = oral contraceptive pills.

Table 2C
Influences on compliance and continuation of contraception in adolescents

Source: author, year	Study population	Enrollment and definition of groups	Design/ time frame	Measures and methods	Results	Conclusions	Quality considerations
Balassone, 1989 [26] Study objective: Compare differences in groups who discontinue OCPs vs. those who continue	Females age < 17 51% white 39% AA 3% Hispanic 7% other	76 teens who attended randomly selected clinic sessions in private FP agency 58 (76%) completed study Inclusion: Received OCPs at that clinic visit	3-mo longitudinal cohort study	Methods: Initial face-to-face interview; follow-up interview at 3 mos in clinic or by phone if subject did not return to clinic Measures: Contraceptive knowledge perceived costs vs. benefits of pill use Cost vs. benefits of pregnancy Susceptibility to pregnancy	42 women continued OCPs and returned to clinic at 3 mos; 16 did not continue OCPs (14 of those located by phone only) The discontinuation group differed significantly from the continuation group by: increased perceived health costs of OCPs ($p = 0.03$); less personal susceptibility to preg ($p = 0.09$); lower problem-solving ability ($p = 0.07$); and more reported side effects from OCPs ($p < .01$) Higher rate given only one pack of pills Rate given referral for further testing Rate of calling clinic with questions or concerns (no p values given for these 3 measures)	Authors: Two categories distinguish consistent OCP users: 1. Individual differences: fewer health concerns, beliefs of higher susceptibility to pregnancy, better problem-solving skills, ability/ empowerment to call with questions/ concerns 2. Provider and clinic characteristics: dispensed more than one pack of pills and did not refer to other providers Reviewers: Study provides some evidence that actions in the clinic may have an impact on contraceptive behavior	Self-report Small sample size Large number lost to follow-up No analysis of those subjects lost to follow-up Follow-up time only 3 mos Generalizability: Study conducted only in one west coast city and in private settings
DuRant et al., 1990 [27] Study objective: To study the relationship between social, attitude, and psychological factors and adolescent contraceptive behavior	Females 12–18 yrs (mean: 14.9) 100% AA All resided in one of six low-income housing projects	Inclusion: 400 teens receiving care through a free comprehensive health care project 125 were randomly chosen to participate 115 (92%) agreed to participate 113 (90.4%) completed the study at 6 mos	Longitudinal Baseline and 6 mos	Methods: A cohort of teen females chosen randomly from all eligibles- Given a questionnaire at time of enrollment with 2 sections (first administered verbally, second self-administered) followed by a medical record review A second questionnaire not specified (method of administration) given at 6-mo follow-up	Higher frequency of unprotected intercourse was most significantly correlated with: Previous pregnancy and coital frequency (explained 12.7% of variance; $p < 0.0001$); knowledge of contraception and number of broken FP clinic appointments (explained 5%; $p < 0.0001$); and level of contraceptive knowledge ($p < 0.026$).	Authors: Although teens who engaged in more frequent coitus worried about pregnancy more, they also had higher frequency of unprotected intercourse. Perhaps as the duration of relationships with partners increase teens increase frequency of unprotected intercourse. Since locus of control, self-esteem and anomia were not related to frequency of unprotected intercourse, attitudes and social forces may be more important predictors of negative	Study subjects identified through randomization from a larger cohort Good follow-up (>90%) Self-report with some verification by record reviews Validated questionnaires

Continued

Table 2C
Continued

Source: author, year	Study population	Enrollment and definition of groups	Design/ time frame	Measures and methods	Results	Conclusions	Quality considerations
				Measures: Dependent variable: Reported frequency of unprotected intercourse in last 6 mos Independent variables: Demographic data Behavior, attitudes and knowledge concerning sexuality, pregnancy and contraception Locus of control, self esteem, attitudes toward physicians, anomia, well-being, future career and educational plans Tanner stage (as determined by subject herself) From medical record: previous pregnancies and outcomes, previous contraceptive method, reported side effects from contraceptive, noncompliance with or discontinuation of contraceptive, contraceptive failure, no. of FP visits	Coital frequency was significantly correlated ($p < 0.05$) with Tanner stage, age, number of partners, duration of relationship with partner, negative parental attitudes toward pregnancy, level of effectiveness of previous contraceptive, contraceptive knowledge, negative attitude about unplanned pregnancy, previous pregnancies, level of worry about becoming pregnant, and previous pregnancy scares. Coital frequency was not significantly correlated with ($p > 0.05$) parental support of sexual activity, locus of control or self-esteem.	contraceptive behaviors in this population than psychological factors. Level of knowledge was positively correlated with unprotected intercourse suggesting that efforts aimed at changing knowledge are not as important as interventions designed to alter attitudes and social influences. Authors and Reviewers: This study provides more evidence that many criteria are involved in identifying teens at high risk for unintended pregnancy and that clinical attempts to identify high-risk patients using one or two criteria will be unsuccessful.	Study subjects identified through randomization from a larger cohort Good follow-up (>90%) Self-report with some verification by record reviews Validated questionnaires Generalizability: Low-income AA teens only

Continued

Table 2C
Continued

Source: author, year	Study population	Enrollment and definition of groups	Design/ time frame	Measures and methods	Results	Conclusions	Quality considerations
Zabin et al., 1993 [28] Study objective: explore relationship between young women's attitudes toward conception, abortion and contraception and behaviors that lead to childbearing in inner-city AA teens	Females, 13–17 yrs 100% AA 60 receive federal assistance	359 females, all previously childless, who presented for pregnancy tests at two clinic sites in Baltimore, MD 87% retention	2-yr longitudinal cohort study	Methods: Face-to-face interview in person at baseline, 1 yr and 2 yrs; phone interviews at 6 and 18 mos Measures: Contraceptive use Conceptions Abortions Attitudes toward childbearing Efficacy of contraception Use of contraception Partner's desire for conception	Important predictors of contraceptive use or pregnancy included: An expressed desire to not want pregnancy ($p < 0.01$); a positive attitude toward contraceptives ($p < 0.05$); and perception of partner's attitude (NS)	Authors: Attitudes are a contributing factor toward contraceptive use and pregnancy in teenagers. Single item measures of attitude may be too simplistic to measure the complex nature of these attitudes and the large degree of associated ambivalence. Association between attitude and behavior may become significant only when young woman is unambiguously committed to preventing pregnancy. Reviewers: Study suggests the influences on contraceptive use are complex, multifactorial and difficult to measure.	Self-report Pregnancy wantedness was measured using a single dichotomous variable, which limits conclusions. Questionnaire not previously validated. Generalizability: AA teens in urban setting only

OCP = oral contraceptive pills; FP = family planning; AA = African American; NS = not significant.

have children, a preference for nonromantic sex and the partner's unwillingness to refrain from sex if the diaphragm was not in place.

This research highlights the complexity of factors that influence behaviors. Unfortunately, the Jaccard et al. report does not provide adequate statistical information to assess fully whether the methods and analyses support the conclusions; as with the team's other report, subjects are not well described. This article also discusses selection bias, retention bias and retesting bias and concludes that potential biases are minimal.

Oakley and associates undertook a study to determine the extent of adherence problems in 103 women who were patients of federally funded family-planning clinics and university health care programs in two states [23]. Utilizing an electronic device that recorded the date and time each pill was removed from its blister pack, the investigators found that 52% of the sample took each active pill or did not miss more than one pill at a time after the first week of the initial cycle; another 21% chose to protect themselves from pregnancy by employing behaviors that reduce the risk of pregnancy when two or more consecutive pills had been missed. The proportion of women who were always protected in some way declined from 93% in cycle one to 87% in cycle two and 75% in cycle three. Using multiple logistic regression, the research team identified three groups of women with significantly elevated numbers of unprotected days: those with a lower level of perceived partner support for effective pill use, unmarried women and those who did not consider it especially important to avoid pregnancy.

Rosenberg and associates examined characteristics that affect consistency of contraceptive use [24]. In this prospective study, a nationwide sample of 992 women completed questionnaires examining their adherence to instructions for proper use of the pill, the quality of their interactions with their providers, satisfaction with the oral contraceptives, and the frequency and costs associated with provider interactions over pill-related side effects. Almost half (47%) of pill

users reported missing one or more pills per cycle, and 22% missed two or more. The following behaviors were associated with improved adherence: took pill at same time every day; read and understood all of package information and took the pill at a routine time other than right before bed. Side effects such as spotting and heavy and extended periods were associated with poorer adherence. The quality of patient–provider interactions as determined by the individual women was also important [24]. Using the Patient Reactions Assessment, which has reportedly been validated, the investigators determined that the less satisfied the patient was with her interactions with the provider, the more likely she was to be dissatisfied with her contraceptive pills. One strength of the Rosenberg et al. study was its prospective design and the many sources of patients. An important limitation of the study, however, was that 36% of the participants were lost to follow-up.

The same study provided a larger cohort of women (n = 1,657) who were followed for 6 months to determine the frequency and reasons for oral contraceptive discontinuation and subsequent contraceptive behavior [25]. Twenty-eight percent of the women discontinued oral contraceptive use during the 6 months of participation; most did so within the first 2 months of use. The only variable that significantly predicted discontinuation of the oral contraceptive was recent initiation of the method (as contrasted with brand switchers). Other variables such as specific side effects, age, and quality of patient–provider interactions approached but did not achieve statistical significance. Other demographic and psychologic variables including internal health locus of control (i.e., "I am in charge of my destiny") and perceived social support were not predictive of oral contraceptive discontinuation. Again, attrition was high; 65% of the initial sample returned the 2-month questionnaire, 55% the 6-month survey.

3.2.3. Investigations among teenagers

Three studies (described in Table 2C) investigated study populations limited to adolescents [26–28]. Balassone used a prospective cohort design to assess determinants of continued use of oral contraceptives among teenagers [26]. Participants were younger than 18 (average age: 15.6 years) and were interviewed at enrollment and again 3 months later. Statistically significant differences in individual factors affecting adherence to contraceptives included concerns about potential health-related problems from the contraceptive, personal estimate of likelihood of pregnancy, and ability to cite options should pregnancy occur. The single provider-clinic variable significantly related to inconsistent use was the dispensing of only one package of pills with continuation dependent on the patients returning for additional medical tests. The study has many weaknesses, most notably that nearly 24% of the sample was lost to follow-up.

Two other studies specifically examined the relationship between attitudes and contraceptive behaviors [27,28]. DuRant and associates investigated the relationship between attitudes and adolescent contraceptive behavior, including social and psychological factors [27]. They administered a pretested questionnaire to a random sample of 115 African American women ages 12 to 18 years who were receiving care through a free comprehensive health care project. Factors positively correlated with engaging in unprotected intercourse included previous pregnancy, birth control knowledge, coital frequency and length of time the woman had been with her present boyfriend; self-esteem and locus of control were not significantly associated with the frequency of unprotected sexual intercourse.

This study underscores how little is known about the determinants of contraceptive use and the decision to delay conception among adolescents. Cultural influences on those decisions may be significant. In this study, the authors reported that the subjects came from a community where adolescent pregnancy rates are high, often occurring across generations, and socially tolerated, thereby making external validity about contraceptive motivations and use poor. The authors concluded that "clinical attempts to identify adolescent patients at risk of pregnancy using only one or two criteria will probably be unsuccessful" ([27], p. 333).

In the study by Zabin and colleagues, 313 young inner-city African American women less than 18 years of age were enrolled in the study protocol when they presented for pregnancy tests and were followed at 6-month intervals for 2 years [28]. Like DuRant and associates [27], these authors concluded that there is no simple measure for the complex nature of an adolescent's attitude toward contraceptive use and pregnancy. Multivariate analyses showed that only when a young woman unequivocally wants to avoid childbearing or is unequivocally positive toward contraception and the belief that abortion would be problematic for her, does her attitude have a significant effect on behavior (i.e., taking steps to delay conception). By contrast, ambivalence about conception was as significantly related to childbearing as the positive desire to conceive, but ambivalence is a more difficult emotion to uncover. In contrast to the work of Oakley and colleagues [21,23], Zabin and associates did not find that beliefs about partners' desires regarding childbearing were significant determinants of attitudes and behaviors [28].

In summary, the influences on contraceptive use and adherence are many and may not be consistent across populations. The heterogeneity of the studies relative to outcome variables, populations and methodologies does not create a body of work that can reliably or exhaustively explain influences on contraceptive use and adherence.

3.3. What is the association between behaviors that support fertility desires and a decrease in unintended pregnancy?

The likelihood of pregnancy in women who identify themselves as users of a contraceptive method is more complex than assigning typical failure rates. That 53% of

unintended pregnancies occur among women who were using a family-planning method during the month they conceived [1] is a startling figure. These conceptions may result from either failures in method effectiveness or user behaviors. A newer conceptual model argues that four indices influence the measures commonly used to compare contraceptive method failure rates or the probability that a woman will conceive while using a method [29]. These four indices are: (a) capacity to conceive; (b) frequency and timing of intercourse; (c) degree of adherence to the method's requirements and (d) inherent protection of the method. Certain subpopulations have higher contraceptive failure rates than others. In general, failure rates are highest among cohabiting and other unmarried women, among those with an annual family income below 200% of the federal poverty level, among black and Hispanic women, among adolescents and among women in their 20s [30]. We had hoped to uncover and understand strategies to impact on user-mediated contraceptive failure rates. Unfortunately, we identified no clinic-based intervention studies addressing this question. One body of research examines unintended pregnancy issues for at-risk populations, particularly teenagers, from a broad-based (ecologic) and community perspective. Published reviews of this literature have concluded that much more research is needed before strong conclusions can be made about the effects of community interventions on unintended pregnancy [2,31]. To assist clinicians in counseling in their own settings, this particular systematic review was undertaken to address clinical rather than community preventive services.

3.4. What are the potential harms of contraceptive counseling?

The theoretical harms to contraceptive counseling (beyond those associated with the methods themselves) are numerous. For instance, counseling could be so directive that it infringes on personal choice; it could be so dense or complex that it is misunderstood by the patient and results in faulty utilization of the method; it could be so time-consuming or inclusive that patients lose interest; or it could be construed as demeaning. We found no experimental research that systematically analyzed harms. Two articles explored issues of coercion related to the use of Norplant [32,33] but neither met the criteria for inclusion in the evidence tables.

3.5. What is the cost-effectiveness of counseling to prevent unintended pregnancy?

Arguably, some approaches to counseling might be more cost-efficient and effective than others. Although economic models can estimate the savings achieved by preventing one unintended pregnancy [34] by use of various contraceptive methods including emergency contraception [35], we uncovered no experimental or observational research that either evaluated actual costs of counseling to prevent unintended conceptions or compared costs and potential cost savings of different approaches for either patients or providers.

4. Discussion

4.1. Limitations of this literature

Few studies have been published that address the effectiveness of counseling in the clinical setting or that provide evidence-based suggestions of how counseling might be improved to increase effectiveness. Research on counseling to prevent unintended pregnancy is heterogeneous in design and generally poor in quality. Only one of the identified studies featured an RCT design; the majority of the longitudinal cohort studies was relatively short and often used convenience samples that likely introduced bias.

Of the studies that addressed the effects of counseling, most did not measure direct outcomes such as a change in unintended pregnancy rates, which would require following samples for extended periods of time. Rather, most of the identified studies measured indirect outcomes such as changes in knowledge or contraceptive practices. Theoretical underpinnings for much of the research were difficult to assess; social and cultural norms were seldom considered in the generation of hypotheses; and randomization was rare. Questionnaires were seldom validated, and other psychometric properties of instruments (e.g., reliability, correlational evidence, factorial validity, etc.) were almost never provided.

Much of the research addressing unintended pregnancy focuses on urban African American adolescent girls, an important population but one that does not begin to cover the range of populations (both women and men) among whom unintended (whether mistimed or truly unwanted) conceptions occur. We uncovered no studies, for instance, that specifically addressed counseling to prevent unintended pregnancy in women over the age of 35, although they have a relatively high rate of such pregnancies. No study dealt with couples; few addressed men.

The outcome variable for much of the work on contraceptive counseling is continued utilization of the chosen method. However, this variable is a moving target, which may explain the large percentages of people lost to follow-up in several of the intervention studies. Individual desires and needs to avoid pregnancy change, sometimes rapidly. For instance, people may become lost to follow-up because they actively decided to become pregnant, become less interested or motivated in delaying conception, or find themselves in different life circumstances that result in sexual inactivity. Possibly, they do not return for follow-up because they did not appreciate the services provided or became disenchanted with the method chosen.

Pregnancy intention itself may change rapidly and is not

easily or reliably measured [36]. It always depends on self-report, which complicates drawing any conclusions about its occurrence relative to an intervention. Moreover, until recently, pregnancy intention was measured as a dichotomous variable (i.e., intended vs. unintended). New thinking in the family-planning field suggests that this is an unrealistic framework and that the majority of women are actually ambivalent about conception [37–39]. Assessment strategies and tools in much of the current research may be inadequate to categorize accurately the nuanced feelings about specific pregnancies; the inability to appreciate the nuances may lead to erroneous research conclusions.

4.2. Recommendations for future research

Needs and opportunities for meaningful research about counseling to prevent unintended pregnancy are many. The IOM publication, *Best Intentions*, outlined many aspects of unintended conceptions that require further investigation, but it put forth no specific agenda about research needs particular to primary care providers and their services [2]. In the current US medical system, primary care clinicians have only a short time with patients and must address multiple health issues in that window of opportunity. For clinicians to spend their time wisely, counseling based on an effective evidence-based approach is ideal. For this reason, a considerable research agenda must be pursued.

First, only limited research has focused on identifying contraceptive patterns in women over time. According to Tyrer [40], during her reproductive years a woman may move among five different behaviors with regard to contraceptive use: nonuse, dissatisfied use, incorrect use, use of inappropriate methods for reproductive aims and satisfied use of methods that present a tolerable level of risk for contraceptive failure. A long-term cohort study of factors that move women from one category of use to another would illuminate a great deal about contraceptive use and nonuse; it would also, most likely, clarify factors in the health care system that influence that movement.

Second, little study has been directed at the current content of routine patient and clinician interactions about contraception. Several cohort studies have investigated patient adherence but have not explored the antecedent quantity and quality of interactions with the provider. Descriptive studies of these interactions coupled with qualitative research to determine and contrast provider and patient desires and impressions are important first steps in designing intervention studies.

Third, one core goal in the IOM campaign to reduce unintended pregnancy is to "address explicitly the major roles that feelings, attitudes, and motivation play in using contraception and avoiding unintended pregnancy" ([2], p. 254). Further psychometric testing and cognitive survey research to create and clarify standard measures of ambivalence toward becoming pregnant for women of all ages are needed [38]. Translating this work into more focused, efficient and effective interactions with patients offers further research opportunities.

Fourth, most questions about men and contraception have not even been explored. Edwards puts forth a number of important questions [41]: Should men be involved in contraceptive decision-making? If so, to what extent? Do men want to be involved or do they prefer to leave this responsibility to women? Are men's concerns about contraception different from women's? Across demographic subgroups, how does the man's relationship with the woman and his desires regarding childbearing influence contraceptive adherence? Does a man's degree of ambivalence regarding pregnancy influence pregnancy rates? Is couple counseling advantageous? Is it feasible? To obtain some background information, the 2002 National Survey of Family Growth survey will include male respondents and, in some states, "family-planning" questions will soon be asked of men in the Centers for Disease Control and Prevention Behavioral Risk Assessment Survey. Nonetheless, much detailed information will still remain unknown.

Fifth, randomized control trials are needed to test various approaches for providing assessment, education and counseling about contraception. We identified only one RCT (a study of adolescent males). Many opportunities exist, however, to develop randomized (or nonrandomized) controlled trials to evaluate clinical approaches to affecting behaviors around contraception. This type of work is methodologically challenging because of the difficulty in measuring impact and the numerous potential biases, but it is not impossible. The RCT in our review occurred in a staff-model HMO, which suggests that managed care organizations may provide a good venue for undertaking successful trials. Many questions warrant examination through such trials. For instance, as suggested by one study, does inclusion of preconceptional health education in wellness visits affect contraceptive use and active decision-making regarding when to become pregnant [42]? New technologies, such as the internet and personal computers, offer untested substitutes or complements for provider interactions that might affect rates of unintended pregnancies. Clinicians and others need to know whether these technologies influence decisions about the contraceptive method, tolerance of side effects and adherence, and if they can be used to answer patients' questions in a timely fashion, thereby avoiding early discontinuation of the method. They also need information on whether other approaches, such as telephone follow-up and mailed communication, can improve adherence for women who continue to desire to avoid conception.

One current standard of care, requiring a pelvic examination before prescribing an oral contraceptive, is under scrutiny at this time. The US Food and Drug Administration and the American College of Obstetricians and Gynecologists both recognize that it is acceptable to defer this examination. The Planned Parenthood Federation of America is currently changing its protocols to allow a prescription for several months of oral contraceptives before a required

examination. Whether unbundling these services improves patient satisfaction, adherence and unintended pregnancy rates warrants explicit study.

Sixth, several contemporary models about behavior change have not been adequately tested relative to contraceptive decision-making and use. Because these models, if proven valid, could provide important and focused structure to patient-provider interactions about desires and actions to prevent unintended pregnancy, they require evaluation. The models include Prochaska's and DiClemente's Transtheoretical Model [43] and the 5As approach, which is recognized for its utility in smoking cessation but has not been tested in counseling for the prevention of unintended pregnancy [44].

Seventh, complex cultural, social, psychological, physiologic and economic factors lie behind widely varying patterns of contraceptive use. This phenomenon suggests that interventions that extend beyond the primary care office could be beneficial in helping women achieve their childbearing desires. No research was uncovered that specifically looked at the interplay between primary care interactions and community-based interventions, although one important case study is evolving in Washington State whereby women can access emergency contraception through a pharmacist without interaction with a medical care provider.

A final issue is whether the outcome of concern should be unintended conceptions and pregnancies or unwanted conceptions and pregnancies. Generally, the burden of suffering for unintended events imposed on women (and their partners, in some cases) does not distinguish between pregnancies that are (truly) unwanted and those that are (simply) mistimed. A recent qualitative study suggested that mistimed pregnancies may not be judged to be problematic by the women experiencing them [37]. More research is needed to determine if the burden of suffering for mistimed pregnancies is sufficient to warrant an extensive research agenda to prevent its occurrence. There is no doubt that the burdens of unwanted conceptions on the political, economic and health outcomes of the nation are sufficient to warrant the allocation of resources to understand fully effective strategies for preventing these conceptions. That many of the factors leading to unintended pregnancy have relatively little to do with clinical interactions and a great deal to do with personal and environmental variables is, however, a very real possibility.

Acknowledgments

This study was developed by the Research Triangle Institute (RTI) International—University of North Carolina Evidence-based Practice Center under contract to the Agency for Healthcare Research and Quality (Contract No. 290-97-0011), Rockville, MD. We thank our liaisons from the US Preventive Services Task Force—Carolyn Westhoff, MD, MSC, of Columbia University College of Physicians and Surgeons, New York City, and Nola Pender, RN, PhD, FAAN, School of Nursing, University of Michigan, Ann Arbor—for their assistance on the full systematic evidence review from which this article has been developed. We acknowledge also the assistance of David Atkins MD, MPH, Director, AHRQ Clinical Prevention Program, and Jean Slutsky, PA, MSPH, for their advice and counsel for this project. Finally, we thank our RTI-UNC EPC colleagues Russell Harris, MD, MPH, Co-Director of the RTI-UNC Clinical Prevention Center (University of North Carolina), and Sonya Sutton, BSPH, and Loraine Monroe (RTI) for their assistance in this project and production of this article.

The authors of this article are responsible for its contents, including any clinical or treatment recommendations. No statement in this article should be construed as an official position of the Agency for Healthcare Research and Quality or the US Department of Health and Human Services.

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