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Vaginal or Cesarean Birth?
Using a Translational Research Model to Promote Informed Health Care Decision Making

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Acknowledgment: This project was funded by the Maternity Center of Association (MCA) of New York City, a national not-for-profit health organization that promotes safe, effective and satisfying maternity care for all women and their families. The authors acknowledge the valuable contributions of Maureen P. Corry, MCA's Executive Director, in this initiative.

Abstract

Background: Translational research models are needed to demonstrate a process for communicating high-quality scientific evidence that enables informed involvement of relevant stakeholders, including informed consumer participation in health care decision making.

Objectives: To describe elements of a translational research model for informing key stakeholders about relative harms of vaginal and cesarean birth, and the rationale for these elements.

Method: The Maternity Center Association (MCA), the oldest national U.S. organization advocating on behalf of mothers and babies identified the need to clarify and translate into practice best evidence about relative harms of cesarean and vaginal birth. MCA engaged leading stakeholder groups in this translational project, carried out a systematic review to fill this research gap, and then carried out an education and advocacy campaign to reach consumers, health professionals and the general public (through media outreach) with review results and related information and guidance. The project was developed in consideration of international standards for systematic reviews and best current research regarding effective professional practice, use of decision aids, and risk communication.

Results: The translational model reported here is reaching a very large number of individuals and organizations through a modest expenditure of resources. Although the model incorporates elements that have been shown to be effective, formal assessment of inpact on behavior, health care and outcomes is not possible.

Key Words: informed consent, informed decision making, translational research, cesarean section

Background

Evidence-based practice is now widely accepted as an important way to improve health outcomes. It is not surprising, therefore, that scientists and policy makers emphasize translational research as a resource for moving research findings rapidly into clinical practice. An international community of scholars is identifying a growing evidence base for effective professional practice and care delivery systems. Recent summaries of this work (Shojania and Grimshaw, 2005; National Institute of Clinical Studies, 2004; Grol & Grimshaw, 2003) clarify that most change strategies are useful, but have a small impact. In general, greater impact is likely with multiple sustained strategies directed to multiple audiences and tailored to the specific situation. A cultural ethos valuing quality improvement and structures for working collaboratively toward this goal have led to notable and relatively rapid change.

Most interest in translating research into practice has focused on influencing clinicians and health care settings. Research and evaluation on involving care recipients in quality improvement is more limited, yet research translation leaders underscore the importance of gaining better understanding of effective ways of engaging consumers for health care quality improvement (Wensing & Elwyn, 2003, 2002). Building such an evidence base would help advance the policy strategy of involving consumers to improve health care quality, which is being advanced in the U.S. and elsewhere (Hibbard, 2003). In addition to clinicians and consumers, other "end users" of high-quality research results include policy makers, journalists and advocacy groups. This broader view of the scope of translational research signals the need to develop additional strategies for effectively conveying and implementing research findings.

In addition to the goal of improving health care quality, effective communication of evidence-based information in clinical settings facilitates important informed consent and informed refusal, consistent with established legal and ethical principles.

Objectives

The purpose of this paper is to describe a model for informing and supporting diverse end users about cesarean in comparison with vaginal birth (see Figure 1). The model was designed and implemented by leaders at the Maternity Center Association (MCA) of New York City. Established in 1918, MCA is the oldest national organization advocating on behalf of mothers and babies. The work was carried out through MCA's long-term national program to promote evidence-based maternity care and support informed decision-making, consistent with the mission of promoting safe, effective and satisfying maternity care for all women and their families through research, education and advocacy (Sakala, 2004).

This paper provides brief background on the topic addressed through a translational model, followed by a description of the remaining elements of the model. These components include early and continuing involvement of a broad range of stakeholder groups, a systematic review of evidence, creation of an educational decision aid and other products, multiple dissemination strategies, and recommendations for evaluating the effectiveness of the model.

Problem: Truly informed decision-making about cesarean versus vaginal birth was not possible without systematic review and dissemination of research

The first element of our model is to clearly establish the nature and scope of the problem or issue to be addressed. In the present context, there was an urgent concern that rapid shifts in belief and practice relating to mode of delivery were taking place without benefit of a systematic understanding of the evidence, especially with regard to harms. A profound cultural shift had

been taking place (and continues), and it had become possible to hear new ideas, such as: "Vaginal birth is harmful," "Having a cesarean will prevent later-life pelvic floor problems," and "Cesarean delivery, especially elective cesarean, is safe."

Dramatic changes in practice paralleled the shifts in belief. The U.S. cesarean rate reached a record level in 2003, at 27.6% (Hamilton, Martin & Sutton, 2004), with a trend toward exponential increase. Cesarean rates were rising for all indications and among all populations, and for no indication (Declercq et al., in press; Declercq, Menacker and MacDorman, 2005). Both physicians and women were initiating cesarean without medical indication (Kalish, McCullough et al., 2004). Rates of vaginal birth, vaginal birth after cesarean, and vaginal instrumental birth were declining. A major surgical procedure was being used with increasing casualness in a primarily well and healthy population without clear evidence to support the trend.

Valuable up-to-date evidence assessments were available for some common indications, such as the evidence report commissioned by the U.S. Agency for Healthcare Research and Quality (AHRQ) on vaginal birth after cesarean versus routine repeat cesarean (Guise, McDonagh et al., 2004; Guise, Berlin et al., 2004). However, no comprehensive and systematic accounting existed of harms that may differ between cesarean and vaginal birth, although all such harms are in fact relevant to individual decision-making as well as related policy, education and research. More conventional "narrative" reviews presented selective evidence, identifying selected harms and coming to divergent conclusions about relative safety. As narrative reviews lack protections against bias, Oxford University's Centre for Evidence-Based Medicine ranks this type of research at the lowest level of evidence, and they should not be used to guide policy, practice, research and education.

A Committee Opinion from the American College of Obstetricians and Gynecologists (2003) contributed further to these concerns. Although acknowledging "limitations of data regarding relative short- and long-term risks and benefits of cesarean versus vaginal delivery," it supported cesarean with no medical indication "if the physician believes that [elective] cesarean delivery promotes the overall health and welfare of the woman and her fetus more than vaginal birth." MCA leaders felt that systematically assessed evidence should inform changes in practice.

In this environment, health professionals have been divided about more casual use of cesarean section, including without indication (Wu, Hundley & Visco, 2005). Some physicians have advocated more liberal use, justified in part by the need to respond to women's preferences (Minkoff & Chervenak, 2003). Other investigators have argued that there is no clear evidence to support women's purported demand for cesarean birth (Gamble & Creedy, 2000).

This confusion and uncertainty have contributed to broad and undesirable practice variation. For example, in 2002 cesarean rates across New York City hospitals ranged from 10% to 37% (Choices in Childbirth, 2005), and in 2004 cesarean rates across Massachusetts hospitals ranged from 22% to 39% (Massachusetts, Health and Human Services, 2005). MCA leaders also felt concerned about the content of media reports, which were often misleading, incomplete, and potentially inaccurate, presenting premature conclusions reflecting opinion rather than science.

MCA encourages women to become informed about labor and birth options, clarify their preferences and goals, and take steps to achieve them well before the onset of labor. MCA was concerned that without access to more carefully gathered and evaluated information, shared decision-making between women and their providers, with the ability to choose among alternatives based on a full understanding by both of available evidence about the full range of harms and benefits, and truly informed consent or informed refusal was not possible. The

challenge that individual providers face in staying abreast of a large, complex and evolving body of relevant research and time constraints in busy clinical settings also posed barriers to full and effective communication and informed choice about mode of delivery.

Method

Project plan: Review relevant evidence and disseminate results

In response, the Maternity Center Association planned to carry out a systematic review to clarify relative harms of cesarean and vaginal birth and publicize results through various channels, including an educational booklet to help pregnant women understand the issues, work effectively with caregivers, and make informed decisions. Other channels included a media briefing and continuing media outreach, online resources for women and health professionals, and additional outreach to health professionals. Plans were made to make the booklet available in a bound and printed version, and to increase access by also offering it as a PDF file that would be available through the Internet on-demand and without charge. The Internet would also offer convenient access to core review documents and transparency about the process.

Broad participation: Engage diverse stakeholders throughout the project

MCA invited a broad range of national non-profit organizations involved with maternity care to join as partners in the project. They were invited to participate in any or all of the following ways: provide feedback on initial plan, share relevant documents that the group had already developed such as policy statements and guidelines, provide feedback on draft review and booklet documents, consider endorsing the final booklet, consider participating in media outreach, and consider distributing the booklet. Several dozen groups participated, generally in multiple ways, and individuals with specific perspectives and expertise were also invited to provide feedback. The review and booklet had input from diverse health professionals

(obstetricians, family physicians, pediatricians, nurses, midwives, childbirth educators, doulas, multi-disciplinary groups), as well as consumers, advocates and researchers.

Multi-disciplinary input is a standard aspect of major Maternity Center Association projects for several reasons. First, the rich diversity of perspectives and experiences strengthens the quality of the work. Second, participation of diverse groups enhances dissemination, as the groups have been involved during the development phase, anticipate the availability of resulting resources, appreciate the opportunity to have been contributed to the work, and are predisposed to take a role in informing their members, web visitors, clients or others about the resources. Third, such collaboration extends the reach and finite resources of a non-profit organization.

Protocol and review: Develop and carry out a plan for the systematic review

An explicit plan for a systematic review of the literature was the next major element of this model. One of the authors of this article (C. Sakala), MCA's director of programs, led the team that developed the plan and carried out the review. She has major responsibility for MCA's national program to promote evidence-based maternity care, has developed guidelines and supported authors who prepared systematic reviews commissioned by MCA (Rooks, Sakala & Corry, 2002), works with the editorial team of the Cochrane Collaboration Pregnancy and Childbirth Group to help ensure that their systematic reviews address consumer concerns, has served as a co-author of a Cochrane Review, and has supported AHRQ's Evidence-base Practice program as a referee and member of Technical Expert Advisory Groups for evidence reports. She also prepares a quarterly column, Current Resources for Evidence-Based Practice, which is published simultaneously in leading nursing and midwifery journals. This level of expertise and experience strengthened the translational model and lent credibility to the project.

The plan established the objectives and set the parameters and scope of the review. The objective was to identify the full range of harms that differ between vaginal and cesarean birth. Key questions reflected the need to distinguish among cesareans overall, planned prelabor cesareans and unplanned cesareans occurring during labor, and among vaginal birth overall, spontaneous vaginal birth and instrumental vaginal birth. It was particularly timely to compare planned cesarean to both unplanned cesarean and vaginal birth, as some had begun to suggest that a planned cesarean might be an optimal way to give birth. Two other timely questions were addressed. First, obstetric and non-obstetric factors that had been associated with adverse pelvic floor outcomes were identified to evaluate the evidence associating vaginal birth and other possible factors with such outcomes. Second, studies of practice variation were reviewed to understand whether conservative use of cesarean section, instrumental delivery and episiotomy had been associated with any increased risk of harm.

Outcomes of interest were any that might be considered “clinically relevant” or “mother relevant”: those that might be of interest to a woman and have an explicit impact on her or her fetus/infant/child. These outcomes included measures of shorter- or longer-term physical or mental health and the mother-baby relationship (e.g., attachment and breastfeeding). Longer-term outcomes extended to future reproductive capacity and any impacts on future pregnancies. Surrogate markers were excluded, as any relationship to meaningful effects on mothers and babies is generally imprecise and uncertain (Grimes & Schulz, 2005).

Advance decisions were also made about such matters as how to identify potentially relevant research reports, and types of studies that would and would not be included in the review, in keeping with established standards for systematic reviews. We adopted the highly regarded research grading system of Oxford University's Centre for Evidence-based Medicine

(2005) and were grateful for the willingness of Centre staff to advise on applying this system. For each outcome of interest, best identified research was included. Most outcomes were supported by level 2 and/or 3 evidence, better quality observational studies and systematic reviews of observational studies.

The large number of potentially relevant outcomes posed a major challenge for completing the systematic review with available resources. Several advance guidelines were established to make the process feasible. Most notably, sources of research reports that might be eligible for inclusion were limited to an a priori set of sources: references included in a similar well-funded review that was being carried out by the U.K. National Institute for Clinical Excellence and was available in draft form at the time (2003), reference lists from a series of recent narrative reviews that had been published in leading journals and had come to differing conclusions, two Medline searches of most recent references to update the narrative review lists, searches of two databases of systematic reviews, and references in the files of MCA.

We were confident that establishing these systematic review guidelines, scrupulously adhering to them without regard to the results of individual studies, and making the process transparent would lead to a notably improved basis for comparing the two modes of delivery, educating women and their providers, and making informed decisions. However, we also recognized that outcome-based searches would identify additional studies that might be relevant for inclusion, and that many relevant studies were continuing to appear during and beyond the review period. An additional strategy was to propose that the Agency for Health Care Research and Quality commission a fully resourced and updated review on the topic. Although AHRQ has subsequently commissioned a new cesarean review, the scope is limited to elective cesarean.

Results

A separate publication is being developed to describe review methods in greater detail and present review results. In addition, several documents are available as PDF files on the Maternity Center Association website: a description of methods and sources, an outline of key questions and outcomes and evidence tables (2005). All of the organizations that were initially contacted about project partnership and had expressed an interest were invited to comment on a draft of these documents, along with a draft of the consumer booklet (see below). Extensive input was received, from both designated representatives of national non-profit organizations and individual referees, representing a broad diversity of health professional and consumer/ advocacy perspectives. This feedback was used to revise and strengthen the documents. We are confident that it contributed to the quality of the resulting products, and we believe that it also contributed to the willingness of many of the groups to endorse and/or promote the booklet.

Decision aid: Develop booklet as tool for promoting informed consumer decision-making

Decision aids can be effective tools for translating evidence to consumers. A Cochrane Review of 35 randomized controlled trials evaluating decision aids found that such tools were associated with greater knowledge, more realistic expectations, reduced decisional conflict related to being informed, greater likelihood of being involved in decision, and reduced indecision. In comparison with simpler decision aids, more detailed tools were associated with improvements in knowledge, more realistic expectations, and greater agreement between values and choice with decision making (O'Connor, Stacey et al., 2003). Applying this evidence to the maternity experience, we felt that a written tool could enable pregnant women to review challenging information at their own pace, consult with partners and caregivers about it, compensate for brief and busy clinical encounters and the challenge of accurately recalling verbal information, clarify goals, and develop strategies for achieving for achieving goals.

The main body of the consumer booklet (Maternity Center Association, 2004) systematic review summarized results, and an appendix provided greater detail for those with such an interest. The appendix is an inventory and description of harms that differed by mode of delivery, sorted into meaningful classes of outcomes, with levels of absolute risk difference. We chose absolute risk as a more appropriate single measure than relative risk (Gigerenzer & Edwards, 2003), with absolute risk difference as the relevant comparator. We adapted an established risk communication tool that standardized risks of different orders of likelihood to five levels: very low, low, moderate, high and very high (Paling, 2003). The booklet also discussed the current health care climate with regard to cesarean issues, women's right to informed consent and informed refusal, and major indications for cesarean, encouraging communication with providers and further information-seeking when possible regarding the woman's specific situation. We also provided many evidence-based tips for reducing risk and reaching goals. Feedback from partners ranging from a cesarean awareness advocacy group and others with consumer concerns to clinicians with highly specialized technical knowledge contributed immensely to the quality of the resulting product. An at-a-glance insert with the printed booklet lists the classes of harms that differed by mode of delivery.

The partners were invited to endorse the booklet. Over 25 national non-profit groups have endorsed the booklet, including many of the partners that helped to develop it and a few groups that had not been involved in the process.

Dissemination: Utilize diverse channels for reaching key audiences

Numerous dissemination channels were used to reach pregnant women and other key audiences. We have encouraged partners and booklet endorsers to purchase the booklet in bulk and distribute it, to publicize it on websites, to print customized public service announcements in

their publications, and to distribute or display the booklet and order forms at meetings. MCA also sells the booklet. The booklet is available as a PDF file on MCA's website, and some partners also make this file available. During the first year, this PDF was downloaded nearly 50,000 times from MCA's website alone.

MCA also created three new in-depth online "Maternity Topics" for pregnant women: "What should I know about cesarean section?," "Should I choose VBAC or repeat c-section?" and "How can I prevent pelvic floor problems when giving birth?" (available at: http://www.maternitywise.org/mw/topics/). All were informed by work on the review and booklet, and the VBAC topic was also guided by the recent AHRQ evidence report on this topic (Guise, Berlin et al., 2004; Guise, McDonagh et al. 2004) . A major health plan and a national advocacy organization plan to adapt the booklet for distribution to their members/constituents.

The booklet and review were released at a media briefing held at the New York Academy of Medicine. National clinical leaders presented review results, and a multidisciplinary panel discussed implications. Representatives from many partnering organizations attended. MCA carries out ongoing media outreach on this topic. A matte release has been highly effective in bringing accurate messages to many middle- and smaller-circulation newspapers.

MCA's staff, board members and partners have assisted with professional outreach, including presentations at meetings, manuscripts for publication, and inclusion of public service announcements in publications. Our review has been consulted for development of position statements by some North American professional organizations, and many partners and individuals are using it within their professional activities. Continuing medical education programs are being developed on the basis of our review.

Evaluation: Assess process and impact and improve continuing cesarean and similar work

The model adopted has engaged and will continue to engage a very large number of individuals and organizations in understanding the relative harms of vaginal and cesarean birth and related issues, and is continuing to create basic resources that are available for policy, practice, research and education. We can tally up the number of endorsers, downloaded and printed booklets, visitors to relevant web pages, media impressions, conference presentations and so forth. The extent of reach for a relatively modest expenditure of resources has been considerable. However, it is impossible to capture the impact of this work on individual childbearing women, clinicians, policy makers, and journalists. We have been gratified by appreciate communications about this work from health professionals, advocates and childbearing women themselves. Unfortunately, resources for a formal, controlled evaluation of the booklet alone have not been available.

The quest for appropriate evidence-guided health care and truly informed decision making occurs in the context of a troubled U.S. health care system suffering from fragmentation, economic incentives that often conflict with optimal care, unresolved liability pressures, and many other severe problems (Institute of Medicine, 2001). In this context and as the literature on effective practice and organization of care is establishing, no magic bullet is likely to dramatically transform practice. Yet initiatives such as our model that are supported by lessons from this literature and from related work on decision aids, risk communication, and so forth have been shown to have an impact and are likely to be of value. As an advocacy organization, MCA considers this work to be worthy of our efforts and is currently extending replicating the model for the topic of labor induction.

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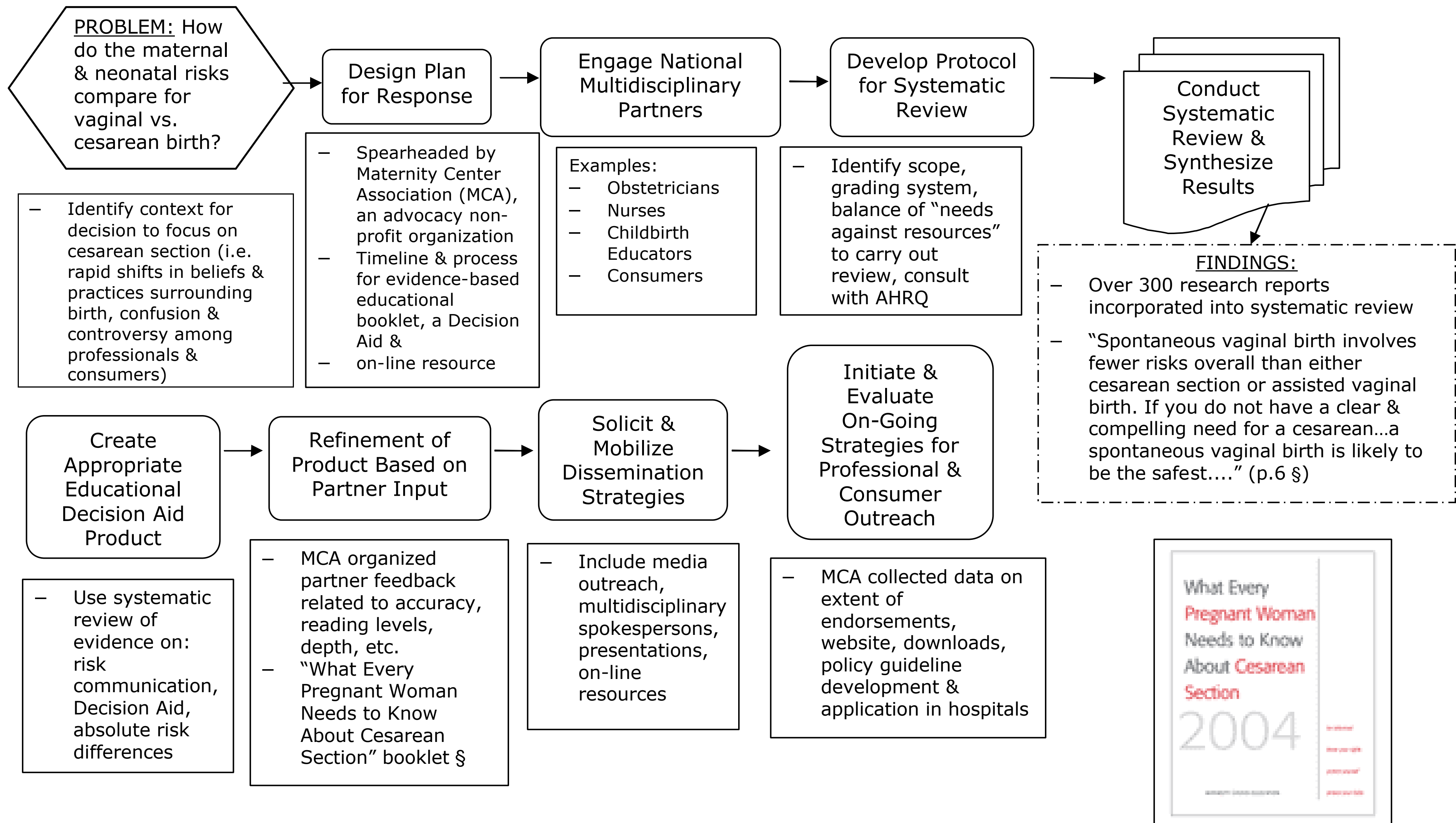
Figure Legend:

Figure 1. Model Components of Comparing Risks of Vaginal and Cesarean Birth: Use of a Translational Research Model for Informed Health Care Decisionmaking



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