Identifying Elements of the Business Case for Certified Nurse Midwife-led Birth Center Care through Systematic Review of Literature & Key Informant Interviews

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Abstract

Childbirth is repeatedly cited as the leading cause of hospitalizations and source of hospital costs in the United States (U.S.). Despite evidence suggesting that the certified nurse midwife-(CNM)-led free standing birth center (FSBC) care model provides safe, effective care, with less resource utilization and costs, as well as increased patient satisfaction for low risk births compared to traditional physician-led hospital based care, less than 0.5% of births in the U.S. occur through this model. The absence of a formal business case that demonstrates a financial return on investment for models shown to improve health care, such as the CNM-led FSBC care model in the U.S., is often cited as a reason for not implementing quality improving innovations in health care. Currently, there are no available criteria to guide the analysis of the business case for establishing and operating a free standing birth center. This paper aims to identify critical elements of a business case for the CNM-led FSBC model. A literature review of the CNM-led FSBC model in the U.S. was conducted applying principles of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher, Liberati, Tetziaff, & Altman, 2009). Exploratory semi-structured interviews were also conducted with two CNM and FSBC representatives. Results of the review and interviews were collectively analyzed using a directed content analysis approach guided by the Business Case for Quality Financial Model framework (Pink, Thomas, Kilpatrick, & Brown, 2005) to identify essential elements to consider when developing a business case for CNM-led FSBCs, including financial factors involved in initial investments and cash flows. This information may allow stakeholders to better understand factors necessary to consider when starting or operating a CNM-led FSBC.

Keywords: Business case, cost, certified nurse midwife, free standing birth center, economics, obstetrical costs, maternity costs
Introduction

Obstetrical Care in the United States

Improving obstetrical care models in the United States (U.S.) to provide safe, effective care, with high patient satisfaction and decreased patient costs has tremendous potential to not only improve the care patients receive, but also to improve the efficacy of economic resource allocation in health care. The United States is currently ranked 60th in the world for maternal mortality, a ranking that has progressively worsened over the past 14 years. This has been attributed to increasing chronic conditions, obesity, and increasing rates of cesarean deliveries in the U.S. (Menard et al., 2015). Childbirth is frequently cited as the leading cause of hospitalizations in the U.S., accounting for 10 percent of hospital stays in 2011 (Pfuntner, Wier, & Stocks, 2013). Childbirth also has been repeatedly cited as a leading cause of hospital costs in the U.S.; it is the most expensive condition billed to Medicaid and private insurers, and accounts for over $12 billion in national hospital aggregate cost (Torio & Andrews, 2011). Despite the U.S. spending more for births than other countries among the Organization for Economic Co-operation and Development, 26 other countries had better birth outcomes than the U.S. in 2010 (MacDorman, Mathews, Mohangoo, & Zeitlin, 2014; Organization for Economic Co-operation and Development, 2011). These outcomes include common quality indicators in obstetrical care used by various national organizations including the Joint Commission on Accreditation of Health Organizations and the National Perinatal Information Center and include inpatient neonatal mortality rates, third or fourth degree perineal laceration rates, and cesarean section rates for low risk births (Mann et al., 2006).

The enormous need to assess and develop solutions towards the paradoxically high cost and poor outcomes of obstetrical care in the U.S. has contributed to the federal and state policy
initiatives to identify and promote lower-cost, higher-quality models of obstetrical care. The CNM-led FSBC model of care for low-risk births has been proposed as a model which may have the potential to improve patient satisfaction and lower health care costs while maintaining or improving patient safety and outcomes (Benatar, Garrett, Howell, Palmer, & 2013; Howell, Palmer, Benatar, & Garrett, 2014; Jackson et al., 2003; Rooks, 1989; Stapleton, Osborne, & Illuzzi, 2013). The American Association of Birth Centers (AABC) defines a birth center as “a homelike facility existing within the health care system with a program of care designed in the wellness model of pregnancy and birth. Birth centers are guided by principles of prevention, sensitivity, safety, appropriate medical intervention, and cost effectiveness” (American Association of Birth Centers, 2014). According to the American College of Obstetricians and Gynecology, and endorsed by the AABC and American College of Nurse-Midwives, this model of care is aimed to provide “peripartum care to low-risk women with uncomplicated singleton term pregnancies with vertex presentation who are expected to have an uncomplicated birth,” in which the primary maternal care provider includes a midwife (Menard, et al, 2015). CNMs are advanced practice registered nurses (APRNs) that have at least a baccalaureate degree in nursing and a master’s degree in midwifery, are board certified by the American Midwifery Certification Board, and can practice legally within all 50 states in the United States. CNMs provide primary care to women of all ages including perinatal care, gynecological exams, newborn care, family planning, preconception care, menopausal management, health maintenance, and disease prevention (Association of Women's Health, Obstetric and Neonatal Nurses, 2009). The FSBC model of care was developed by CNMs and applies the midwifery philosophy of childbirth, in which childbirth is viewed as a natural, positive, and healthy process, in which routine technological care is minimized and high-touch care to enhance a women’s confidence in her
ability to give birth is maximized (American College of Nurse-Midwives, 2014). CNM-led FSBC’s must be licensed by individual states, maintain accreditation based on standards set by the commission for the Accreditation of Birth Centers, and maintain transfer agreements with nearby hospitals (Menard et al., 2015).

This paper aims to identify critical elements of the business case for the CNM-led FSBC model of care for low-risk births in the U.S. A business case is an analysis of the return on investment for establishing and managing an intervention and is conducted by assessing cash flows over time to determine if the investment is profitable (Leatherman et al., 2003; Reiter, et al., 2006). First, background information on obstetrical care systems of other developed countries will be discussed to examine health care systems that use CNM-led care more than the U.S. Further information on clinical outcomes, policy initiatives, and implementation barriers for the CNM-led FSBC model in the U.S. will then be presented to provide background on this model within the context of the U.S. healthcare system. Next, methods for the two modes of data collection, literature review and qualitative interviews, will be presented and results will be summarized. Lastly, results will be discussed and implications for the findings, including limitations and directions for future research will be presented.

**Obstetrical Care Systems of Other Developed Countries**

When examining obstetrical care delivery systems of countries with lower birthing costs and better birthing outcomes than the US, a common key difference is noted. Other countries, including the Netherlands, United Kingdom, and Sweden have increased availability and use of CNM-led care outside of hospital settings for low-risk obstetrical care (Organization for Economic Co-operation and Development, 2011). In the U.S., medical physicians are the primary provider for most childbearing women; in comparison, other countries, like Australia,
New Zealand, the Netherlands, the United Kingdom, and Ireland, have a better distribution of midwife-led, medical-led, and shared models of care (Sandall, Soltani, Gates, Shennan, & Devane, 2013). This may be attributed to the midwifery model of care being historically integrated into the healthcare systems of these countries, including the National Health Service of the United Kingdom.

There are also notable differences in educational regulations for midwifery in the U.S. compared to other countries. To become a registered midwife in the United Kingdom, at least 3 years of university-based education with clinical rotations and board examination are required. However, in the U.S., there are varying pathways to become a “midwife” ranging from direct entry midwives with little formal education to CNMs with formal university and clinical based training. Additionally, in December 2014, the United Kingdom passed guidelines through their National Institute for Health and Care Excellence promoting midwifery-led births outside of hospitals as the standard for low-risk births (National Collaborating Centre for Women’s and Children’s Health, 2014). This is strikingly different than in the U.S., where federal and state level debates exist around practice rights and privileges of CNMs.

A large body of literature demonstrates that the CNM-led model of care for low-risk births, including the FSBC model, offers a safe and effective model of obstetrical care delivery that lowers costs and improves quality. A review on midwife-led versus other models of care for child bearing women included 13 trials with 16,242 women and revealed that midwife-led care is consistently associated with outcomes as good as, or in some cases better than, other models of care. The review only included studies in which women were randomly allocated to midwife-led or other models of care during pregnancy, which decreases the likelihood of results being skewed from a different demographic of women choosing midwifery care versus other models of
care. This review suggests that CNM-led care is associated with reduction in regional analgesia use, fewer episiotomies or instrumental births, increased reports of feelings of control and satisfaction with birth experience among mothers, and lower overall costs (Sandall, Soltani, Gates, Shennan, & Devane, 2013). However many of the large scale studies on CNM-led care included in this review are based in other countries, like the Netherlands or the United Kingdom. As aforementioned, these countries have obstetrical care systems that differ from the U.S, suggesting that further investigation of CNM-led care in the U.S. is needed to better understand this model of care within the context of the U.S. health care system.

**CNM-led FSBC model of care in the United States**

For low-risk pregnant women, who make up over half of pregnancies in the U.S., multiple studies have consistently demonstrated the benefits of the CNM-led FSBC model of providing safe, effective care, with less resource utilization and costs, and increased patient satisfaction compared to the traditional physician-led hospital model of care (Benatar et al., 2013; Howell et al., 2014; Jackson et al., 2003; Rooks et al., 1989; Stapleton et al., 2013). Despite evidence suggesting this model of care provides higher quality, lower cost care, less than 0.5% of births in the U.S. are attended by CNMs in free standing birth center settings (Martin, Hamilton, Osterman, Curtin, & Mathews, 2013).

Outcomes from studies on CNM-led FSBC care support the federal and state policy initiatives to identify and promote lower-cost, higher-quality models of obstetrical care. For example, the American College of Physicians has recently placed an emphasis on “High Value Care”, or care delivery systems that prioritize quality patient care while simultaneously reducing unnecessary healthcare costs (American College of Physicians, 2015). Similarly, outcomes demonstrated by these studies embody the Institute of Healthcare Improvement’s “Triple Aim”
of care that increases patient health and patient experience while decreasing health care costs (Berwick, Nolan, & Whittington, 2008).

The outcomes from studies on the CNM-led FSBC model have influenced federal policies within the Patient Protection and Affordable Health care Act of 2010 to include provisions to expand access to CNM-led care. In 2012, the Centers for Medicare & Medicaid Services began including birth center care as an option for enhanced prenatal care under the Strong Start Initiative (Centers for Medicare & Medicaid Services, 2012). Other provisions in the Affordable Health Care Act that aim to increase utilization of CNM-led care include increasing Medicare reimbursement for midwives to 100% of that received by physicians, requiring Medicaid programs to provide coverage for birth center services, and the services of providers working in birth centers, as well as providing assistance for CNM education.

**Barriers to implementation of CNM-led FSBC model**

Despite the seemingly large body of empirical and policy support for CNM-led birth center care in the U.S., this model is not widely used in the U.S. In 2012, 7.9% of all U.S. births were attended by a midwife; in which 94.9% occurred in hospitals, 2.6% occurred in FSBCs, and 2.5% occurred in homes. (Martin et al., 2013). Barriers to increased utilization of CNM-led FSBC care are directly linked to barriers to other types of ARPN practice, as CNMs are a type of ARPN. These barriers are detailed in the Institute of Medicine (IOM) Report on The Future of Nursing: Leading Change, Advancing Health. The first key message of IOM report is that “nurses should practice to the full extent of their education and training.” (Institute of Medicine, 2011). The barriers to ARPN practice delineated in the IOM report can be categorized into four barriers: regulatory obstacles, professional resistance, systems obstacles, and business obstacles.
Regulatory obstacles are rooted in the history of regulation of health professions in the United States. Physicians were the first health care professionals to be legislatively recognized, and provisions were placed making it illegal for any providers who are not physicians to practice under the defined physician scope of practice, which is to “diagnose, cure, advise, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, physical, mental, real or imaginary, by means or instrumentality.” The language in this definition is still used in many states’ scope of practice legislature, which may contribute to the limitations in allowing APRNs to practice to the full scope of their education (Institute of Medicine, 2011).

Professional resistance is often defended by physician group concerns for potential decreased patient safety and increased patient harm, mortality, or complications, from increased APRN practice. However, research studies examining the safety, efficacy, and efficiency, of care delivered by APRNs consistently do not support this claim. Professional obstacles to CNM-led FSBC care include physicians lobbying against the independent practice of CNMs, contributing to lack of physicians willing to enter in collaborative practice agreements with CNMs or become medical director of FSBCs, which are required in many states for CNMs to legally provide intrapartum care in a FSBC (Institute of Medicine, 2011).

Systems obstacles include the fragmentation of the health care system in the U.S., in which weak connections between various components of the health care system make patient and payer navigation of health care system increasingly difficult. Better communication and collaboration between FSBC, CNMs, providers, and hospitals may make the FSBC model more accessible for patients (Institute of Medicine, 2011). Furthermore, as hospitals increasingly became the predominant location of birth in the U.S. in the 1920s, associated processes, such as payment by insurers, filing of birth certificates, and administration of state newborn screening
tests, were developed using hospital protocols, thus making transition to models outside of the hospital, like the FSBC model, difficult (Feldhusen, 2000; Romano, 2013).

*Business obstacles* include insurance policies of private companies that have become outdated after provisions of the Affordable Care act, making it difficult for patients to locate ARPN services. Other factors include the perception of birth centers as financial competitors for hospitals, the requirement of capital investment to start a birth center, and a low return on investment for some FSBCs leading to lack of financial sustainability (Institute of Medicine, 2011).

**Conceptual Framework: Business Case for Quality**

This paper focuses on addressing a component of the business-related barriers to CNM-led FSBC care. The absence of a formal business case for innovations proven to enhance quality, such as the FSBC model in the U.S., is frequently cited as a reason for not implementing quality improving innovations in health care (Reiter, Kilpatrick, Greene, Lohr, & Leatherman, 2006). Despite an explosion of nurse managed centers over the past 2 decades, including FSBC, many have closed due to inability to achieve financial self-sufficiency. (Vincent, Oakley, Pohl, & Walker, 2000). For a FSBC to be successful, it must not only demonstrate that it can provide safe and effective care through patient outcomes, but also that it is economically and financially sustainable through careful cost and effectiveness analyses.

In this study, *The Business Case for Quality: Financial Model* outlined in *The Business Case for Quality: Tracking the Cash Flows Progress Report* is applied as a conceptual framework for data categorization and presentation of elements of the business case for CNM-
led FSBC care in the U.S. (Pink, Thomas, Kilpatrick, & Brown, 2005). This model is presented in Figure 2, Part a.

*The Business Case for Quality: Financial Model* divides categories of business case into initial investment, changes in cash flows, adjustments, estimated net cash flow, issues to consider, core benefits, and evaluation mechanism while depicting relationships between these components of the financial model (Pink, et al, 2005). This model was originally made to assess interventions in an existing infrastructure. Therefore modifications to definitions within changes in cash flow were required to fit the assessment of the business case of FSBC care. In *The Business Case for Quality: Financial Model*, changes in cash flow, including cash inflows and cash outflows, are derived by examining expenses and revenue within an organization before and after an infrastructure. In this paper, changes in cash flow were operationalized by examining expenses and revenue differences between starting and operating a CNM-led FSBC versus a traditional obstetrician-led hospital unit model (OB-led hospital model). Furthermore, this paper does not aim to attribute monetary value associated with various costs, and instead describes the categories of costs one must consider when starting or operating a FSBC.

Initial investment includes equipment, labor/supplies/startup expenses, facility adaptation, and technology costs. Cash inflows are finances received by an organization that arise from financing, operations, or investments and include operating revenue, grant revenue, spillover revenue, and expenses. Changes in cash inflows refer to differences in finances received by a FSBC versus an OB unit. Cash outflows are costs paid for by an organization that result from expenses of operation and include direct/indirect labor and supply costs, overhead costs, and taxes (Pink et al., 2005). Direct costs are readily identifiable and include costs of supplies, services, and lab tests, medications, personnel, and facility. Indirect costs, or business
overhead, can be challenging to pre-determine and represent secondary expenses like cleaning or security services (Vincent et al., 2000).

In a business case analysis, costs are usually adjusted to account for inflation. This is often achieved by considering nominal cash flows, which account for projections in inflation, instead of real cash flows which count cash flows for current and future costs at the current preset value (Reiter et al., 2006). However, since this study does not attribute monetary value to costs of a FSBC, and instead presents categories of costs, adjustments in cash flows were not considered and categories of costs were contextualized at present value.

Following the format outlined by *The Business Case for Quality: Financial Model*, this paper estimated net cash flow by subtracting changes in cash outflows by initial investment and changes in cash inflows. Core benefits, including improvements in patient care, and issues to consider, including evaluation period, discount rate, sensitivity analysis, and multiple stakeholder perspective, were then presented and considered to determine the final evaluation mechanism. This evaluation mechanism was then used to measure return on investment by net present value, which measures discounted aggregate effect of cash flows accumulating to an organization as a result of an intervention, with respect to discounting (Vincent et al., 2000; Pink et al., 2005). Organizational readiness for the FSBC model was not listed as an issue to consider in *The Business Case for Quality: Financial Model*, but is considered in this paper based on suggestions delineated by *How to Develop a Business Case for Quality* by Reiter et al. (Reiter, et al., 2006).

By presenting elements of a model for business case analysis of CNM-led FSBCs, stakeholders can better understand what factors are necessary to consider when starting and/or operating a birth center.
Methods

This paper analyzes data from two sources, results from a review of literature on the CNM-led FSBC model, and results from semi-structured interviews about financial components of this model of care, to identify key elements to consider when developing a business case for this model of intrapartum care. The results were categorized according to categories in the *Business Case for Quality Financial Model* framework of initial investment, cash inflows, cash outflows, adjustments, issues to consider, and core benefits.

Systematic Review

A review of the literature was conducted in February 2015 using CINAHL, MEDLINE, EMBASE, and ProQuest from inception to 2015. Grey literature, including masters or doctoral theses, conference abstracts, and other unpublished literature, was not included in this study. The search strategy applied to all electronic databases applied search terms across entire documents, instead of using key words or MeSH terms, to avoid exclusion of studies that do not aim to assess business implications, but include a brief assessment in the discussion section of the study. This strategy was employed due to limited number of articles aiming to assess business or economic aspects of the CNM-led FSBC model of care.

The search terms (midwif* OR midwiv*) AND ("birth centers" OR "birthing centers" OR "birth center" OR "birthing center") AND (economic* OR cost* OR resourc* OR financ* OR budget* OR business* OR sav* OR admin*) AND ("united states" or "U.S."%) were applied to all data bases. Studies were included if they were published in a peer-reviewed journal and focused on CNM-led free standing birth center care in the United States. Due to the small number of relevant studies, inclusion criteria based on quality or type of study were not applied.
Studies were excluded if they were not conducted in the United States, focused mainly on other forms of obstetrical care delivery (i.e. homebirths or hospital births), and/or had no relevancy to a business case model.

Titles and abstracts of 123 papers resulting from the search were read and 4 relevant papers were retrieved. The bibliographies of these papers were subsequently assessed for further relevant studies, resulting in 3 additional papers, contributing to the final total of 7 papers being included in the study. A detailed description of the search strategy is presented in Figure 1. These papers were read and data were extracted about study design, results, relevancy to business case, and overall quality and scientific rigor of the paper. This data are presented in Table 1, which consists of 7 columns, which include: (1) First author’s name, study year, and study title, (2) study type and number of participants, (3) purpose, (4) inclusion criteria, (5) clinical results, (6) business case implications, and (7) appraisal of research quality/rigor.
Figure 1: Flow chart of the search strategy employed in this review, which was developing according to guidelines set by the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement (Moher et al., 2009). The relevant number (n) of articles at each point is provided.

**Interviews: Study Design**

An exploratory-descriptive study design was applied for interviews with key informants during the development of interview design, data collection, and data analysis components of this study. Due to lack of sufficient previous literature on the business case of the CNM-led FSBC model of care, limited time to conduct research, and small sample size, an exploratory approach was chosen over a confirmatory approach (Kraemer, & Thiemann, 1987). A qualitative directed content data analysis approach, guided by the *Business Case for Quality*
Financial Model framework, was used to identify key elements of the business case for the CNM-led FSBC care model. This data analysis technique is often used in exploratory-descriptive qualitative methodologies, and was chosen to provide structure to data by limiting inclusion of data irrelevant to business case analysis (Groves, Burns, & Gray, 2013; Hsieh, & Shannon, 2006).

Semi-structured individual interviews with 2 CNM-led FSBC key informants were conducted to provide information on essential factors for stakeholders to consider when analyzing the return on investment, or business case, for establishing and operating a free standing birth center. A primary consideration during planning this research was available time to conduct the research. Due to time constraints of the researcher and limited availability and time of participants, convenience sampling was used to recruit participants to the study. Key informants were identified through professional and informal networks from professors within The University of North Carolina’s School of Nursing. Participants were selected based on previous CNM experience, administrative knowledge about the CNM-led FSBC model, and/or experience in business case analysis. Participants from different practice settings were included to increase diversity of perspectives analyzed. The selected eligible candidates agreed to participate in the study.

Two individuals were enrolled and participated in individual, semi-structured, face-to-face interviews, lasting approximately thirty minutes, in a location of their choosing. A detailed review of the relevant literature, and consultations with a business case researcher and a CNM were used to develop the interview questions and format. The interview consisted of four general questions about financial factors involved in starting or operating a birth center, financial benefits and disadvantages of this model of care, and organizational factors associated with this
model of care. Questions were developed based on *The Business Case for Quality Financial Model* framework. A copy of the questions and *The Business Case for Quality Financial Model* was given to participants as a visual reference during interviews (Figure 2). All interviews were conducted by the primary investigator of the study. Demographic data was not collected due to small sample size to avoid making participants identifiable and assure their confidentiality.

**Interviews: Data analysis**

Brief notes were hand-written throughout the interview to record responses to interview questions, and comprehensive information form interviews were typed immediately after the interview from memory and interviewer notes taken during the interview, as interviews were not audio-recorded. Data was analyzed by the qualitative directed content analysis approach, guided by the *Business Case for Quality Financial Model* framework, to identify key elements of the business case for the CNM-led FSBC care model. Coding was begun immediately with the predetermined categories of codes: (1) initial investment, (2) cash inflows, (3) cash outflows, (4) issues to consider, (5) core benefits, and (6) organizational readiness, as identified in the *Business Case for Quality Financial Model* framework. Data that could not be coded into identified categories were later analyzed to determine if they represented a new category or subcategory of an existing code.

**Interviews: Ethical Considerations**

Prior to conducting interviews, this study was submitted for Institutional Review Board (IRB) approval through the Office of Human Research Ethics of the University of North Carolina Chapel Hill’s IRB. The Office of Human Research Ethics subsequently determined that this study was exempt from further review under the Code of Federal Regulations section
46.101(b). Participants were invited to voluntarily participate in the study and assured that their answers were confidential. All participants received a written and verbal explanation of the study purpose, confidentiality regulations, and voluntary participation policy. After participants verbalized understanding of the study purpose and policies, a written consent was obtained. All participants signed consent forms and verbally authorized their permission to transcribe and analyze conversation from interview.

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**Business Case for Quality: Financial Model**

- **Initial Investment** + \( \triangle \) **Cash inflows** - \( \triangle \) **Cash outflows** +/- **Adjustments**
  - Equipment
  - Labor/supplies/start-up expenses
  - Facility adaptation
  - IT
  - Operating revenue
  - Grant revenue (ongoing support)
  - Splitter revenue
  - Expenses
  - Direct-labor/supplies
  - Indirect-labor/supplies
  - Overhead
  - Taxes, if applicable
  - Incremental new investment
  - Depreciation
  - Change in working capital (if significant)

- **Issues to Consider**
  - Evaluation period
  - Discount rate
  - Estimation factors
  - Variables (i.e., change in reimbursement)
  - Sensitivity analysis
  - Multiple stakeholder perspective

- **Core Benefits**
  - Improved patient care
  - Improved name recognition
  - Improved market perception
  - Splitter improvements

- **Evaluation mechanism**
  - Discounted cash flow (net present value)

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1. What are some broad costs one considers when wanting to start a birth center?
2. Financially, what are the pros and cons of free standing birth center design/model?
3. What are the projected categories of costs of starting a birth center? Consider direct, indirect, recurring, capital costs of birth center operation in answer. Identify some factors you can think of that contribute to:
   a. Startup costs (initial investment)
   b. Incremental (new) cash inflows (compared to traditional hospital based obstetrical care)
   c. Incremental (new) cash outflows (compared to traditional hospital based obstetrical care)
   d. Ongoing costs
   e. Are there other factors one should consider when constructing a business case model for birth centers?
4. Increased utilization of birth centers in the US would require organizational change within our healthcare system. What are factors that are currently pushing towards and away from this type of change occurring?
Figure 2: Interview questionnaire. Above diagram was used as a visual aid of the financial model framework used when asking interview questions. Interview questions were based on this model. Part a. represents Business Case for Quality: Financial Model conceptual framework applied in this study. Organizational readiness for business case was also assessed as an issue to consider. Part b. represents semi-structured questions asked during interview.

Results

Data from the literature review and interviews were collectively analyzed using a directed content analysis approach guided by the Business Case for Quality Financial Model framework (Pink et al., 2005) to identify essential elements to consider when developing a business case for CNM-led FSBCs. Results are presented in order of categories defined in the Business Case for Quality Financial Model, including financial factors involved in initial investments, cash inflows, cash outflows, issues to consider, and core benefits. A visual depiction of the Business Case for Quality Financial Model is presented in Figure 2, Part a., and the components and relationships of this model have been delineated in the “Conceptual Framework: Business Case for Quality” section of this paper. A detailed summary of the review of literature results is presented in Table 1. Data extracted from interviews are cited as “(Interviews, 2015)” to distinguish from data extracted from the literature review. Monetary values presented from years before 2013 were converted to 2015 U.S. dollars using the U.S. Inflation Calculator tool to adjust for inflation, so that monetary values listed from previous studies better reflect current costs (Bureau of Labor Statistics, 2015).

Initial Investment

Costs that are categorized into initial investment are expenses one must consider when initially opening a FSBC. This includes startup expenses like finding a location to rent, AABC
fees, licensing fees, equipment, labor, staff recruitment, and supplies (Interviews, 2015).

Expenses considered in the initial investment section may also represent ongoing costs that are again assessed in the cash inflow and cash outflow sections of a business case analysis. In 1995, the cost of moveable equipment required to open a FSBC was estimated to be $18,125, which equates to $27,795 in 2015 U.S. dollars (Stone et al., 1995). After a location is identified, the facility must be adapted to meet standards of a FSBC. Maternal facility costs have been proposed to be the most expensive cost component of starting a FSBC (Howell et al., 2014). Other factors that must be considered for a facility to be adapted for a FSBC are waiting areas, exam rooms, birthing rooms with baths and toilets, staff areas, storage space, and family or staff bathrooms. The birthing room should contain at least a bed, infant basinet, table, chair, overhead radiant heat warmer, O2 and suction hook ups, and bathrooms. Furthermore, technology costs, like implementing an electronic health record system like EPIC, must be considered (Interviews, 2015). Implementation costs of an electronic health record system for a five-physician practice have been estimated at $162,000, with $85,000 in maintenance expenses, during the first year of use (Fleming, Culler, McCorkle, Becker, & Ballard, 2011). An interviewee, who was a CNM-led FSBC representative and has experience in presenting a business model of BC care to capital investors, estimated a $1.5 million dollar investment required to comprehensively invest in and open a birthing center. The aforementioned expenses are an outline of primary costs that must be considered, but do not offer a comprehensive list of costs to consider when starting a FSBC.

**Cash Inflow**

Cash inflows are finances received by an organization from operations, financing or investments (Pink et al., 2005). In this paper, we considered not only revenue coming into a FSBC, but costs that would be avoided by individual payers and insurance companies for CNM-
led FSBC care compared to traditional OB-led hospital care. Operating revenue describes finances received by the FSBC through providing health care services, namely perinatal care. Payments received by the FSBC are likely from various sources, like Medicaid, self-pay, and private insurance, and must be adequately balanced to remain profitable. Currently, Medicaid is the largest payer for maternity services in the U.S. (Howell et al., 2014). Various studies from the literature review revealed that the patient population traditionally served at birth centers paid with private insurance (Stapleton et al., 2013; Stone et al., 1997; Stone et al., 2000). However, a successful FSBC model described a payment mix of 50% Medicaid, 20% self-pay, and 30% private insurance to be successful, which better represents the actual current payment mix for maternity services in the U.S. (Stevens et al., 2012).

Other operating revenue may come from laboratory services, postpartum home visits, offering tours, consultation visits, family planning care, parent support groups, and perinatal classes, breast-feeding support, infant care, and exercise programs (Jackson et al., 2003; Interviews, 2015). A CNM representative stated that for a FSBC to remain profitable, routine women wellness and gynecological care must also be offered, as gynecological care is more profitable than obstetric care (Interviews, 2015). Grant revenue, or funding brought in by external sources, is often considered when assessing cash inflows. This optional form of revenue may occur by having designated personnel to bring in a designated sum of grant money on a regular basis (Interviews, 2015).

Lastly, avoided costs of the CNM-led FSBC model versus the OB-led hospital model can be assessed. Potential stakeholders in a FSBC model will likely be interested in why a FSBC is a better investment of their finances than a hospital model. Multiple studies have demonstrated the CNM-led FSBC model to be more cost effective than a OB-led hospital model due to avoided
costs in cesarean sections, resource utilization, lower gestational age distribution, lower payments of midwives, lower cost of vaginal delivery at a FSBC versus a hospital, and lower length of stay in a FSBC versus a hospital (Howell et al., 2014; Jackson et al., 2003; Stapleton et al., 2013; Stone et al., 1997). Costs associated with CNM-led FSBC vaginal births in the year 2000 were $597, with OB-led hospital vaginal births were $1759, and with OB-led hospital cesarean births were $2082, equating to $810, $2,387, and $2,825 2015 U.S. dollars, respectively (Stone et al., 2000). The Howell et al. study estimated a $2.44 million per 10,000 births cost saving attributed to a 21% difference cesarean rates in FSBC care versus OB led care. These savings from reduction in cesarean births are also highlighted in the Stapleton et al., study in which a cesarean rate of 6% in FSBC care versus 25% in hospital care was projected to save $4,487,524 by the 15,574 births in this study. Based on the overall costs of uncomplicated cesarean birth in a hospital versus uncomplicated vaginal birth in a BC ($3998 vs $1907), the Stapleton et al., study estimates that $27,245,469 was saved by the 15,574 births in this study. The Jackson et al. study further highlights this point by attributing reduction in operative deliveries in the FSBC model to significant reduction in resource utilization in the FSBC model. Other sources of cost savings for the FSBC model of care include a lower gestational age distribution of late pre-term and early term births and associated NICU costs, lower payments of CNMs versus physicians of 27.7%, and lower facility costs of FSBC versus hospital, summing to savings of $11.64 million per 10,000 births (Howell et al., 2014). Lastly, a lower length of stay of less than 24 hours for the FSBC model compared to 2-3 days in the hospital model contributes to significant savings (Jackson et al., 2003; Stone et al., 1997). Overall, the Howell et al. study estimates a 16% cost reduction in the FSBC model versus a hospital model for obstetrical care.

**Cash outflow**
Cash outflows are finances paid for by an organization from expenses of operation, including direct costs, indirect costs, and overhead costs (Pink et al., 2005). In this paper, not only expenses being paid by a FSBC for operation were considered, but extra costs associated with a FSBC model versus a hospital model were also considered. Direct costs are readily identifiable expenses a FSBC must pay to maintain operation, like cost of supplies, services, lab tests, medications, staffing, and facility, and were defined throughout various studies.

The Stone et al. study from 1995 defines direct costs as “costs directly related to the care, like cost of interventions and fee of providers.” Some direct costs outlined in this study include facility costs of vaginal delivery at a FSBC to be $1962 versus $2791 at a hospital or $4,916 for a cesarean birth, equating to $3,008, $4,280, and $7,538 in 2015 U.S dollars, respectively. This study also assessed transfer costs associated with ambulance fees and advanced life support equipment, which have been proposed as a direct cost associated with why FSBCs are not economical when compared to hospital based care. However, it was found that transfer rates need to exceed 62% for a FSBC to become an economical option (Stone et al., 1995).

The Stone et al. study from 2000 defined direct costs as “the value of goods, services, and other resources consumed in the provision of an intervention.” Direct costs assessed in this study included expenses associated with ultrasounds, non-stress tests, biophysical profiles, lab fees, intravenous fluids and equipment, Pitocin, narcotic analgesia, fetal scalp electrode, lidocaine, and vacuum extraction. Other direct costs include provider costs, induction, oxytocin augmentation, amniotomy equipment, tub/shower, oral fluids/food, fetal monitoring equipment, episiotomy equipment, and intermittent Doppler monitoring of fetal heart tones equipment (Jackson et al., 2003). The Stone et al. study in 1997 also examined similar direct costs and noted that direct costs of the FSBC group was 60% less costly than the OB group, due to reduction in use of
invasive uterine monitoring, IV fluids, episiotomies, length of stay, anesthesia, and electronic fetal monitoring.

Costs of salaries and benefits of providers and costs associated with birth are also considered direct costs. In the Stone et al. study in 2000, salaries and benefits of CNM care of $69,525 versus physician care of $125,472, equating to $94,358 and $170,288 2015 U.S. dollars, respectively. The Stevens et al. paper in 2012 described an example of staffing patterns for a successful birth center model. In their model, the following fulltime equivalents (FTEs) of staffing produced safe, effective, and profitable patient care: 2.75 FTE of registered nurses who have roles in contraceptive management, office visits, telephone triage, home visits, 1 week postpartum visits, birth assistance, ordering of supplies, sterilizing equipment, venipuncture, and quality assurance; 3.25 FTE of medical technicians who have roles in office support, assisting in office visits, processing laboratory specimens, maintaining rooms and equipment, and assisting providers as needed; 7 FTE of clerical staff who have roles in scheduling all appointments, answering phone calls, clerical/office work; 0.25 FTE of per diem lactation consultations who are available for clients through 6 weeks postpartum as needed and provides per diem staff in-services; 4 FTE of CNMs who provide full scope OB/GYN care, are first call for practice, perform limited third trimester ultrasound, provide all out of hospital care, and are primary provider for births; and 1 FTE of OB who is the director and owner of the BC who performs full scope OB/GYN care in a separate OB office only, performs all routine ultrasound and procedures in OB office, manages surgeries, is second call, performs all C-sections and instrument-assisted births, and has a role in normal birth only if woman chooses OB as provider (Stevens et. al., 2012).
Other direct costs that were not described in the literature review, but were revealed during interviews with CNM representatives include emergency equipment and supplies for patient stabilization, including airway management equipment, ambu-bags, AEDs, and emergency medications. Other direct costs include blood pressure equipment, thermometers, instruments for delivery, instruments for episiotomy repair, portable lights, an autoclave to equipment sterilization, and separate refrigerators for infant milk, staff/patient food, and medications (Interviews, 2015).

Indirect costs are more difficult to identify and represent secondary expenses necessary to operate a FSBC but are not directly associated with patient care (Pink et al., 2006). This may include costs to fix equipment or educate clinicians (Stone et al., 1995). This may also include emergency electrical generators, janitorial services, linen and laundry services, preventative maintenance on birthing equipment, smoke alarms, fire extinguisher, and kitchen facilities (Interviews, 2015). Overhead costs are often included as a component of indirect costs and include expenses associated with utilities, advertising, taxes, and rent. An estimation on an annual building lease for a FSBC was provided by the Stone et al. study in 1995 of $42,000, or $64,407 2015 U.S. dollars, but this value is greatly influenced by the geographical location and size of the FSBC practice. Malpractice insurance is also considered an indirect overhead cost, and accounts for one of the largest costs for obstetrical care (Interviews, 2015).

Lastly, changes in cash outflow were assessed by identifying extra expenses paid for by a FSBC that would not be paid for by a hospital model. The Stone et al. study in 2000 revealed that prenatal care associated with the FSBC model is more expensive than a hospital model. This study found that the FSBC model they assessed was not significantly more cost effective than hospital care. Average total cost of maternity care was $6,087 for BC care and $6,803 for
hospital care, or $8,261 and $9,232 2015 U.S. dollars, respectively. Although intrapartum care was $1,472 lower in BC group than the hospital group, prenatal care for BC group was $751 higher, or $1,997 and $1,019 2015 U.S. dollars, respectively. Sensitivity analysis of impact of patient volume on costs of care was performed and revealed that if FSBC saw its full capacity of volume of patients, FSBC has potential to decrease prenatal care costs by greater than $1,000 per patient, or greater than $1,357 2015 U.S. dollars, respectively (Stone et al., 2000). All other studies reviewed suggested cash outflows of the FSBC model to be less than hospital models.

**Core benefits**

The core benefit of this model echoed throughout the review of literature and interviews is that it provides safe and effective care with increased patient satisfaction and decreased costs (Howell et al., 2014; Jackson et al., 2003; Rooks et al., 1989; Stapleton et al., 2013; Interviews, 2015). Furthermore, this model of care embodies multiple initiatives in the United States to improve healthcare while lowering healthcare costs, including initiatives within the Institute of Medicine’s Future of Nursing: Leading Change, Advancing Health, the Affordable Care Act, The Institute for Healthcare Improvement’s Triple Aim, and the American College of Physician’s emphasis on “High Value Care.” Lastly, this model offers a unique conceptualization of childbirth, in which high-touch, low-technology care is used to help empower mothers and families to have a healthy and positive birthing experience (Interviews, 2015).

**Issues to consider**

Issues to consider in the Business Case for Quality: Financial Model include evaluation periods, discount rates, estimation factors, future changes to environment, sensitivity analysis, and multiple stakeholder perspectives (Pink et al., 2006).
An evaluation period of costs grouped by the first prenatal visit of a patient to 6 weeks postpartum may be useful. Furthermore, discounting may not be required, since the time horizon for business case analysis would be less than one year (Stone et al., 2000).

Estimation factors may include costs of readmissions shortly after a birth, which have not been studied (Howell et al., 2014). Other factors one must consider include the diversity of the patient population and payer mix. A lack of patient diversity in FSBC care, in which the majority of the population is Caucasian, educated, and has private insurance, may be a barrier to increased utilization of CNM-led FSBC since this population is unrepresentative of the actual patients needing obstetrical care in the U.S. (Stapleton et al., Stone et al., 1997; Stone et al, 2000).

Potential changes to the current obstetrical care environment include increased availability of FSBCs through initiatives like provisions in the Affordable Care Act, the Strong Start initiative, or the CHIP program (Stapleton et al., 2013). Currently, some insurance companies maintain outdated policies which limits coverage of CNM-led FSBC care. However, as insurance companies update their policies to comply with governmental regulations to cover CNM-led FSBC care, consumers may be able to more readily access this care model (Institute of Medicine, 2009; Interviews, 2015).

Sensitivity analyses, in which future outcomes are projected based on current factors, may also provide information for stakeholders when assessing the business case of the FSBC model. For example, a sensitivity analysis determined that the transfer rate from BC to hospital care must be greater than 62% for BC to become an uneconomical choice. (Stone et al., 1995). Another sensitivity analysis of impact of patient volume on costs of care was performed and revealed that if a FSBC saw its full capacity of volume of patients, the FSBC has potential to decrease prenatal care costs by greater than $1,000 per patient (Stone et al., 2000).
Multiple Stakeholder perspectives must be considered when assessing a business case for quality, as they may view the model from varying approaches. When costs are assessed from the Medicaid perspective, cost effective care is prioritized. As Medicaid is the leading payer for maternity services in the U.S. and faces increasing budget constraints, cost effective care is increasingly important to them making the FSBC model of care an appealing option (Howell et al., 2014). In contrast, hospitals and physicians may view the FSBC model as financial competition (Institute of Medicine, 2009; Interviews, 2015). However, hospitals or physicians could make additional revenue through collaboration with FSBC. In the FSBC model outlined by Stevens et al., referrals from a FSBC to hospital and physician services like surgical or gynecological care provided steady additional revenue to physicians. Lastly, women’s opinions towards the CNM-led FSBC must be assessed to determine how many women would choose this model if it were increasingly available. Although studies demonstrate increased patient satisfaction associated with this care model compared to a hospital based models, women’s perspective needs to be further empirically assessed (Stapleton et al., 2013). The growing waiting list of women to be seen at the Women's Birth and Wellness Center CNM-led FSBC in Chapel Hill, however, suggests that women want this model of care (Interviews, 2015).

Organizational Readiness

Lastly, organizational readiness for change was assessed in this paper to determine what organizational factors may influence and impede use of the CNM-led FSBC model. Although there is a need for more qualitative studies to empirically assess the organizational readiness for increased use of the CNM-led FSBC model, interview data collected in this study suggest that regulations on ARPN practice, high risk of liability in obstetrics, and lack of profitability from low-risk obstetrics are major obstacles to CNM practice in FSBCs (Stapleton et al., 2013;
Interviews, 2015). In both interviews, the CNMs stated that the Southwest region of the United States, especially N.C., is a “stifling environment” for CNM practice compared to their previous practice experiences in other regions. They stated that the stringent regulations on APRN practice in this region make CNM practice especially difficult. At Rex Healthcare Hospital in Raleigh, N.C., for example, there currently are no CNMs available for births because this hospital requires a physician in house for a CNM to practice, making hiring CNMs an extra burden on physicians. Furthermore, they report that obstetrics is dominated by Caucasian, male physicians in N.C., whereas CNMs are generally females with more varied diversity. When asked about patient perspectives on the CNM-led FSBC care model, both CNMs used phrases like “absolutely” and “oh yes” to emphasize the patient demand for this model. They report that the high demand is what prompted UNC to open their hospital CNM practice 12 years ago, which was a big feat for a tertiary care hospital. They also give the example of the Women’s Wellness Center in Chapel Hill, N.C., a non-profit FSBC operating for over 20 years with a competitive waiting list for patient enrollment. They both report that the “bottom line is women are demanding this care model.”
Table 1: Summary Table of Literature Relevant to Business Case of CNM-led FSBC model

<table>
<thead>
<tr>
<th>Author, Year, Study title</th>
<th>Study Type &amp; Number</th>
<th>Purpose</th>
<th>Inclusion Criteria</th>
<th>Clinical Results</th>
<th>Business Case Implications</th>
<th>Appraisal of Research Quality &amp; Rigor</th>
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<tr>
<td>Howell et al., 2014, Potential Medicaid Cost Savings from Maternity Care Based at a Freestanding Birth Center</td>
<td>Secondary cost effective analysis of prior quantitative comparative case study analysis of maternal and infant health outcomes at the Family health and Birth Center in Washington, D.C. comparing 872 women receiving FSBC care versus 42,987 women receiving traditional care</td>
<td>To determine whether FSBC care reduces Medicaid costs for low income women.</td>
<td>All women who delivered singleton births with a gestational age of at least 24 weeks and received minimum of two prenatal visits were included in “birth center care” group, regardless of where they delivered. Women who gave birth in the District of Columbia who had greater than 2 prenatal visits and delivered after 24 weeks were included in the “usual care” comparison group.</td>
<td>Prematurity, birth weight, vaginal birth rates, and rates of cesarean section are better on average for FSBC group than usual care group, while costs are lower.</td>
<td>48% of births in 2010 were paid for by Medicaid. Birth center care is estimated to save average of $1,163 per birth, or $11.6 million per 10,000 births per year, for low risk women receiving Medicaid. The Centers for Medicare &amp; Medicaid services (CMS) have launched the Strong Start initiative which includes a funding opportunity to test and evaluate the effectiveness of enhanced prenatal care approaches, including FSBC care, for women enrolled in Medicaid or Children’s Health Insurance Program (CHIP), to determine if these approaches can reduce rates of preterm births, improve health outcomes of pregnant women and newborns, and decrease anticipated total cost of medical care during pregnancy, delivery, and the first year of life for children born to mothers in Medicaid or CHIP. Methods for estimating cost to Medicaid for Birth Center Care and Usual Care is outlined. Physician cost, midwife costs, maternal and infant hospital costs, and birth center (BC) costs are defined and estimated. BC costs are defined as average cost of care and delivery at a birth center for mother and newborn. BC cost is estimated by average total charges. This study controls for more risk variables between groups, unlike many previous comparative studies, increasing the validity and rigor of this study. This study analyzes data from a study that used propensity score reweighting to create comparison groups that, when weighted, had nearly identical observed characteristics as the birth center group. This study carefully controls for risk selection, a problem in previous studies in which women who have lower risk are in FSBC group and higher risk are in usual care group. Also, unlike similar prior comparative studies, this study does not exclude transfers from birth center care or exclude high-risk women delivering at hospitals, accounting for all women followed at the birth center, regardless of where they delivered. Limitations to study include limitations of results being based on single observational study, possible unaccounted differences in risk between groups, and unknown cost exclusions, like transportation from a FSBC to a hospital or readmission costs, in study.</td>
<td>This study controls for more risk variables between groups, unlike many previous comparative studies, increasing the validity and rigor of this study. This study analyzes data from a study that used propensity score reweighting to create comparison groups that, when weighted, had nearly identical observed characteristics as the birth center group. This study carefully controls for risk selection, a problem in previous studies in which women who have lower risk are in FSBC group and higher risk are in usual care group. Also, unlike similar prior comparative studies, this study does not exclude transfers from birth center care or exclude high-risk women delivering at hospitals, accounting for all women followed at the birth center, regardless of where they delivered. Limitations to study include limitations of results being based on single observational study, possible unaccounted differences in risk between groups, and unknown cost exclusions, like transportation from a FSBC to a hospital or readmission costs, in study.</td>
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<td>*Jackson, et al, 2003, Outcomes, Safety, and</td>
<td>Prospective Cohort study with concurrent comparison</td>
<td>To compare outcomes, safety, and resource</td>
<td>Low risk, low-income women; inclusion into study based on</td>
<td>Major antepartum, intrapartum, and neonatal</td>
<td>Fewer operative deliveries and medical resources (including reduction in rates of induction, oxytocin augmentation, epidural anesthesia, episiotomies, cesarean sections,</td>
<td>This study was the first large prospective cohort study to rigorously balance initial perinatal risk across FSBC group and traditional care group. By applying the</td>
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<td>Resource Utilization in a Collaborative Care Birth Center Program Compared with Traditional Physician-Based Care</td>
<td>groups of low-income pregnant women presenting for obstetrical care at collaborative BC site vs physician led site. – 2957 women receiving care at The BirthPlace San Diego BC or hospital, 1808 receiving “BC care” and 1149 receiving “traditional care.”</td>
<td>utilization in BC model of perinatal care versus traditional physician-based care.</td>
<td>complications were similar; NICU admissions were similar; Collaborative BC care led to greater number of normal spontaneous vaginal deliveries and less use of epidural anesthesia. and assisted vaginal delivery) were observed in collaborative BC care than in traditional physician led care. IV fluids were used equally. The BirthPlace delivers 500 deliveries per year, and is the largest nationally accredited FSBC in the US. It is located within 15 minutes of 3 tertiary hospitals, provides a low-tech environment, uses intermittent Doppler auscultation of fetal heart tones, encourages ambulation, has tub baths, and provides narcotic analgesics for pain relief. Epidural analgesia is unavailable. Mothers and infants are discharged within 24 hours after delivery. Evaluation of newborn and mother is made via home visit by a nurse within 24 to 48 hours after discharge and again by a pediatric provider within 5 days. The mother is seen again at 6-weeks postpartum unless complications occur. Formal cost analysis or cost estimation was not performed. Limitations to study include limitations of results being based on single FSBC site, possible unaccounted differences in risk between groups, lack of quantification of costs saved from differences in resource utilization between groups, and lack of formal cost analysis.</td>
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| Stapleton et al., 2013, Outcomes of Care in birth Centers: Demonstration of a Durable Model | Prospective cohort study of women from 79 CNM-led birth centers in 33 U.S. states, total of 15,574 women | To examine current safety and effectiveness outcomes of birth center care and compare to results of BC outcomes from previous studies. – cost implications were noted in discussion section, but were not main | Low-risk women previously planning and eligible for birth center birth at onset of labor. Intrapartum fetal and neonatal mortality comparable to studies of general population of low-risk women. Cesarean rates were 6% versus estimated 25% for similarly low-risk women. Mortality, based on difference in cesarean birth rates in BC vs hospital (6% vs 25%), $4,487,524 was saved by the 15,574 women in this study. Based on costs of uncomplicated cesarean birth in a hospital vs uncomplicated vaginal birth in a BC ($3998 vs $1907), this study estimates that $27,245,469 were saved by the 15,574 women in this study. This paper analyzes data from multiple BCs throughout the country, increasing generalizability of results. A threat to design validity is discussed in which a potential for data entry bias exists since data is collected and entered by providers; however, a validation study on this data set has shown 90% consistency of data across BC, increasing the validity and reliability of this data. Data were analyzed using descriptive statistics, which require further inferential analyses to determine extent of generalizability of results. |
| **Purpose of study** | transfer rates, complication, and operative birth rates consistent with findings from Cochrane reviews of place of birth and midwifery-led care, British studies of place of birth, and U.S. studies comparing midwifery and obstetric care. | Costs were projected in discussion, but formal cost analysis was not performed. The majority of participants are white, non-Hispanic, college educated women. This population is indicative of what women choose and are eligible to deliver an AABC certified BC, not of selection bias in the study. The lack of diversity in the patient population and lack of inclusion of all birthing centers may limit generalizability of the study to all BCs. 33% of participants were enrolled in federal or state government programs like Medicaid or CHIP, compared to the national average of 48% of births being paid for by Medicaid. Only AABC accredited birth centers are included in the study, which have more resources, structure, and federal support than non-AABC centers. | *Stevens, et al., 2012, Description of a Successful Collaborative Birth Center Practice Among Midwives and an Obstetrician*  
Descriptive study – 3 year birth statistics from The Reading Birth and Women’s Center in Reading, PA on 892 women provided care at and planning to give birth at this BC.  
To describe a successful collaborative model among 4 CNMs and 1 OB that provides safe, individualized, high-quality, cost-effective care with good outcomes while optimizing use midwifery care model.  
N/A  
Out of 892 women planning to give birth at BC, 87% were attended by CNMs, 88% had spontaneous vaginal delivery, 9.5% had an unplanned cesarean, 73% had successful VBACs.  
Payer breakdown of 50% Medicaid, 20% self-pay, and 30% private insurance is successful in this practice.  
Staffing full time equivalents and duties are outlined for entire practice, including director/administrative roles; Necessary components of successful collaborative model are outlined.  
Before merging of BC and OB/GYN practice, physician’s practice earned additional revenue from referrals of women needing gynecologic surgical care. After merger, payroll expanded and the practice saw a 5% increase in revenue, despite a “difficult economy.”  
Limitations include limitations in generalizability due to description of single case study and lack of formal cost analysis or estimation.  
Cost breakdown unclear.  
Replication of model guidelines include need for an in-depth financial base, in which payroll must be met, sporadic cash flow must be accounted for, and a working budget and spending plan are “very important,” but details on how to achieve this financial model are not given. |
| Stone et al., 1997, Clinical and Cost Outcomes of a Free-Standing Birth Center: A Comparison Study | Pilot quasi-experimental comparative study comparing FSBC care with a mixed staff women’s clinic, and a traditional OB practice. Each group randomly selected 23 BC eligible participants, and 2 additional participants in each group were purposely sampled with emergency cesarean deliveries, totaling to n=75. | To compare the processes and outcomes of care (clinical and cost) for comparable birth center-eligible pregnant women choosing different structures of prenatal and child birth care in a single community. | Subjects were randomly selected from a pool of birth center-eligible women. Birth center eligibility was established at 37 weeks gestation by the FSBC protocol by CNMs in the FSBC group. | FSBC group used less electronic fetal monitoring, and anesthesia, although this difference was not statistically significant. The FSBC group used significantly less invasive uterine monitoring, intravenous fluids, episiotomies, and had a 3-4 times lower length of stay. Total direct costs of FSBC group were 60% less costly than care for the two groups receiving hospital care. | Lower use of technological childbirth care affects lowered cost of care, and does not negatively affect clinical outcomes. Total costs included fixed and variable costs from BC, hospital, and physician practices obtained through accounting departments. Fixed costs were based on shared overhead costs and length of stay. Variable costs were based on salaries and supplies. Provider prenatal and delivery fees were determined from fees charged to patient and/or insurer. Professional fees were added to costs. The Nurse Midwifery Clinical Data Set, which has been previously reliability and validity tested, was used to collect data in all settings, increasing the validity and reliability of the results. Four multivariate analyses of variances were computed to detect differences between groups. To prevent type 1 error, a Bonferroni correction was applied to all analyses. No statistically significant differences were detected between groups for prenatal care. OB group had fewer prenatal visits. FSBC group used fewer technological diagnostic processes. OB and FSBC group consisted of mainly white, educated women, in their late 20s, for whom this was a second or third pregnancy, and had private insurance. Mixed staff women’s clinic had disproportionately higher women who paid through Medicaid younger age, and increased ethnic diversity of patients. This was a pilot study with a small sample size, limiting the power to detect differences between groups. The generalizability of the study is limited due to single comparative case study. The small sample size and purposeful sampling of emergency cesarean cases make this study prone to selection bias. |
| Stone et al., 1995, Cost-Effectiveness Analysis: Birth Center vs. Hospital Care | Cost effective analysis using a decision analytic model to compare cost of BC care to a hospital care for To determine if BC care is a cost effective choice for delivering a baby, what percentage of Low risk deliveries specific definition or eligibility criteria are not defined. Clinical outcomes were assessed by review of literature of previous studies on Major costs associated with low-risk delivery at a birth center and a hospital are defined based on hotel costs, provider fees for type of care, ambulance fees if transfer is required from BC to hospital care, and advanced life support used if transfer is required from BC to hospital care. Initial perinatal risk across FSBC group and traditional care group was not performed. Selection bias is not addressed. |
low risk deliveries.

Data on clinical outcomes of n= 11,814 participants in BC care and n=2,256 in hospital care were extracted from previous literature.

transfers to the hospital is optimal to make a BC an economical choice, and what costs need to be accrued during transfer to make BC care an uneconomical choice.

clinical outcomes of FSBC vs hospital care. Previous studies

Results literature review are categorized into quality outcomes of serious vs. minor vs. serious complications; C-section; maternal or infant mortality, to determine probability of events occurring and possible outcomes of each model of care. All serious quality outcomes were assumed to require hospital transfers.

Direct costs included cost of interventions, fee of providers, ambulance charges, and hotel costs.

Indirect costs included fixed equipment costs, and cost of education of clinician.

Fixed costs of BC were minimal with cost of moveable equipment needed totaling $18,125, and annual building lease being $42,000.

Diagnosis related groupings were used to generate 1 charge per diagnosis.

Costs are defined as economic impact of charges to insurer and/or patient.

In this study, the average cost of delivery is $3,385 for BC care and $4,673 for hospital care; cost of total care.

A sensitivity analysis determined that the transfer rate from BC to hospital care must be greater than 62% for BC to become an uneconomical choice. Current transfer rates are 7.3% for parous women and 28.6 for nulliparous women.

Demographic data is unavailable. BC and OB group in which this study is based off of is unavailable.

Field research, in the form of interviews of BC and OB financial managers, was used to collect information on OB and BC costs. Details of method of information retrieval during these interviews is unavailable.

The decision analysis was performed on the assumption that charges reflect costs when determining 4-year projections.

Quality outcomes were measured in crude units of utility, however method for deriving utilities is not described.

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Design</th>
<th>Methodology</th>
<th>Findings</th>
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<tbody>
<tr>
<td>Stone et al., 2000</td>
<td>Quasi-experimental comparative economic analysis of two models of low-risk maternity</td>
<td>To determine the actual costs of care of FSBC model of care compared to medical model</td>
<td>No significant differences between groups in sociodemographic variables</td>
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<td>care: A freestanding birth center compared to traditional care</td>
<td>physician-led hospital care (n=77) in rural central New York.</td>
<td>criteria for BC eligibility.</td>
<td>clinical outcomes and patient satisfaction; Increased satisfaction, 6 week breastfeeding rates, and intact perineum were observed in FSBC group.</td>
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was found by t-test and chi-squared analysis. However, most women were in late 20s, and had graduate education, parous. Furthermore, 74% married, 95% Caucasian, 63% private insurance coverage. Sample is unrepresentative of U.S. childbearing population. This study is based on one rural community, limiting the generalizability of the study. However, study notes this allowed thorough analysis of specific costs in study. Other limitations in study design include women self-choosing what type of birthing care they receive, sample size too small for sufficient power to detect statistically significant differences, and large number of women declining participation. Costs of care of women transferred to hospital were included in BC group, increasing thoroughness of economic evaluation. However, some costs were based on stepdown reports which reflect cost-shifting, not actual costs of care. Sensitivity analysis assumes FSBC can increase volume without impact on outcomes or staffing; further multivariate analysis is necessary to fully assess.

*These papers do not describe a truly CNM-led FSBC model, since an OB owns and directs the BC. However, the CNMs act as independent care providers within these centers. Furthermore, various states require a physician to be in a collaborative agreement with and/or the director of a FSBC for operation. These studies were therefore included in this literature review*
Discussion

Although this paper focuses on business implications of the CNM-led FSBC model of care, it is paramount to note that the ability of a healthcare model to facilitate the provision of quality care remains the primary factor to consider when developing and implementing the model. This was a key theme revealed in all studies and interviews assessed. All studies either prefaced cost analyses with patient and clinical implications of the model, or focused mainly on the clinical and patient outcomes of the FSBC model. Furthermore, both interviews emphasized the importance of patient outcomes and satisfaction associated with the CNM model of care. They suggested that one should assess financial aspects of a model of care only after the model is shown to provide quality care, as “profitability rests on the foundational pillars of patient safety and satisfaction.”

Providing quality care is crucial. However, despite several studies demonstrating a FSBC’s ability to provide safe and effective patient care with increased patient satisfaction, this model of care is not frequently used in the United States (Benatar et al., 2013; Howell et al., 2014; Jackson et al., 2003; Rooks et al., 1989; Stapleton et al., 2013). Although the studies assessed in this review support a FSBC’s ability to provide high-quality and cost effective care, various birth centers continue to close; this may be partially attributed to these FSBCs’ inability to achieve financial self-sufficiency (Interviews, 2015; Vincent, 2000). Even if a healthcare program has been proven to offer quality care, the program may not be feasible to implement if a return on investment cannot be accrued (Reiter et al., 2006). This paper can help guide what factors a stakeholder considers when opening and maintaining a CNM-led FSBC by outlining the essential factors associated with the Business Case for Quality: Financial Model for FSBC care.
The older studies included in the literature review point to a lack of prospective cohort studies to assess clinical outcomes associated with FSBC care, but multiple large-scale prospective cohort studies have been performed since then and reiterate the safe outcomes associated with FSBC care (Jackson et al., 2003; Stapleton et al., 2013). The literature review also reveals that clinical and cost outcomes associated with the FSBC model versus hospital based models have remained consistent over time, in which the FSBC is associated with clinical outcomes as good as or better than hospital based care while being more cost effective (Howell et al., 2014; Jackson et al., 2003; Stapleton et al., 2013; Stone et al., 1997; Stone et al., 1995; Stevens et al., 2012). However, one study concluded that although the FSBC model has outcomes as good as hospital care, it is as expensive as hospital care if the whole perinatal episode is considered due to lower costs of intrapartum care but higher costs of perinatal care associated with the FSBC model compared to the hospital model (Stone, et al., 2000).

Limitations

This paper is limited by exclusion of Grey literature from the literature review, limited sample for interviews, limitations associated with the interview methodology, lack of additional researchers to cross-examine data collected, lack of pilot testing for validity and reliability of business case interview questions, and lack of quantitative monetary values assigned within the business case. Furthermore, weaknesses of the literature reviewed contribute to overall limitations of this paper.

The largest limitation to this study is the exclusion of Grey Literature, including reports, news articles, dissertations, or memoranda, from the systematic review of literature included in this study. The review was pragmatically limited to peer reviewed academic articles due to time constraints of this study. However, valuable information may have been excluded from this
study, including business reports and market research reports which may have provided further
detailed information for the business case of the CNM-led FSBC model. It is likely that detailed
but privately owned business models of CNM-led FSBCs exist, but are not publicly available for
proprietary reasons. For example, the AABC has a “How to Start a Birth Center” workshop that
teaches a cost-containment model, but details of this model, like evidence it based upon, are only
available to AABC members who pay for and attend this workshop (American Association of
Birth Centers, 2014). Furthermore, exclusion of Grey literature makes this paper prone to
publication bias in which only results of successful FSBC models are included. To better assess
problems associated with the FSBC model of care, examining factors that contributed to the
closing of unsuccessful FSBCs may prevent stakeholders from making similar mistakes.

Another limitation to this study was inclusion of only two select CNM-FSBC
representatives for interview data. Due to time constraints, a convenience sample of participants
readily willing to participate in interviews was used in this study. The small sample size is prone
to selection bias and is not generalizable to CNM-led FSBCs across the United States. To
improve the diversity of the sample, we plan to revise this paper after interviews are conducted
with eight additional participants, including directors and business managers of various FSBCs.

Limitations associated with conducting interviews may also be considered in this study.
The Hawthorne effect, in which subjects know they are participating in a research study, may
have contributed to interviewees skewing answers to interview questions to represent the CNM
profession in a positive manner. Furthermore, since both CNMs interviewed in this study have
not participating in births in the past few years, their answers may be prone to recall bias.
Additionally, data presented in this paper was collected and analyzed by a single researcher, potentially decreasing the reliability and validity of the data collected. To avoid interviewer and interpretation bias in this study, data from studies reviewed and interviews conducted were searched for information not supporting the quality or cost-effectiveness of FSBC care. For example, during interviews, participants were asked about not only the pros to the FSBC model, but also the cons to this model of care.

The interview questions used in this study were not evaluated to determine the extent to which they effectively assess the business case components this study aims to assess. To increase the validity and credibility of the questions used in this study, the questionnaire could have been pilot tested on select CNM-FSBC representatives to determine the efficacy of questions at assessing components of the Business Case for Quality: Financial Model.

Although a formal business case analysis requires one to assess all monetary costs, this study did not assign concrete monetary values to all of costs identified due to lack of details within studies reviewed, exclusion of Grey literature, and lack of detailed questions on monetary values for costs during interviews. Similarly, although this study presented various key components to consider when starting and operating a FSBC, the categories of cost are not comprehensive and must be adjusted for one’s specific FSBC needs. Although the main categories of cost associated with obstetrical care within a FSBC are consistent, like provider fees or birthing room equipment costs, other costs vary with amount of patients served and services offered. For example, some FSBCs offer prenatal yoga and massage or boutiques while others focus solely on obstetrical care.

Lastly, components of the business case for CNM-led FSBC care identified in this paper are limited by the quality and rigor of studies included in the literature review used to identify
these components. Various studies in the literature review were based on single observational studies which need to be repeated and expanded to multiple FSBCs across the United States to increase generalizability of results (Howell et al., 2014; Jackson et al., 2003; Stevens et al., 2012; Stone et al., 1997, Stone et al., 2000). Additionally, since various studies reviewed did not aim to perform a formal cost analysis, cost savings were instead projected at the end of the study or categorized by resources saved without attributing monetary value to these resources (Jackson et al; Stapleton et al., 2013; Stevens et al., 2012). Furthermore, although this paper adjusted for cost inflation by converting dollar years from previous studies into 2015 U.S. dollars when discussing monetary values, this method of cost adjustment does not account for all factors involved in changes in costs over time, such as changes in cost of technological equipment from mass production or provider fees from legislative action. There was also a lack of diversity in the sample of women included in FSBC samples, in which the majority of women were Caucasian, educated, and had private insurance (Stapleton et al., Stone et al., 1997; Stone et al, 2000). Although this is representative of the type of women choosing to birth at a FSBC, the lack of diversity limits the generalizability of the results to all women in the U.S. All studies assessed were also subject to unknown cost exclusions, in which certain categories of costs are unknowingly or purposely not included cost effective analysis. While there was some overlap in categories of costs included in cost analysis of previous studies, the studies generally varied in what was included to assess cost effectiveness of FSBC care. Other limitations to studies reviewed included use of only three search engines to identify relevant studies and inclusion of studies dating back to 1995 due to limited relevant literature available on this topic.

A common criticism associated with comparative analysis of CNM-led births versus OB-led births is risk adjustment of women choosing certain models of care. Since a women’s
pregnancy must be considered low-risk to be eligible for a CNM-led birth, they usually have better maternal and infant outcomes compared to OB-led births which also provide care for high-risk pregnancies with increased likelihood of negative maternal and infant outcomes. All studies included were subject to selection bias associated with women with lower risk pregnancies choosing the CNM-led FSBC versus the OB-led hospital model. A randomized controlled trial in which women are assigned to the differing models was not performed due to ethical reasons. Many studies attempted to control for differences in prenatal risk by using low-risk criteria for inclusion into the study (Howell et al., 2014; Jackson et al., 2003; Stapleton, 2013; Stone et al., 2000). However, some studies that do not systematically account for prenatal risk between groups are at increased risk for selection bias (Stevens et al., 2012; Stone et al., 1997; Stone et al., 1995).

Directions for Future Research

Limitations to previous studies assessed in the review of literature suggest several key implications for future research. All previous formal cost analysis studies are based off of single observational studies, and need to be systematically repeated across multiple FSBC sites to better assess cost effectiveness of this care model across the U.S. Furthermore, a systematic method for cost analysis of FSBC care, in which categories of costs are uniformly defined and applied in analysis, may allow better comparison between studies in the future.

The limitations of this paper also suggest key directions for future research, including assigning monetary values to categories of costs presented in this paper for the business case of birth center care and obtaining and analyzing interview data from a more diverse sample of CNM-FSBC representatives. Also, the Grey Literature excluded in this study, like business reports or private business models within the AABC or ACNM, needs to be assessed in future
studies for business case implications. Lastly, instead of looking at successful FSBC models, it may be beneficial for future studies to assess factors contributing to the closing of unsuccessful FSBCs. Ultimately, we hope this paper contributes to the development of a detailed CNM-led FSBC business case analysis tool that is stakeholders can use and apply when assessing finances of a FSBC.

**Conclusions**

Although various studies have assessed the cost effectiveness and economic implications of the CNM-led FSBC model of care, this paper systematically presents the financial aspects of this care model using the *Business Case for Quality: Financial Model* framework. By presenting elements of a model for business case analysis of CNM-led FSBCs, including initial investments, cash inflows, and cash outflows, this paper may allow stakeholders to better understand factors necessary to consider when starting or operating FSBC.
References


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