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FACTORS THAT CONTRIBUTE TO THE MORBIDITY AND MORTALITY RATE FOR  
PRE AND POST NATAL CARE IN RURAL WOMEN OF PAKISTAN

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## ABSTRACT

As the population of Pakistan continuously rises, there is a greater need for proper healthcare, especially for females throughout their childbearing ages. It is estimated that the current population of Pakistan is equivalent to 2.63% of the total world population, making it the 6<sup>th</sup> most populous country in the world. This thesis examines the factors that contribute to the high rates of morbidity and mortality during pre and post natal care in women who live in the rural areas of Pakistan. Surveys and questionnaires were conducted addressing issues such as women's access to care, education levels and financial status. Both the surveys and questionnaires were completely anonymous. In total, there were 106 patients and 93 physicians surveyed from the cities of Lahore and Islamabad. Average assessments, standard deviations and t-tests were generated for similar questions between patients and physicians. The results from the t-tests suggested that some of the data was approaching statistical significance (values were slightly above 0.05), while some of the data was statistically insignificant. These values could have occurred due to human error or if patients and physicians were shading their answers, to not give away information about their work and personal lives. Therefore, the data suggests that many patients and physicians were satisfied with the treatments they were receiving and providing at the hospitals, which shows that the initial hypothesis was not correct. Although results of this research were not as expected, additional work must still be done on this topic and Pakistan must improve overall access and quality of care in other hospitals across the country.

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## **Chapter 1**

### **Introduction and Background on Pre and Post Natal Care in Pakistan**

The quality of healthcare in Pakistan is declining rapidly due to a variety of reasons. It is noted that the infant mortality rate in Pakistan is 66 per 1,000 births. Life expectancy in Pakistan for women is 67 years while the maternal mortality rate in Pakistan is 170 per 100,000 live births (Malkani, 2016, p.1). This rapid decline of healthcare can mostly be seen in Pakistani hospitals located in rural areas where there is a lack of proper resources and equipment to take care of patients. As of the year 2014, the total GDP for healthcare in the country is approximately 0.9% (World Bank, 2014, p.1), which shows that the government does not spend a lot of money on healthcare and explains why the quality of healthcare in the country is abysmal. Another factor leading to poor quality of healthcare in Pakistan is the fact that most hospitals follow the “first come-first served” pattern of provision of healthcare services. This system neither takes into account the severity of symptoms of the patients nor fully assesses the relative needs of patients requiring treatment (Noorani et al., 2014, pg.1).

It is widely known that women who reside in rural areas of Pakistan, unfortunately, do not have access. This is especially seen since accessing healthcare for women is predominantly influenced by gender roles. Essentially, the poor health status of women in Pakistan is as much a social as a medical problem. The underlying factors are the lack of awareness of attention to women’s health needs; women’s lower educational and social status; and social constraints on women and girls, including the practice of seclusion (WHO, 2007, p. 17).

Serving as head of household, men assume the responsibility for making decisions. As a result, women's subordinate position to men limits women's access to healthcare services (Panzai, Ahmad, and Saqib, 2017, para. 2). Since most women have limited access to healthcare, it can be difficult for them to receive care when they need it most, such as when women reach their childbearing age and do not have access to proper pre natal and post natal care. Limited access to care can also be due to a number of other factors. These factors include women living in remote areas where hospitals are inaccessible, hospitals not having enough funds to support proper OB GYN care and inaccessibility to proper medications for treatment due to education, cultural and religious reasons.

As stated by the United States National Conference of State Legislators, women, who are key in maintaining healthy families, access the healthcare system more than men, both for themselves and on behalf of their children. Many become pregnant and give birth, a significant health event, then typically become their child's primary caregiver, a role that greatly influences household health overall (2013). In addition, other research examining access to care for women in Pakistan conclude that healthcare for women should become a priority. Indeed, without proper medical help for women, there is no guarantee that they will be able to take care of their families.

Proper medical help begins with pre natal care when a woman first becomes pregnant, followed throughout her pregnancy and continued after childbirth until the child themselves reaches adulthood. As seen in most healthcare systems around the world, more specifically the healthcare system of the United States, proper medical care can be done in a number of ways, including, understanding the quality of care in Pakistan, learning about the types of hospital infrastructure that provide pre and post natal care in Pakistan, understanding how gender roles,

poverty, education, religion and culture play an important role in access to healthcare, training and educating more female doctors, and finally providing access for pre and post natal care treatment.

## **Background**

The health profile of Pakistan is characterized by a high population growth rate; a high infant and child mortality rate; and a high maternal mortality ratio (WHO, 2007, para. 6). The purpose of this literature review was to identify how the quality of care in Pakistan, how gender roles, poverty, education, religion and culture, the training of female doctors and access to pre and postnatal care treatment can play a big role in the morbidity and mortality rate for women in the rural areas of Pakistan. This portion of the paper will work to describe the methods used to search for data on the quality of healthcare for women in Pakistan in order to determine the final articles used for this analysis.

## **Search and Review Process of Past Research**

Even though the quality of healthcare that women are receiving in regards to pre and post natal care in Pakistan is lamentable, little new information was found in the literature on what advancements the country has made in the last 1-2 years. Journal articles were accessed by online databases such as: BioMed Central, Journal of Midwifery & Women's Health, Global Journal of Health Science, JOGC, Springer, J Ayub Medical College, Public Library of Science (PLOS), International Journal of Health Policy and Management, The Lancet, American Journal of Public Health, Elsevier, J Pak Medical Association and Research Gate. The key search phrases used in each of these databases were "Women's Healthcare in Pakistan," "Pre natal Care in Pakistan,"

“Post natal Care in Pakistan,” “Education and Maternal Care in Pakistan,” “Gender roles and Maternal Care in Pakistan,” “Poverty and Maternal Care in Pakistan,” “Religion/Culture and Maternal Care in Pakistan,” “Female Doctors in Pakistan,” “The Role of Female Doctors in Pakistan,” “Training Female Doctors in Pakistan,” “Access to Pre natal Care in Pakistan,” and “Access to Post natal Care in Pakistan.” Since there was limited new information on the above topics, there were no publication date limits in this literature search, therefore articles dating from 2007 to 2018 were included in this literature review.

From databases such as PLOS and BioMed Central, more than 100 articles were flagged by searching the phrases “Women’s Healthcare in Pakistan,” “Pre natal Care in Pakistan,” “Post natal Care in Pakistan,” “Access to Pre natal Care in Pakistan,” and “Access to Post natal Care in Pakistan.” These search results were then reviewed and narrowed further to approximately 15-20 articles each. In the remaining databases such as Elsevier, J Ayub Medical College and The Lancet, the phrases “Education and Maternal Care in Pakistan,” “Gender roles and Maternal Care in Pakistan,” “Poverty and Maternal Care in Pakistan,” “Religion/Culture and Maternal Care in Pakistan,” “Female Doctors in Pakistan,” “The Role of Female Doctors in Pakistan,” “Training Female Doctors in Pakistan.” Led to approximately 5-10 articles being flagged. However, many of the article topics were either too broad or too old to be used in this literature review.

In total, 60 full-text articles were reviewed. Thirty-five of these articles were eliminated because they did not align with the purpose of this review, as the articles did not include too much information on quality of healthcare for women in Pakistan, access to care for women in Pakistan and pre and post natal care in Pakistan. For example the article, “Obstacles to Contraceptive Use in Pakistan: A Study in Punjab” was considered early on in the literature review process, but proved to be too focused on contraceptive use, which was not a focal point in this particular review.

With the remaining 25 articles, the following literature review was written. Eleven articles came from BioMed Central, one from the Journal of Midwifery & Women's Health, one from the Global Journal of Health Science, one from JOGC, one from the Springer, two from J Ayub Medical College, two from the Public Library of Science (PLOS), one from the International Journal of Health Policy and Management, two from The Lancet, one from the American Journal of Public Health, one from Elsevier, one from J Pak Medical Association and one from Research Gate.

### **Review Methods of Past Research**

The 25 articles that were included in this synthesis were reviewed and placed into a matrix chart so further analysis of the articles could take place. The matrix was divided into four different categories: article title, article focus, limitations, and conclusions. The matrix helped to show why the articles fell under particular categories. These four categories were included in the matrix because they helped to show how the research was conducted for each piece of literature, along with providing any limitations and conclusions to each study.

## **Chapter 2**

### **Literature Review**

#### **Introduction**

Improving maternal, newborn, and child health indicators remains one of the most important global health challenges, especially in developing countries like Pakistan, where the situation remains unsatisfactory (Ansari, Manzoor, Siddiqui and Ahmed, 2015, para. 1). More than 0.5 million women die every year worldwide due to pregnancy and childbirth-related complications. Almost 0.03 million of them are in Pakistan (Majrooh et al., 2013, para. 1). Due to the complications during pregnancy and delivery, it is noted that 33% of neonates in Pakistan die, while the lifetime risk of maternal death for Pakistani women is 1 in 93 (Majrooh et al., 2013, para. 6).

Pakistan has one of the highest rates of mortality in children younger than 5 years in South Asia and many of these deaths occur in the newborn period, most in the first few days after delivery. Most neonatal deaths are largely preventable and attributable to preterm birth complications (34%), intra-partum related complications (25%), and infectious causes (22%) such as sepsis, meningitis and pneumonia (Turab et al., 2014, para. 2). Many newborns die not only due to lack of specialized care, but also due to improper management during perinatal period. Many of these deaths can be prevented (Rehman et al., 2011, para. 1).

Within Pakistan, the risk of neonatal death is higher in rural areas than in urban areas, in the lowest wealth quintile than in the highest wealth quintile, and to mothers with no education than to mothers with higher education (Unicef Pakistan, page.7). In rural Pakistan, most newborn

deliveries occur at home with minimal supervision from skilled birth attendants. The problem is further compounded by the frequent adoption of unsafe newborn care practice including the use of unsterilized instruments to cut the umbilical cord and the application of unsafe substance to the umbilical stump. Together, these newborn care practices are associated with increased risk of neonatal sepsis and mortality (Turab et al., 2014, para. 4). The potential of community-based interventions to reduce newborn morbidity and mortality is well recognized. Such interventions include community health workers (CHWs) delivering preventive and therapeutic interventions such as antibiotics at home, community mobilization through women's support groups or community mobilizers working through individual and group sessions, and community-based interventions delivered through non-governmental organization or community volunteers (Bhutta et al., 2011, para. 3).

Another component of care that is vital for an expectant mother is antenatal care. It gives women and their families an opportunity to learn about the risks associated with pregnancy and guides their health seeking practices and decision making thereby preventing maternal and infant morbidity and mortality (Majrooh, Hasnain, Akram, Siddiqui and Memon, 2014, para.18). One of the ways that antenatal care can help expecting mothers is by educating them on how important it is to deliver babies in a health facility, thereby reducing the rate of infection and increasing the chances that the baby will live a healthy and happy life. The WHO defines antenatal care as a dichotomous variable, having had one or more visits to a trained person during the pregnancy. It includes routine follow up provided to all pregnant women at the primary care level from screening to intensive life support during pregnancy and up to delivery (Sadiq et al., 2011, para. 2).

Standard of care for an expecting mother is comprised of seven elements of quality that women should receive during pregnancy: urine sample, blood sample, blood pressure, iron tablets,

two tetanus shots, measurement of weight and advice about danger signs of pregnancy (Agha and Williams, 2016, para. 13). Women who receive one element of quality during an ANC visit have a 1.70 times higher odds ratio of delivering in a health facility, those who receive three elements have a 3.83 times higher odds ratio, those who receive five elements of quality have a 7.32 times higher odds ratio and those who receive seven elements of quality have a 10.64 times higher odds of delivering in a facility (Agha and Williams, 2016, para. 22).

According to mothers, a decent number of deliveries attended by traditional birth attendants (TBAs) occurred on soil or wood. This is an important issue and needs to be addressed for improving safe practices for women who deliver at home (Hassan et al., 2011, para. 19). In Pakistan, clean home delivery kits are available, usually containing a new blade, sterilized disposable gloves, soap, gauze, cotton balls, antiseptic solution, an umbilical cord clamp and a polythene (sterile) sheet that would provide a hygienic surface for delivery (Hassan, Jokhio, Winter and MacArthur, 2011, para. 10). However, the majority of mothers and health workers report that clean delivery kits are not used, suggesting that hygiene is compromised even at health facilities. The findings also suggest that deliveries at home or primary health-care facilities attended by unskilled workers are highly prevalent in rural areas, a practice that will be difficult to change (Hassan et al., 2011, para. 15).

### **Types of Hospitals Available for Pre and Post natal care in Pakistan**

Maternal healthcare services utilization is important for early detection of mothers who are at high risk of illness and mortality during pregnancy as reported by the World Health Organization (Majrooh et al., 2013, para. 5). Early detection of high-risk illnesses in mothers can only be done

in hospitals by trained professionals. In Pakistan, there are a number of different types of hospitals a patient can go to depending on their healthcare needs. RHCs are relatively larger PHC facilities serving 10,000-50,000 rural people while BHUs are relatively smaller health facilities providing PHC services to 5,000-10,000 rural people (Majrooh et al., 2013, para. 12). Medical Officers are in-charge of RHCs/BHUs and Antenatal Care (ANC) services are supposed to be provided by the Lady Health Visitors (LHVs) at these facilities (Majrooh et al., 2014, para.4). When looking at a particular area of rural Pakistan (Sindh), basic health units and rural health centers act as primary care facilities providing B-EmONC services. While, Taluka hospitals and district civil hospitals provide 24-hour C-EmONC services. However, coverage, access, and utilization levels remain unsatisfactory (Ansari et al., 2015, para. 2).

Most say they prefer to go to a private sector facility due to 24-hour availability of female healthcare providers, the better quality of care, availability of services, and attitude of staff (Ansari et al, 2015, para. 28). Nearly a fifth of patients in the public sector and less than a tenth of patients in the private sector have to wait for more than an hour to receive services. Given that patients who come to C-EmONC facilities require immediate medical attention, such long waiting times need to be addressed to minimize complications and adverse health outcomes due to delays in service provision (Ansari et al., 2015, para. 37).

Public sector health infrastructure should be improved because it would enhance universal access. Improvement in the infrastructure can be enabled by the reform of primary health care and hospitals. An agenda for integration is crucial for the reform of primary health care (Nishtar et al., 2013, para. 14).

Facilitating factors to visit a particular health care facility were: availability of qualified healthcare providers (private facility); trust in healthcare providers; recommendation from a family

member, friend or lady health worker (in rural areas); availability of good quality services including medical equipment and lab facilities; low cost (public facility); and easy access to the health facility (private facility) (Nisar et al., 2016, para. 3). The absence of female care providers at public sector facilities, and the tendency of public sector employees to divert patients to their private practices (so that they could charge fee for services), is an unfortunate but common practice in Pakistani hospitals (Ansari et al., 2015, para. 28).

The reasons for visiting a private health facility for ANC services as reported by urban women included: availability of qualified and skilled providers, trust on healthcare providers at the private health facility, recommendation from a family member or a friend, availability of good quality services including medical equipment and pathology facilities, easy to reach a private health facility, and availability of an after-hours doctor (Nisar et al., 2016, para. 21). The reasons reported by urban women for visiting a public health facility for ANC services were: low cost as there was no consultation fee and often availability of free of cost medicines, the husband or the women herself was a government servant, and facilitation from a relative who was working at the public health facility. The availability of blood pressure monitoring equipment, pathology and ultrasonography services and prescriptions of medicines were also important reasons for visiting a health facility for ANC services (Nisar et al., 2016, para. 21).

The reasons for visiting a public health facility reported by rural pregnant women for ANC services were: low cost in terms of medicines and pathology services, being recommended by a local LHW, and trust in a government health system (Nisar et al., 2016, para. 22). The common reasons reported by rural pregnant women for visiting a private health facility for ANC services: easy to reach recommendation from a family member, trust in healthcare provider and availability of ultrasonography and pathology services (Nisar et al., 2016, para. 22).

If there is a lack in public sector health infrastructure, more people will turn to faith healers (*pirs*) who provide insufficient knowledge about danger signs during pregnancy. It is noted that the traditional and customary practices of *taweez dhaga*, *saya*, *pardah*, are due to the non-availability of health care providers and lack of trust on young community midwives, which leads to people favoring the home based package of services provided by traditional birth attendants (*Dai's*) (Sarfranz, Tariq, Hamid and Iqbal, 2015, para. 1). *Pardah* is a common practice among women in certain Muslim societies, where the women live in a separate room or behind a curtain, in order to stay out of sight of men and strangers.

When dealing with complicated childbirths and acute illnesses of neonates, most prefer facility-based services for seeking antenatal Care (ANC), but for normal childbirth they preferred home-based services provided by 'Dai' (traditional birth attendant). Mothers reported that they were more comfortable with 'Dai' while fathers were of the view that it is a cost saving option. They also perceived that post natal visits are 'not necessary' and they seek care only in case of complications or life threatening complications (Riaz, Zaidi, and Khowaja, 2015, para. 10). Dais are easily accessible, are part of the local community with networks within, particularly in remote areas. The service package that the dais provided include support in household chores, post natal care and care of the new-born (bathing, changing, washing of clothes). Many women also prefer them, as Dai's services are free of any 'cash' cost attached. The payments made in kind to Dai's (wheat, lentils, milk, poultry, eggs) are home produce of the local community and hence are not considered as having an economic burden on the family who might need help with delivery of a healthy newborn (Sarfranz et al., 2015, para. 30).

## **Gender Roles, Poverty, Lack of Family Support, Education and Religious/Cultural Hindrances**

World Health Organization recommends that pregnant women with no complications should visit a healthcare provider at least four times to receive sufficient antenatal care services. In Pakistan only 37% of women reported to have had four or more antenatal care visits during their last pregnancy (Nisar, Aurangzeb, Dibley, and Alam, 2016, para. 1). Poverty, ethnic, cultural, and religious factors all have an impact on women's status and their ability to access healthcare (Majrooh et al., 2013, para. 7).

Common barriers to visiting a health facility for antenatal care services were: financial limitations; perceived absence of any major health problems during pregnancy; difficulties in reaching the health facility; restriction from husband or mother-in-law; busy performing household chores; no previous experience of antenatal care visits; and perceived unavailability of healthcare providers and/or services (Nisar et al., 2016, para. 3). Among those who never used the antenatal care, permission to use the facility and ignorance were the main reasons (Sadiq et al., 2011, para. 1). According to many mother-in-laws, delivery is a 'normal process' and there is no need to go to a center. Cultural influences and concept of 'normality' (no need to seek care unless there is an emergency or complication) is deeply rooted in Pakistani society where use of preventive services is not deemed necessary (Riaz et al., 2015, para. 21).

Husbands can help reduce maternal mortality and morbidity by: 1) Encouraging and facilitating their wives' use of pre natal care; 2) Ensuring better nutrition and rest for their wives during pregnancy and the postpartum period; 3) Arranging for a skilled birth attendant for delivering the baby; 4) Preparing for the possibility of obstetric emergencies by arranging

transportation and finances; and 5) Reducing the delay in the decision to seek medical care in case of obstetric emergencies (Midhet and Becker, 2010, para. 6).

Gender inequality in Pakistan is particularly acute. Gender roles are clearly demarcated; men are socially constructed as providers and women as dependents. The social institution of *pardah* further demarcates boundaries between men and women and sets standards of female morality. Consequently, large differentials exist between women and in access to resources of all types (Mumtaz et al., 2012, para. 14). A majority of Pakistani women are illiterate and dependent on their male guardians (e.g. father, husband, brother, son) for seeking health care or accessing the resources and information needed to maintain their health (Zakar, Zakar, Qureshi, and Fischer, 2014, para. 1). In rural areas of Pakistan, women are usually denied access to information and the information they do get is scrutinized and controlled by their male guardians (Zakar et al., 2014, para. 5). It is noted that highly educated women are over three times more likely to be attended by skilled birth personnel than women with no education (86% vs. 27%) (Mumtaz, Salway, Shanner, Zaman, and Laing, 2012, para. 12). However, highly educated women are more commonly seen in the urban areas of Pakistan, whereas in the rural areas of Pakistan, most women have a very low level of education. Irrespective of location, women need information on family health, food and nutrition, family planning, and child education as well as opportunities to become involved in socioeconomic growth. Nonetheless, a majority of rural Pakistani women are deprived of access to knowledge and information (Zakar et al., 2014, para. 44).

Per person income has a strong correlation with the achievement of health status as levels of employment, poverty reduction, and pro-poor inclusive growth matter are crucial for health gains (Nishtar et al., 2013, para. 20). In countries like Pakistan, where insurance and social security arrangements are almost non-existent and households rely almost exclusively on out-of-pocket-

expenditures to pay for their medical care, the concentration of poor health indicators among low-income groups adds to the vulnerability of these households. In particular, households whose incomes are just above the poverty line, can fall below the poverty line as a result of an accident or a sudden illness. Medical emergencies are found to be the most common source of economic shocks faced by households in Pakistan (Malik and Ashraf, 2016, para. 4).

Pakistanis express that due to inability to pay for MNH (maternal and newborn health outcomes) services, they opt for home remedies and spiritual healers (Riaz et al., 2015, para. 15). In the absence of monetary resources, compromising on healthcare is the ultimate way of coping for the families for MNH ailments. Compromise on healthcare may be either not seeking care at all, or seeking care from local unqualified providers who are generally unable to manage complications at the community level. Though they realized that compromising healthcare for MNH is a matter of 'life and death', Pakistanis become helpless in such a condition (Riaz et al., 2015, para.15). For example, in an emergency, a pregnant lady could not afford travel costs due to poverty, and her parents arranged a traditional birth attendant, and her parents arranged a traditional birth attendant who delivered her baby at home. The newborn was very weak and the mother was unable to feed the baby due to her illness (Ansari et al., 2015, para. 19).

When looking at a particular caste of people present in Pakistan (Seyal caste - a vulnerable population in Pakistan), women are not allowed to go to hospitals for treatment even in cases of emergency during pregnancy. The Seyal women strictly observe *Pardah*. In case of obstetric emergency, Seyal women would take treatment from traditional birth attendants at home, and were not permitted or able to access facility-based services (Ansari et al., 2015, para. 23). Much like the Seyal women, it is noted that some rural women do not go to a health facility because they are afraid of being diagnosed to have complications or complications related to hospitalization (Ansari

et al., 2015, para. 23). Pakistan Demographic and Health Survey confirms that maternal deaths are not merely a result of treatment failure; rather they are the final outcome of a complex interplay between a myriad of social, cultural and economic factors (Majrooh et al., 2014, para.2).

Pakistan is a large and heterogeneous country, and women's gendered experiences and social relations are shaped by socioeconomic, ethnic and regional variations. Nonetheless, the coexistence of social stratification in relation to class and gender means a woman may be disadvantaged because she is a woman, but her disadvantage is compounded if she is a woman belonging to a lower status or *zaat* (Mumtaz et al., 2012, para. 16). Resources such as counseling during ANC can help to provide a critical opportunity for women to learn when to seek help and where to give birth. It also helps prepare women for the mental and physical challenges they may face during pregnancy and childbirth (Majrooh et al., 2014, para.18).

### **Training and Education of Female Doctors**

It is noted that the unavailability of healthcare providers (especially female providers) has a high impact on MNH in Pakistan. While any unpleasant interactions with healthcare providers during pregnancy can compromise women's access to vital services, they can also lead a woman and her family to not wanting to get proper care at health facilities, which can lead to a number of future complications. Perinatal and neonatal mortality rates in the country have remained constant over the last two decades. Birth Asphyxia, Sepsis, LBW/Prematurity and neonatal tetanus are responsible for the majority of neonatal admission and mortality. This is not surprising as most deliveries take place at home and are conducted by untrained birth attendants (Rehman et al., 2011, para. 5).

In Pakistan, there are a number of different types of healthcare providers for expecting mothers. For example, there are Lady Health Visitors (LHVs), Female Health Technicians (FHTs), Lady Health Workers (LHWs) and also TBAs (Dai's). LHVs are midwives who provide community care, which includes child and maternal care. FHTs are mid-level health workers who provide emergency care and basic health care at rural health centers and basic health units. LHWs are primarily involved in community-based health promotion in child and maternal health.

Overall, 39% of all births are supervised by “skilled” birth attendants. When use is broken down by wealth quintile, 77% of women in the highest wealth quintile report “skilled” birth attendance, compared to 16% of women in the lowest wealth quintile (Mumtaz et al., 2012, para. 12).

The LHV program trains and equips locally resident women to provide basic obstetric care and provides care to the poorest and most marginalized women (Mumtaz, O'Brien, Bhatti, and Jhangri, 2012, para. 6). Unfortunately, midwifery students do not have sufficient access to human and material resources to learn midwifery theory and practice skills to practice safely. Furthermore, students are unable to practice intrapartum skills because of a lack of availability of hospitals or maternity homes where students are able to conduct deliveries under supervision of a doctor or midwife. As a result, many nurses in Pakistan are licensed as midwives but do not have the necessary skills or knowledge to practice as midwives (Rukanuddin, Ali, and McManis, 2007, para. 13).

LHWs have no medical or nursing and midwifery qualifications but receive a few months of training in primary health care including antenatal and newborn care. They are often present at, but do not directly participate in, deliveries (Hassan et al., 2011, para. 5). LHWs are mostly young women, resident in the local communities, have at least 8 years of formal schooling, and are trained

for 15 months to deliver care in community setting either through home visits or from their residences, which are known as health homes (Bhutta et al., 2011, para. 2).

At present, around 93,000 lady health workers and 6,000 midwives are working in rural communities of Pakistan. Lady health workers were not initially mandated to provide newborn care but were progressively involved in newborn care during the last decade. To cover almost all rural areas of Pakistan 30 times more midwives are required than are presently working in the rural areas. Therefore, at present these services are inadequate to cater for the large rural population of Pakistan (Nisar and Dibley, 2014, para. 4). Urgent attention is needed for the provision of adequate basic and emergency newborn care facilities in the health system, and the LHW program might also consider inclusion of interventions for immediate newborn care such as emergency resuscitation, kangaroo mother care, and oral antibiotic treatment for suspected respiratory infections (Bhutta et al., 2011, para. 34). The quality and outreach of lady health workers can be improved by optimization of their role and integration of key interventions relevant to their role in primary care and family planning, and provision of services such as screening and prevention of non-communicable diseases (Nishtar et al., 2013, para.13).

Unfortunately, even significant current investments do not look promising for the previously identified issues. For instance, the ongoing training of midwives seems unlikely to increase access to skilled care among the very poor, first because they are to be deployed in the private sector, and second because their training includes no explicit attention to why and how they should direct good quality care to marginalized women (Mumtaz et al., 2014, para. 29). To improve the quality of services health care providers should be trained to improve their technical skills for assessment, treatment and counseling of clients. Providers should get motivation and

training to encourage them to follow the standard protocols for provision of quality ANC services (Majrooh et al., 2014, para.26).

### **Access to Hospitals for Pre and Post Natal Care Treatment**

For some people who live in rural areas of Pakistan, the nearest hospital can be as far as 15 km (3.1 miles) away. For pregnant women who are about to give birth, this can be quite the distance, especially for those whose only means of transport is by foot. Commonly cited barriers to women seeking facility based births were long distance to facility, and difficulty in finding transport. Other barriers included the fear of Caesarian Section and vaginal examination. Shortage of female provider, blood bank and supplies at public sector facilities was a deterrent to use facility-based services and most respondents were apprehensive of the expense of private sector facilities (Memon, Zaidi, and Riaz, 2016, para. 19). Most maternal deaths are attributed to delays in getting medical care during obstetric complications. The main delay occurs when the decision to seek medical care has been made and precious time is lost in transporting women to hospitals because of the lack of telephones and regular ambulance services (Khan, Bhutta, Munim and Bhutta, 2009, para. 11).

Women have a lower chance of receiving pre and post natal care treatment if they live in a rural area. Using Islamabad (the capital city of Pakistan) as the referent, women in all other regions had lower odds of receiving four or more pre natal visits. Pregnant women residing in Balochistan, and the Northern Areas had lower odds of delivering at a medical facility and of having a skilled attendant at delivery, and the mothers in the Northern Areas also had lower odds of receiving post natal care (Budhwani, Hearld and Harbison, 2015, para. 21).

In Punjab area of Pakistan, only 53% of pregnant women have access to antenatal services (ANC) services from medical professionals at least once during their pregnancies, and only 41% have access to post natal care (Majrooh et al., 2013, para. 7). The availability of services is generally determined by the geographic distribution of fixed and mobile healthcare facilities and their service hours. The accessibility of services includes both the cost to users in money and time and their social accessibility (Majrooh et al., 2013, para. 9). For example, one man recounted his visit to a public sector facility when his wife had an emergency in her pregnancy. The senior obstetrician was said to be on leave, but when they visited the obstetrician's private hospital, she was available (Ansari et al., 2015, para. 25).

Many have expressed that scanty transport and resulting high expenditure, difficult terrain, poor condition of roads, and unfavorable weather conditions (e.g. rains and snowfall), sometimes influence decisions to use facility based services. They were also afraid of facing complications on the way to RHC given the distance (Riaz et al., 2015, para. 16). Barriers to health service utilization have been categorized into access, availability, acceptability and cultural and traditional preferences, confidence in care and quality of services, health awareness and knowledge, and affordability (Byrne, Hodge, Jimenez-Soto, Morgan, 2014, para. 2). Unfortunately, 90% of women are not interested in post natal care (PNC) due to lack of awareness, mobility and transportation issues, and the cost of health care (Sultana and Shaikh, 2015, para. 1).

## **Summary**

In summation, developing countries such as Pakistan must work on improving maternal, newborn, and child health care. This can be done by creating more hospitals for pre and post natal

care, crossing the gender role and religious/cultural barrier, educating family members, providing free health care, training more female doctors and finally, allowing for more access to pre and post natal care treatment.

In Pakistan alone 0.03 of 0.5 million women worldwide die annually due to pregnancy and childbirth-related complications. In other words, the lifetime risk of maternal death for Pakistani women is 1 in 93. In rural areas of Pakistan, the risk of death is a lot higher than those women who come from urban areas. Additionally, women with no or low education are at a higher risk of death than women who are highly educated.

A component of care that is vital for expectant mother is antenatal (pre natal) care, which allows women to understand the risks that are associated with getting pregnant and guides women to seek healthcare. Seeking healthcare can help to prevent any type of maternal and infant morbidity and mortality.

In Pakistan, there are a number of different types of hospitals. Most rural women prefer getting treated at private sector facilities due to availability of female healthcare providers and better quality of care. With that being said, many private sector facilities are very costly, therefore most women are left with only the option of going to public sector hospitals, which have long wait times, delays in service and not as many female providers. Another issue that is of common practice in many Pakistani hospitals is the tendency of public sector employees diverting patients to their private practices (so that they can charge fee for services), which is a rather unfortunate concern that must be rectified.

There are many common barriers that women in Pakistan face when accessing healthcare. These include financial limitations, difficulties in reaching health facilities, and restrictions from family members. Due to many health facilities being a far distance from rural areas, many women

face numerous challenges and will therefore prefer to have home deliveries over hospital deliveries, which tends to be an unhealthy practice. Along with this, there are many gender gaps that are present in the country. Men typically dominate the household and most women cannot leave their homes unless given permission, which can complicate receiving health care for many women.

Furthermore, unavailability of healthcare providers has a high impact on maternal and newborn health outcomes. When female physicians are not available, women prefer to stay home for their health care needs which leads them to having deliveries with untrained birth attendants. In Pakistan, there must be an increase in the number of Lady Health Visitors/Workers, Female Health Technicians and TBAs (Dai's). This will allow more women in the rural areas to have access to better child and maternal care.

Finally, when comparing women receiving healthcare in the urban areas of Pakistan versus women receiving healthcare in the rural areas of Pakistan, women in the rural areas had lower odds of delivering at medical facilities and having a skilled attendant at delivery. Only about 53% of women have access to pre natal care, while 41% have access to post natal care. Lastly, 90% of women are not interested in receiving post natal care because they cannot afford cost of treatment, lack awareness or they face mobility and transportation issues.

## **Chapter 3**

### **Methods**

#### **Introduction**

The researcher chose to conduct in-person surveys and questionnaires of patients and physicians because it was easier to collect and answer any confusing questions that the interviewees may have had. Additionally, the researcher did not have any knowledge of whether hospitals were equipped with internet access, therefore online surveys were out of the question. Lastly, since a vast majority of women patients were either uneducated or had a low level of education, the researcher had to go through each individual question with each patient, which may have not been able to be accomplished as successfully, if other methods of data collection were used.

Surveys and questionnaires were the primary method of conducting this research. Both patients and physicians were given the opportunity to fill out surveys, while only physicians were given the questionnaires. Surveys for the patients and physicians consisted of a total of 10-13 questions that consisted of closed-ended questions where users ranked their answers on a scale of 1-3 (not at all true – very true). The questionnaires allowed physicians with the ability to elaborate and answer open-ended questions regarding better access to care for women in Pakistan.

## **Population**

The sample used for the patient survey was drawn from a number of different sources. These sources include women who came in for gynecological issues between the ages (15-59), women who have recently given birth, and women who are currently pregnant between the ages (15-49). The survey was completely anonymous and the researcher did not request any personal information such as name, address or ethnic background. However, of the patients surveyed, information about gender and age were asked for data collection purposes. In total, there were 106 patients surveyed most of whom were from the rural areas outside of Lahore. The sample frame was completely random and subjects were selected for the survey based on availability and whether or not they were willing to be a part of the study.

The sample for the physician survey was also drawn from a number of different sources. These sources include, physicians who are OB GYN, Family Medicine and Pediatrics. This survey was also completely anonymous and the researcher did not request any personal information such as name, address or ethnic background. However, of the physicians surveyed, information about gender and age were asked for data collection purposes. In total, there were 93 physicians surveyed most of who were from Lahore, with a few physicians from Islamabad. Of the 93 physicians that were surveyed, approximately 16 physicians from Fauji Foundation Hospital in Islamabad were given the opportunity to answer a questionnaire that pertained the barriers women face when seeking healthcare. Unfortunately, the researcher was only able to get 16 questionnaires filled because most physicians in the hospital were too busy to answer and could only make time for the quick questions. Physicians for the the sample frame were selected for the survey based on availability and whether or not they were willing to be a part of the study.

It should be noted that these surveys do not include all health providers (OB GYN, Family Medicine and Pediatrics) or patients (with gynecological issues, recently given birth, pregnant) in Pakistan. Therefore, any generalizations that are drawn from these surveys are limited to the patients who responded to the surveys and the physicians that responded to the surveys and questionnaires.

### **Sampling**

It was found that response rates were generally good for patients and physicians since approximately 106 patient surveys, 93 physician surveys and 16 physician questionnaires were gathered. The researcher did run into a couple of major issues, such as the patients and physicians not understanding the questions asked by the researcher, the patients and physicians not answering every question fully or some patients and physicians absolutely refusing to answer certain parts of the surveys and questionnaires.

Various questions and question types in the form of surveys and questionnaires were made. The surveys were made user friendly by using a scale of 1 to 3, from not at all true to very true. The questionnaires for the physicians was made of 6 quick, short answer questions. As respondents filled out the surveys and questionnaires, they were assured that both were completely confidential and anonymous.

There were a few differences between the patient survey and the physician survey due to the nature of the subjects that were surveyed. Because most physicians in Pakistan do similar work, they did not require as large of a sample to ensure that the data recorded was valid. Since patients come from all over the country to various hospitals in the country with many different experiences, it was mandatory to survey a much larger number of women. Thus, the goal for the number of

physician responses from each hospital was around 23, while the goal for the number of patient responses from each hospital was around 26. The survey for the patients was slightly longer, since there were a few more questions necessary for the patient to complete in order to better understand their access to care. However, a majority of physicians were asked to also complete additional short answer questions to elaborate on their answers from their completed surveys.

The original sample size was to recruit approximately 100 patients and around 50 to 80 physicians from Pakistan for a total goal of 150-180 responses. In reality, 199 responses were collected since additional responses were collected from both patients and physicians. Furthermore, while the patient population surveyed was majority pregnant women, patients with gynecological issues who recently had children were also surveyed. Along with this, data was collected from physicians who were fresh out of medical school (aged 19+) as a comparison against physicians who had years of experience.

Sampling and recruitment took place via paper and pencil. The researcher worked with local hospitals and contacts to recruit physicians and patients. No reference was made in oral or written reports that could link participants to the study. All participants were informed of the content of the study during the consent process to ensure their ease with the research that was conducted. Consent was asked from each patient and physician to ensure that there was no discomfort in the questions asked.

### **Data Collection**

The researcher prepared a letter of consent for both the physicians and patients which was provided at the beginning of each and every survey and questionnaire that was conducted. For patients, even though consent was given in letter form, most preferred to be given it verbally. This

was mostly seen for the patients who had no education or a very basic (primary/middle) grade level education. Each participant in the study was given the opportunity to decline participation and also ask questions in regards to the research being conducted. Surveys and questionnaires were created on Microsoft Word and results were kept in excel sheets on the researcher's private and locked computer.

To collect data included in this study, anonymous one-time surveys and questionnaires were used to determine the quality of and access to healthcare care offered to patients and physicians. All methods and plans were passed by The Pennsylvania State University Institutional Review Board before beginning this research and contact with several University faculties was maintained throughout the project. Any observed or reported adverse event experienced by a patient or physicians during the research process was agreed to be reported to the Institutional Review Board, however, none occurred. Each survey and questionnaire took everyone approximately 10-15 minutes.

Data was collected from numerous hospitals in two different cities of Pakistan. These cities included Lahore and Islamabad. Research was conducted at the following facilities Fauji Foundation Hospital (Islamabad), Services Hospital (Lahore), Jinnah Hospital (Lahore) and Lady Wellington Hospital (Lahore).

### **Analytical Approach**

The analyses for the surveys was done using Microsoft Excel Spreadsheets. Clustered bar graphs were created to analyze the survey results from both patients and physicians. Basic statistics such as median and average assessment were also calculated. T-tests were used to analyze the

relevance to answers between similar questions asked to both patients and physicians. These values were then compared with each other to reach a conclusion. For the open-ended questions, responses by physicians were grouped together by similarities in answer.

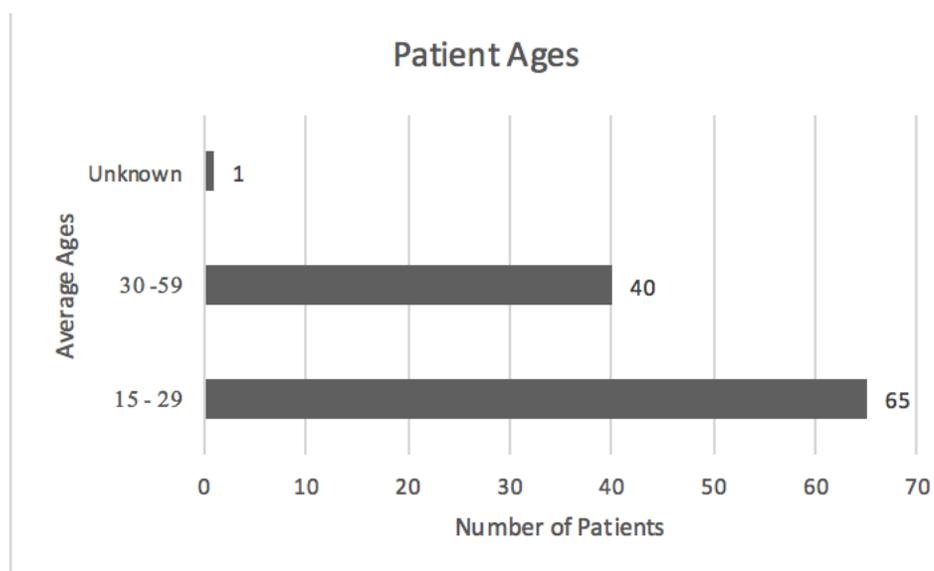
## Chapter 4

### Results

#### Patient Survey Results

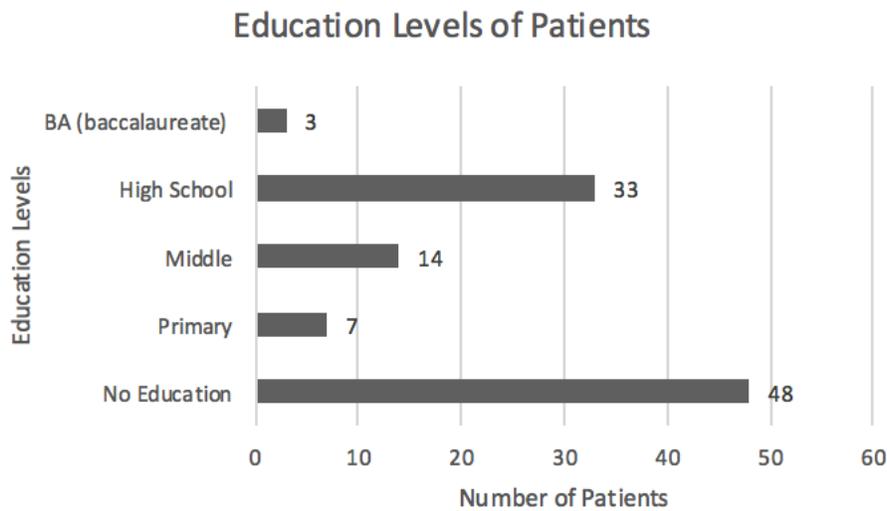
Of the 106 patients who responded to the survey, 105 of the patients had known ages while only 1 patient did not disclose of their age. Most patients that were receiving care at the hospitals were between the ages of 15-29, while a smaller majority were older than 30 years of age. All 106 patients were eligible to complete the survey based on the inclusion criteria that was set in the “Methods” section of this thesis.

Figure 1: Average Ages of Patients, Patient Survey



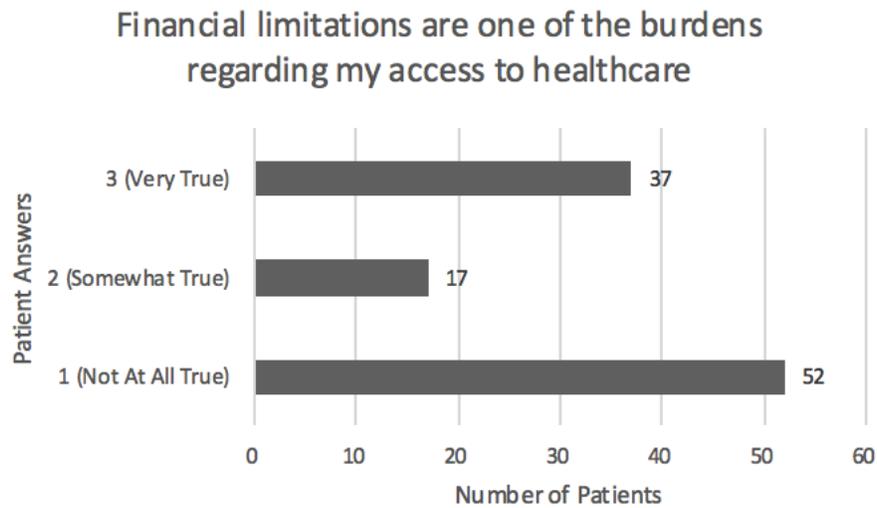
Question 1 of the survey assessed the education levels of the patients interviewed on a scale of 1 to 3 (not at all true to very true). Of the 106 patients who responded to the survey, 48 of the respondents had an unknown level of education or no education. 7 respondents had a primary (1<sup>st</sup> to 5<sup>th</sup> grade) level of education, while 14 respondents had a middle (6<sup>th</sup> to 9<sup>th</sup> grade) level of education. 33 respondents had a slightly higher level of high school education (10<sup>th</sup> to 12<sup>th</sup> grade). It is noted that there were also 3 respondents who had their baccalaureate degree.

**Figure 2: Education Levels of Patients, Survey Question 1**



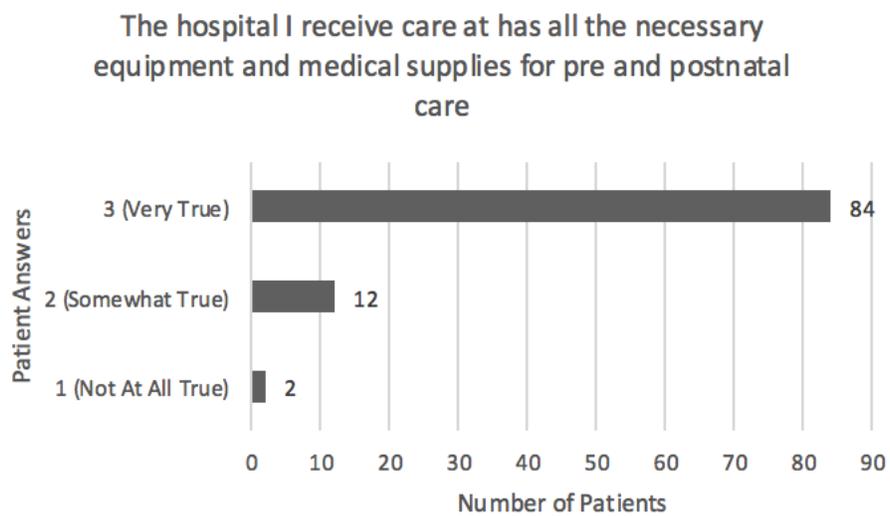
The second question of the patient survey asked respondents if financial limitations are one of the burdens regarding access to healthcare on a scale of 1 to 3 (not at all true to very true). For this question, the average assessment was 1.86.

**Figure 3: Patient Survey Results, Question 2**



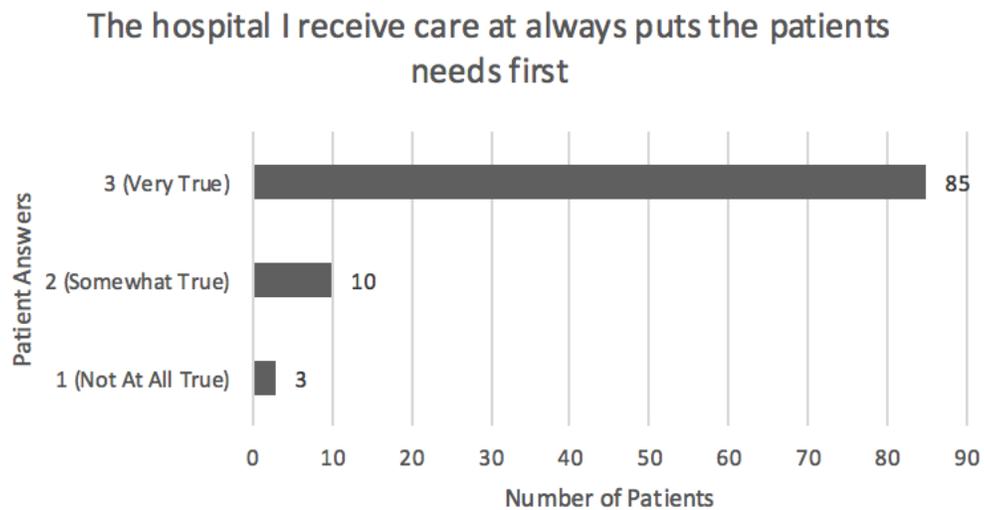
Question 3 of the survey assessed how strongly the patients felt about whether or not the hospitals they received care at had all of the necessary equipment and medical supplies for pre and post natal care on a scale of 1 to 3 (not at all true to very true). It is noted that some respondents did not answer the question asked. Patients responded with an average assessment of 2.84.

**Figure 4: Patient Survey Results, Question 3**



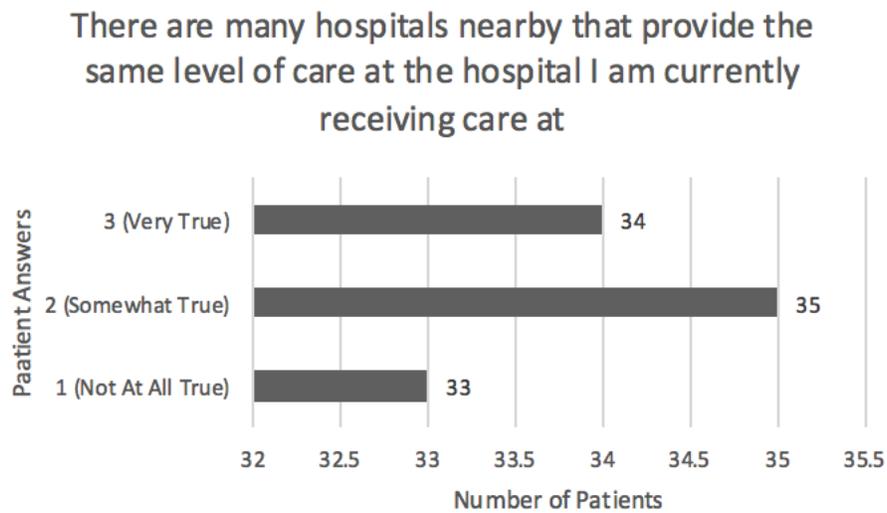
The fourth question looked at how strongly patients felt that the hospital they were receiving treatment from put the patients needs first on a scale of 1 to 3 (not at all true to very true). It is once again noted that some patients did not answer the questions asked. Patients responded with an average assessment of 2.84.

**Figure 5: Patient Survey Results, Question 4**



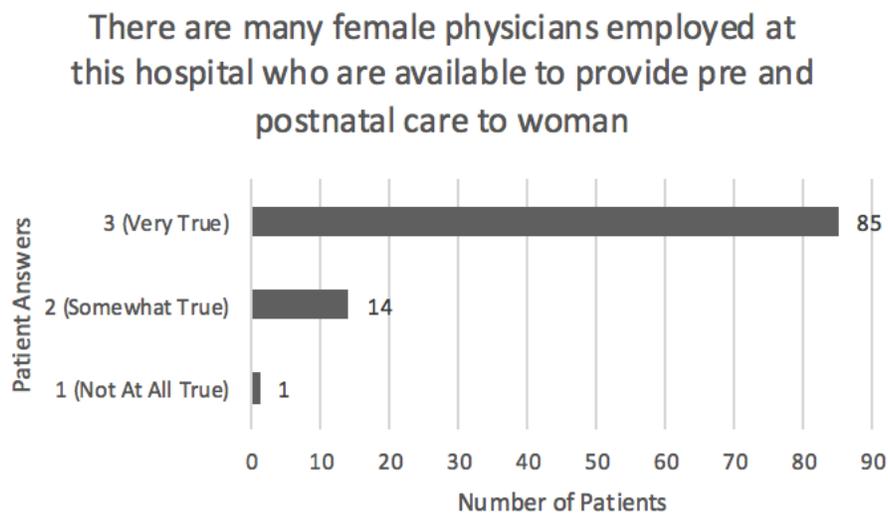
Question 5 from the patient survey assessed whether or not patients felt as if there were other nearby hospitals that provided the same level of care as the hospital they were currently receiving care from on a scale of 1 to 3 (not at all true to very true). Once again, there were patients who did not answer this question. Patients responded with an average assessment of 2.01.

**Figure 6: Patient Survey Results, Question 5**



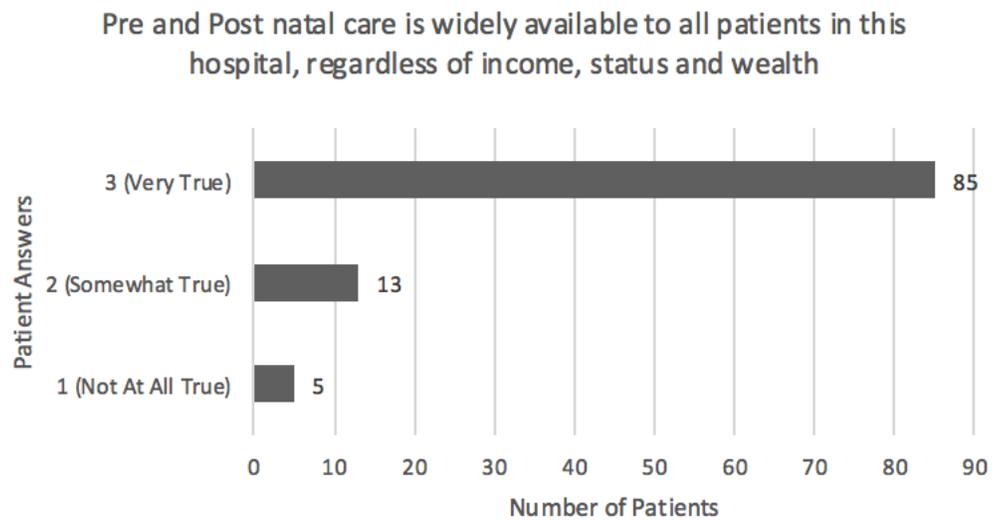
The sixth question asked participants to rate on a scale of 1 to 3 (not at all true to very true) the availability of female physicians to provide pre and post natal care at the hospital that they were currently receiving treatment. It is noted that there were once again patients who decided not to answer the question. Patients responded with an average assessment of 2.84.

**Figure 7: Patient Survey Results, Question 6**



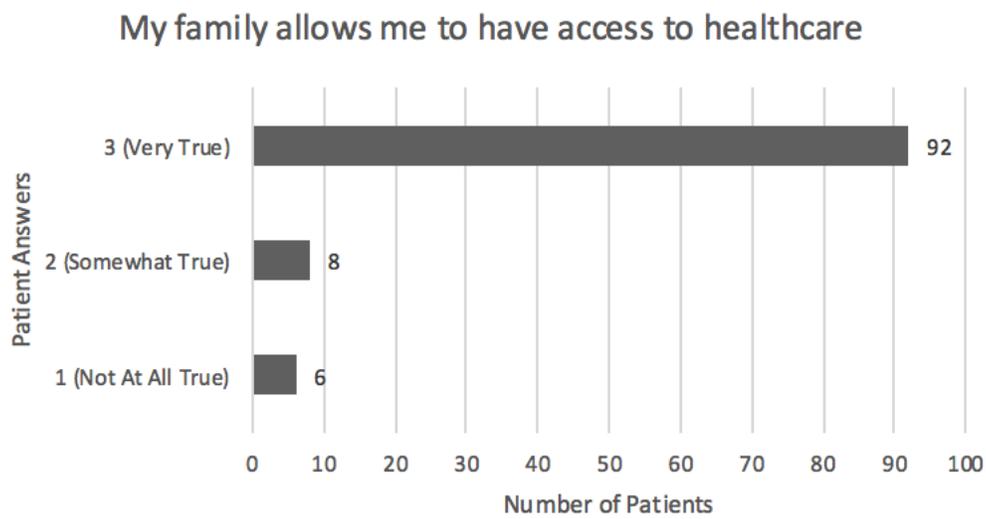
Question 7 assessed whether or not pre and post natal care was widely available to all patients in the hospital they were receiving treatment regardless of income, status and wealth on a scale of 1 to 3 (not at all true to very true). Out of the 106 patients surveyed, there were a few who did not answer this question. Patients responded with an average assessment of 2.78.

**Figure 8: Patient Survey Results, Question 7**



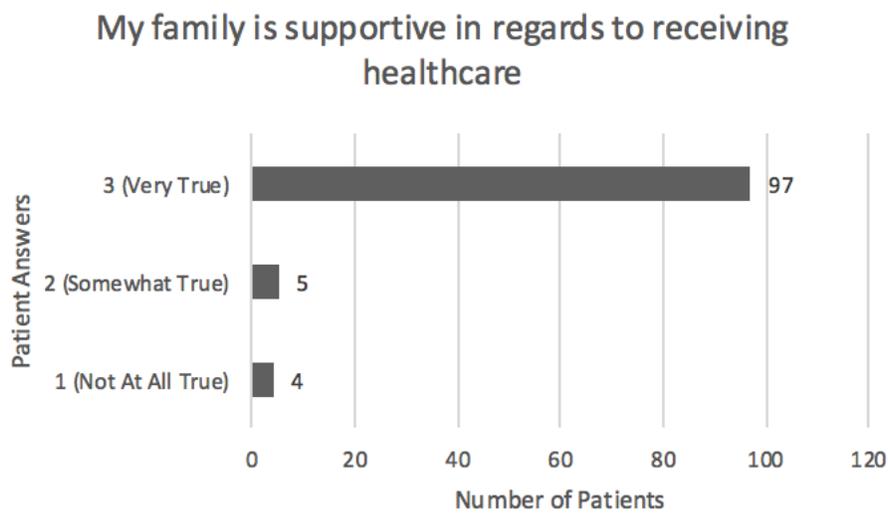
The eighth question of the study asked patients if their family members allowed them to receive healthcare on a scale of 1 to 3 (not at all true to very true). Surprisingly, all 106 patients interviewed answered this question. For this question, the average score was 2.81.

**Figure 9: Patient Survey Results, Question 8**



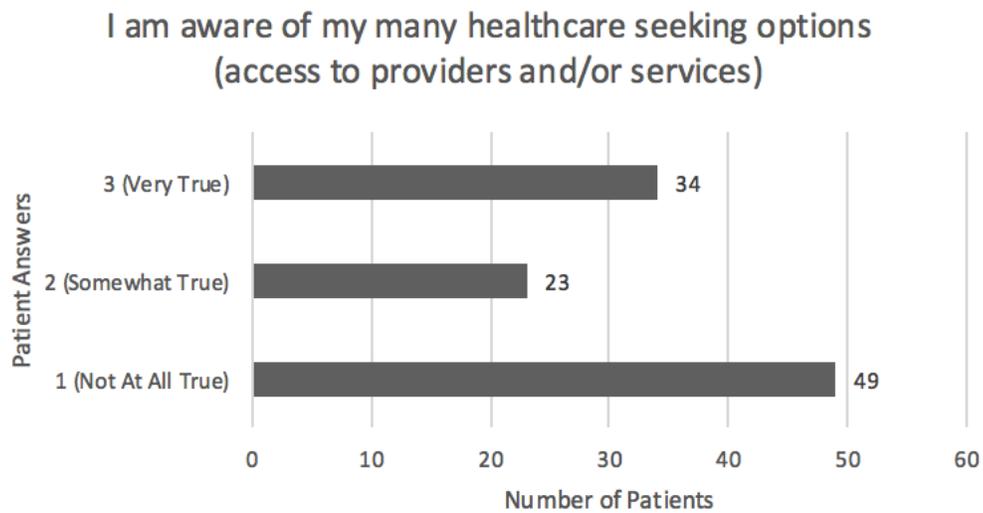
Question 9 was very similar to question 6, but asked if family was supportive in receiving additional healthcare, regardless of cost of care on a scale of 1 to 3 (not at all true to very true). All 106 patients once again answered this question. It is noted that the average assessment was 2.88.

**Figure 10: Patient Survey Results, Question 9**



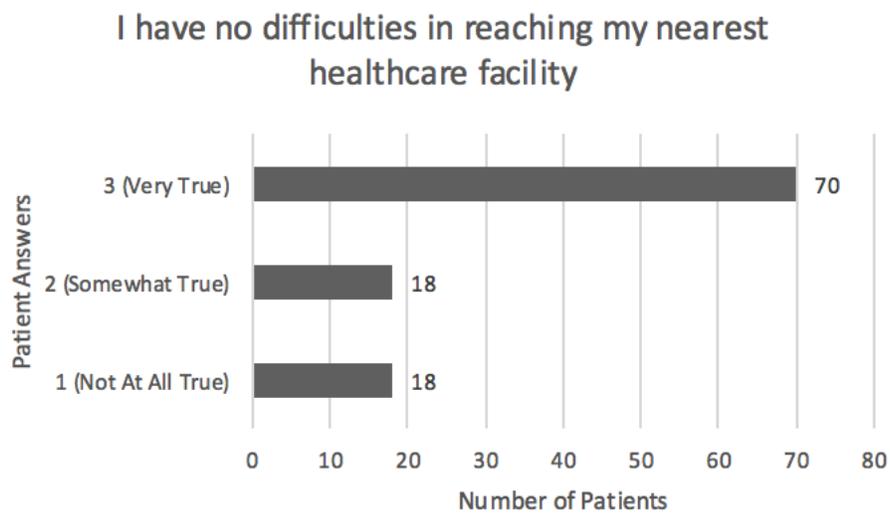
Question 10 asked patients whether or not they were aware of their many other healthcare seeking options (access to other providers and services) on a scale of 1 to 3 (not at all true to very true). All individuals who took part in this survey answered this question. The average assessment was 1.86.

**Figure 11: Patient Survey Results, Question 10**



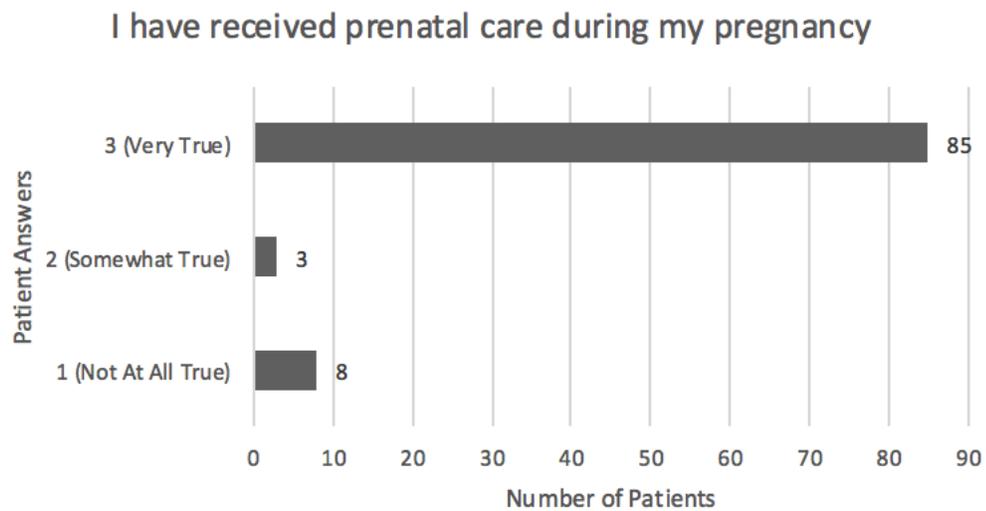
The 11<sup>th</sup> question of the survey asked patients if they had any difficulties in reaching their nearest healthcare facility on a scale of 1 to 3 (not at all true to very true). The average assessment was 2.49.

**Figure 12: Patient Survey Results, Question 11**



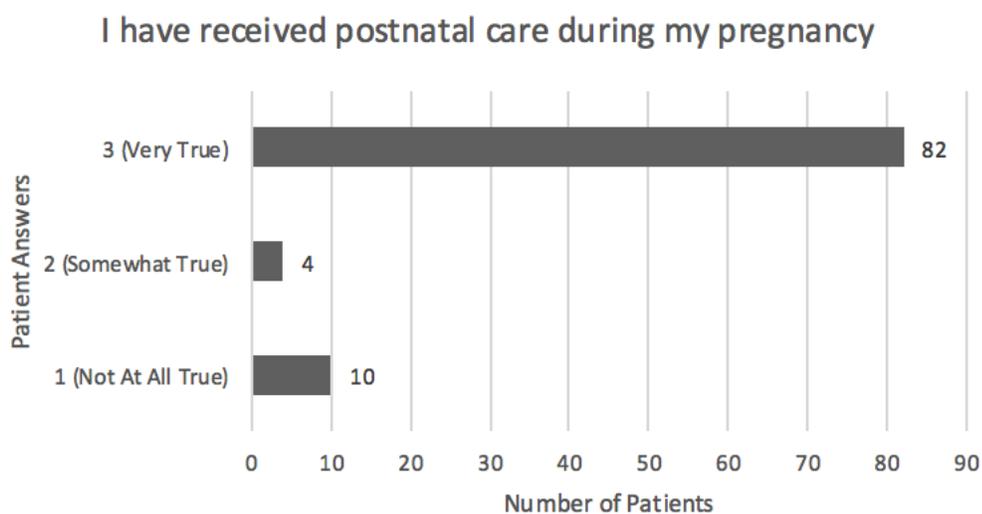
Question 12 assessed whether or not patients if they received any time of pre natal care during their pregnancy on a scale of 1 to 3 (not at all true to very true). It was seen that approximately 10 of the 106 patients surveyed did not answer the question. The average assessment for this question was 2.80.

**Figure 13: Patient Survey Results, Question 12**



Finally, the last question in the survey asked respondents to answer whether or not they received post natal care after their pregnancy on a scale of 1 to 3 (not at all true to very true). Again, there were approximately 10 patients of the 106 surveyed who did not answer the question. The average assessment for this question was 2.75.

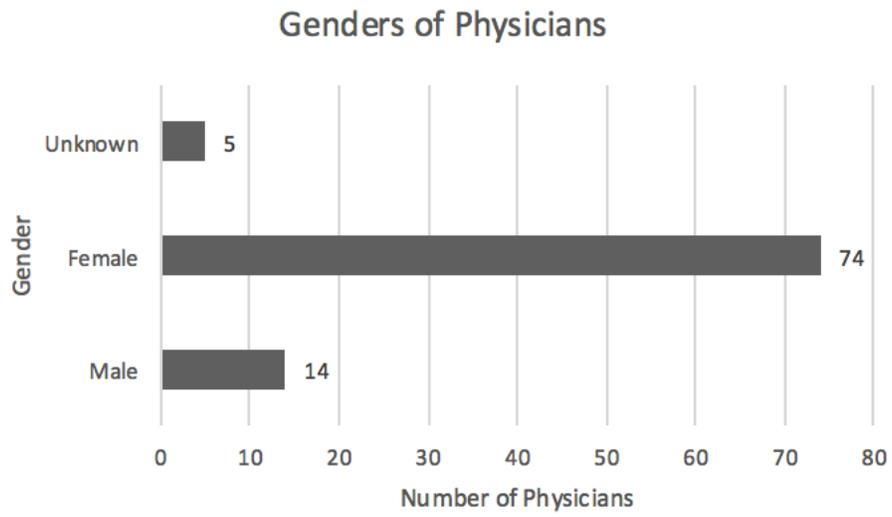
**Figure 14: Patient Survey Results, Question 13**



### **Physician Survey Results**

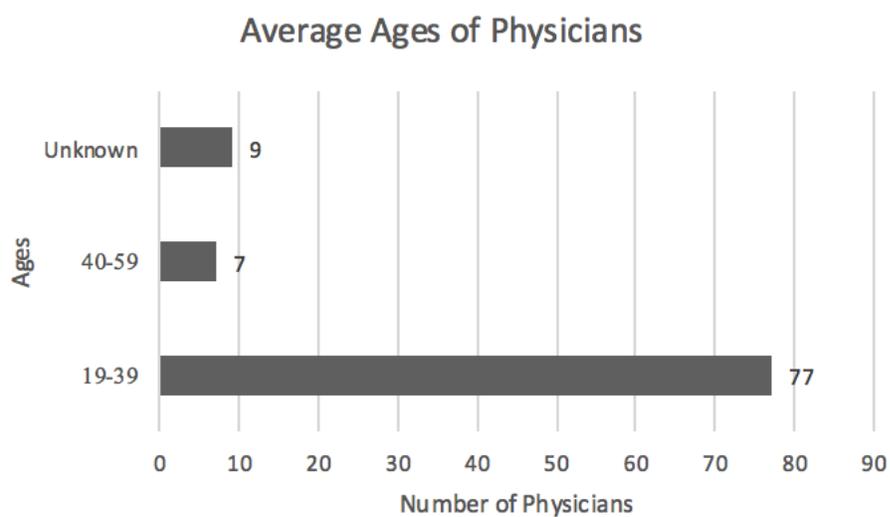
Of the 93 physicians who completed the physician survey all were eligible to complete the survey based on the inclusion criteria that was set in the “Methods” section of this thesis. Healthcare professionals in Pakistan that provided pre and post natal care were primarily female, while there were approximately 5 physicians with unknown genders (as they did not answer this question in the survey).

Figure 15: Gender of Physicians, Physician Survey



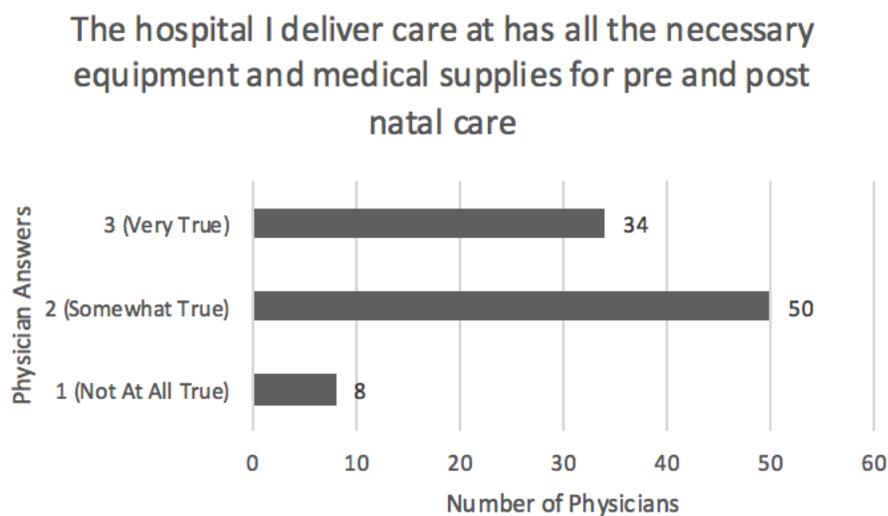
Most physicians in Pakistan were between the ages 19-39, while some were between the ages 40-59 and about 9 were unknown (as they did not answer this question in the survey).

**Figure 16: Average Ages of Physicians, Physician Survey**



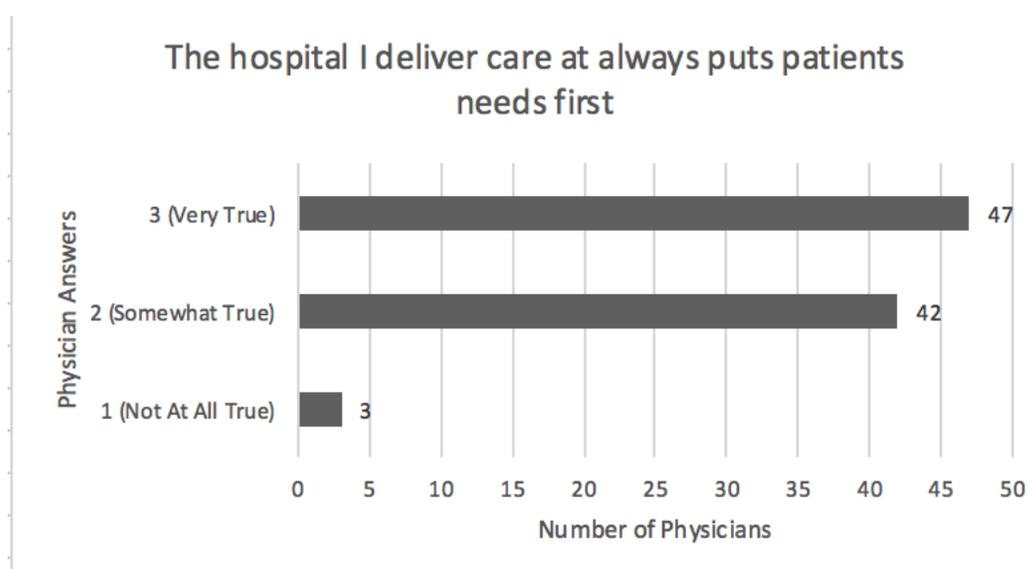
Question 1 of the physician survey asked participants whether or not the hospital they delivered care at had all the necessary equipment and medical supplies for pre and post natal care on a scale of 1 to 3 (not at all true to very true). This question was used to evaluate the quality of care that was provided to the patients at each hospital. There was one physician who did not answer the question, but the other 92 physicians surveyed answered the question to a varying degree. The average assessment for this question was 2.28.

**Figure 17: Physician Survey Results, Question 1**



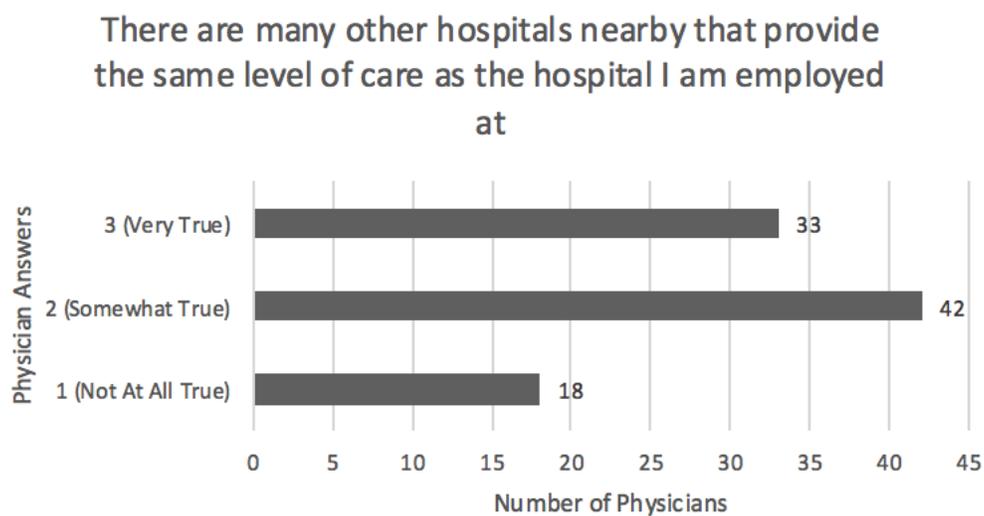
The second question of the survey asked physicians to answer whether or not they put patients needs first when delivering care on a scale of 1 to 3 (not at all true to very true). Once again, only 1 physician chose not to answer this question. The average assessment for this question was 2.48.

**Figure 18: Physician Survey Results, Question 2**



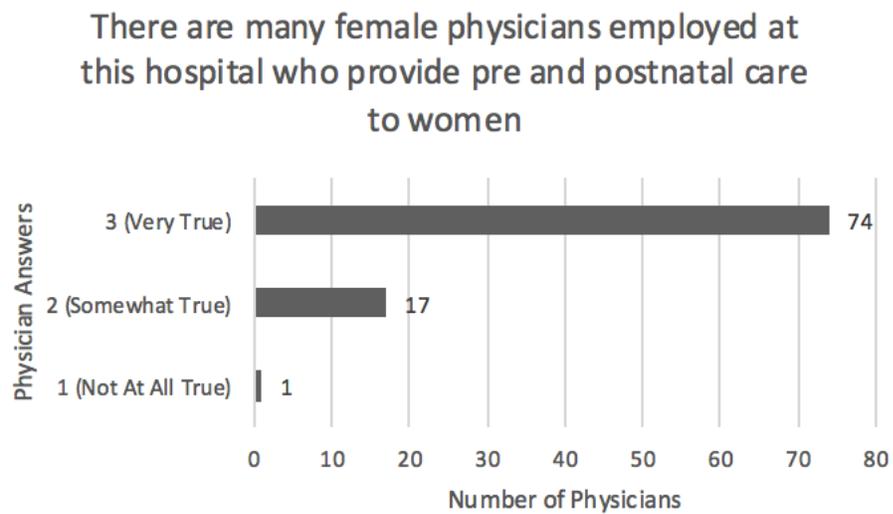
Question 3 asked physicians to identify if there were hospitals nearby that provided the same level of care as the hospital that they were currently employed at. This was done similarly to previous questions on a scale of 1 to 3 (not at all true to very true). It was noted that all physicians answered this question. The average assessment was 2.16.

**Figure 19: Physician Survey Results, Question 3**



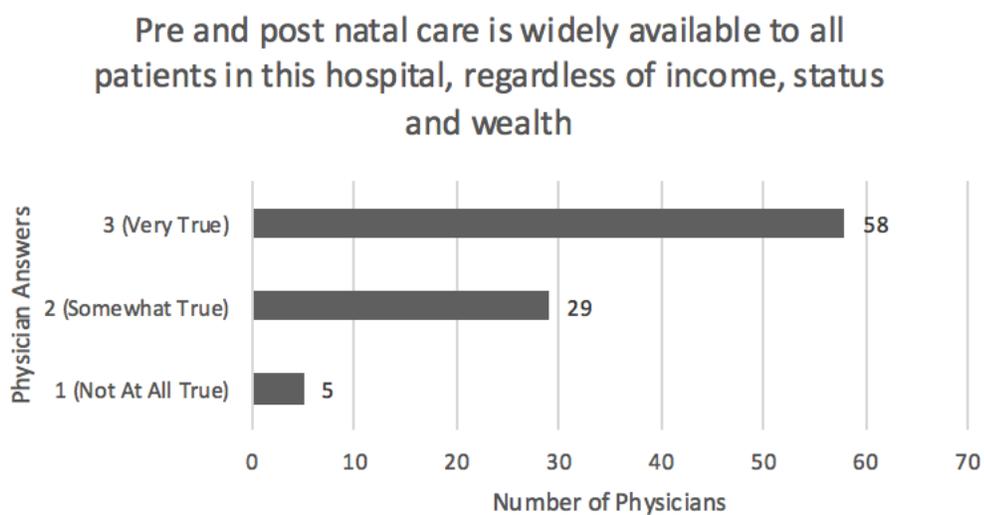
The fourth question asked physicians whether or not there were more females or males who provided pre and post natal care to women in the hospital they were employed at on a scale of 1 to 3 (not at all true to very true). The average assessment was 2.79.

**Figure 20: Physician Survey Results, Question 4**



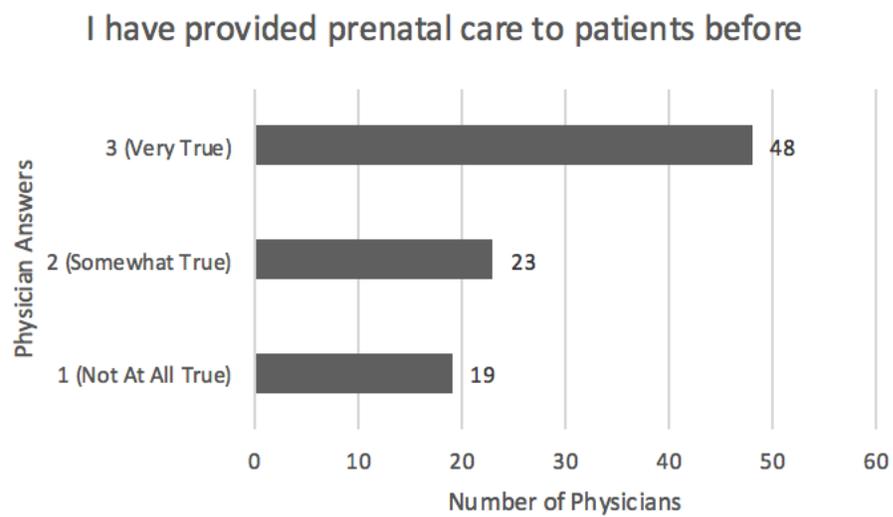
Question 5 of the survey was asked to physicians to determine whether or not patients received pre and post natal care in the hospital that they were employed at regardless on income, status and wealth. This question asked respondents to rank on a scale of 1 to 3 (not at all true to very true) about their opinion on this subject matter. It is noted that 2 physicians did not answer this question. The average assessment was 2.58.

**Figure 21: Physician Survey Results, Question 5**



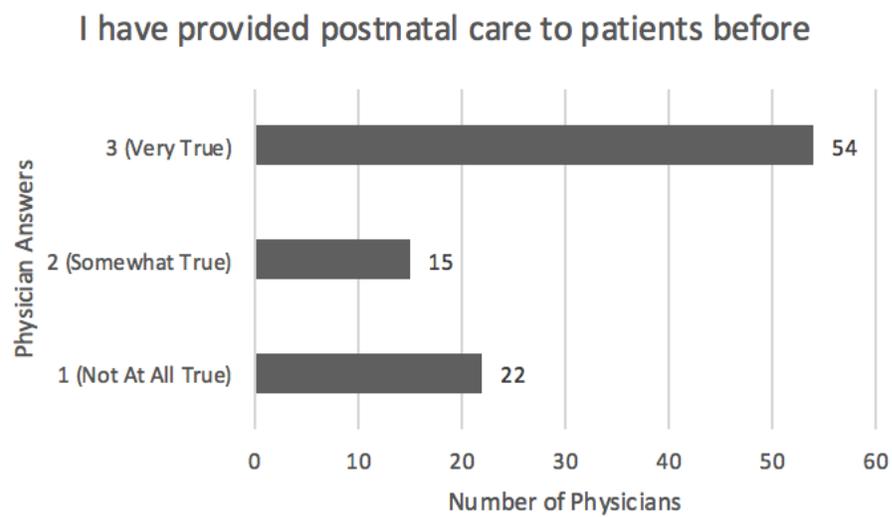
The sixth question was the first question that truly assessed if certain physicians had the ability to provide pre natal care to patients before. Using a scale ranked from 1 to 3 (not at all true to very true), physicians were asked to answer this question to the best of their ability. 2 physicians did not answer this question. The average assessment was 2.32.

**Figure 22: Physician Survey Results, Question 6**



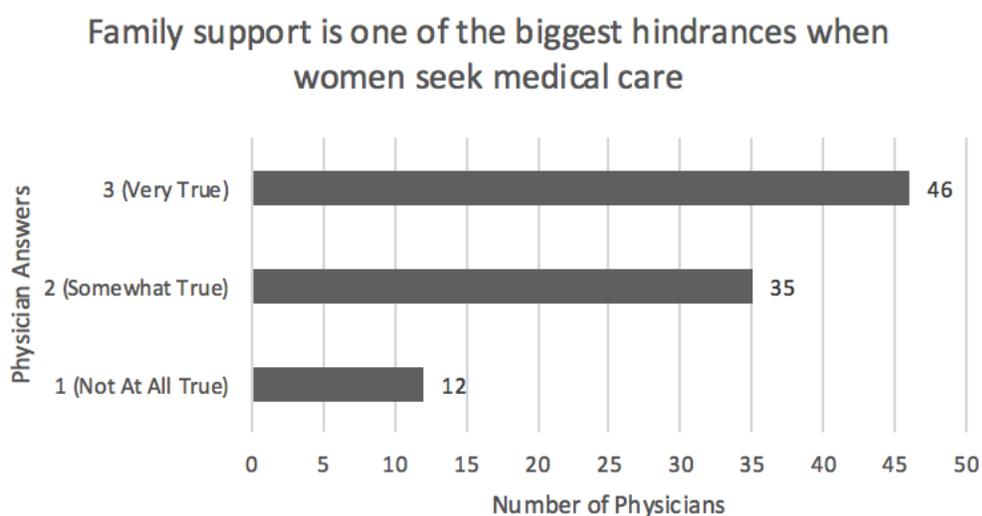
Question 7 was very similar to question 6, except it asked physicians to identify whether or not they have provided post natal care to patients before. Using a scale ranked from 1 to 3 (not at all true to very true), physicians were asked to answer this question to the best of their ability. Again, 2 physicians did not answer this question. The average assessment was 2.35.

**Figure 23: Physician Survey Results, Question 7**



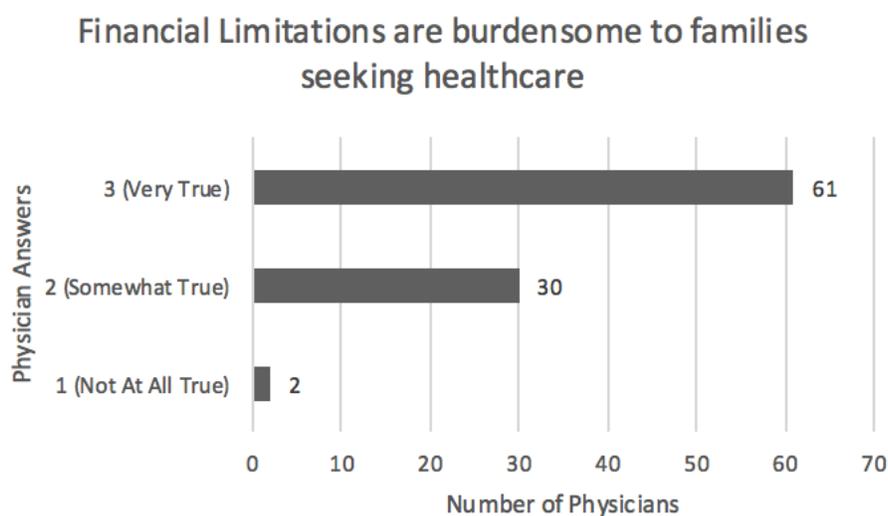
The 8<sup>th</sup> question was used to recognize how often physicians believe that family support is the main hindrance when women seek medical care using a scale ranked from 1 to 3 (not at all true to very true). All healthcare providers answered this question. The average assessment was 2.37 for this question.

**Figure 24: Physician Survey Results, Question 8**



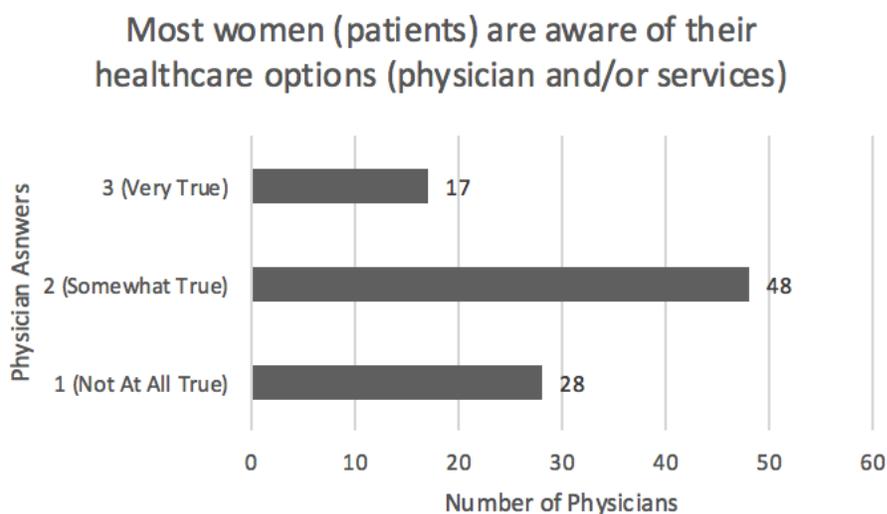
Question 9 assessed whether physicians believed that financial limitations were a burden to families (mainly females) when seeking healthcare. Using a scale ranked from 1 to 3 (not at all true to very true), physicians were asked to answer this question to the best of their ability. All physicians answered this question. The average assessment was 2.63.

**Figure 25: Physician Survey Results, Question 9**



Finally, the last question on the physician survey asked whether or not women (patients) were aware of their many other healthcare options (physician and/or services). This once again employed the ranked scale method of 1 to 3 (not at all true to very true). All physicians answered this question. The average assessment was 1.88.

**Figure 26: Physician Survey Results, Question 10**



### Physician Questionnaire Results

There were 6 open-ended questions that were asked of the 16 physicians who had the time to answer the questionnaire. This section allowed respondents to provide their own opinions and ideas regarding the questions asked. Note: Many of the answers between physicians were very similar; therefore, not all answers are included in these tables.

The first question asked respondents what some of the main barriers women in their particular area faced when wanting pre natal care. Physicians responded with answers such as “low

socioeconomic level,” “lack of family support,” “social myth,” “lack of information,” and “lack of education.” The second question asked physicians what some of the main barriers women in their particular area faced when wanting post natal care. Physicians responded with answers such as “lack of family support (from husband and mother in law),” “lack of education,” “lack of information,” and “large family size.” It can be noted that physician answers for questions 1 and 2 were very similar when responding about questions regarding both pre and post natal care.

The third question asked respondents what they believed were strategies to improve pre natal access. Some of the physician responses included “easy availability/accessibility of hospital services,” “use of media/more communication with masses,” “improve communication with women during office visits,” and “strengthen health system.” The 4<sup>th</sup> question asked physicians what some strategies were to improve post natal access. Some of the responses included “enhance family support,” “education of women,” “we should offer more jobs to health visitors who come and care for pregnant women and women who have recently given birth,” and “distance to facilities should be closer.”

The 5<sup>th</sup> question in the questionnaire asked physicians to provide suggestions on how to encourage more women to seek healthcare. Physicians responded with answers such as “antenatal counseling,” “using media (news and online resources),” “improve the education system (incorporate sex education in school curriculum),” and “women empowerment.” Finally, the sixth question asked physicians to describe some of the challenges that poor women face in regards to receiving pre and post natal care. Some of the physician answers included “large family size,” “pregnancy related anemia and sepsis,” “social myths,” “women are malnourished,” “no access to healthcare (facilities are too far),” and “psychological issues.”

**Table 1: Physician Questionnaire Results, Question 1**

<b>What are some of the main barriers women in this area face when wanting pre natal care?</b>
<ol style="list-style-type: none"> <li>1. Low socioeconomic level</li> <li>2. Lack of family support</li> <li>3. Poverty</li> <li>4. Lack of education</li> <li>5. Social myth</li> <li>6. Lack of information</li> <li>7. Distance to nearest hospital</li> <li>8. Lack of independence (for women)</li> </ol>

**Table 2: Physician Questionnaire Results, Question 2**

<b>What are some of the main barriers women in this area face when wanting post natal care?</b>
<ol style="list-style-type: none"> <li>1. Lack of family support (from husband and mother in law)</li> <li>2. Lack of education</li> <li>3. Lack of information</li> <li>4. Lack of family/kids</li> <li>5. Social myths</li> <li>6. Large family size</li> <li>7. Poverty</li> <li>8. Total neglect of mother, child gets all the care</li> <li>9. Belief in getting treatments from “faith” healers rather than trained doctors</li> </ol>

**Table 3: Physician Questionnaire Results, Question 3**

<b>What are some strategies to improve pre natal access?</b>
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1. Easy availability/accessibility of hospital services
2. Use of media/more communication with masses
3. Improve communication with women during office visits
4. Strengthen health system
5. More trainings of midwives, nutritionists, nurses and lady health workers (at the basic level)
6. Information leaflets
7. Counseling of families and attendants at time of delivery
8. Availability of pre natal/post natal services at their homes
9. Supply free supplements to mothers and provide free medical care
10. Doctors should consider calling patients and scheduling follow-ups
11. Create more screening clinics and more access to basic health units

**Table 4: Physician Questionnaire Results, Question 4**

<b>What are some strategies to improve post natal access?</b>
<ol style="list-style-type: none"> <li>1. Post natal midwifery visits to homes</li> <li>2. Improve and provide proper education/counseling to post natal patients and their families</li> <li>3. Easy accessibility of hospital services</li> <li>4. Counseling of patient and attendants at time of delivery</li> <li>5. Women empowerment</li> <li>6. Enhance family support</li> <li>7. Education of women</li> <li>8. We should offer more jobs to health visitors who come and care for pregnant women and women who have recently given birth</li> <li>9. Distance to facilities should be closer</li> <li>10. Know the importance of care (for women) → otherwise it can lead to susceptibility to deadly diseases</li> <li>11. Create more policies in regards to female health care</li> <li>12. Have more healthcare workers in rural areas and use the media to encourage more women to seek care especially during and after pregnancy</li> <li>13. Create birthing and coaching classes for mothers (this can teach them what to expect during and after pregnancy)</li> </ol>

**Table 5: Physician Questionnaire Results, Question 5**

<b>How do you suggest we encourage more women to seek healthcare?</b>
<ol style="list-style-type: none"> <li>1. Antenatal counseling</li> <li>2. Using media (news and online resources)</li> <li>3. Improve the education system (incorporate sex education in school curriculum)</li> <li>4. Women empowerment</li> </ol>

5. Proper health care system
6. Information leaflets
7. Show women the hazards of not seeking healthcare
8. Creating awareness seminars to show the importance of care
9. Improve literacy levels of women
10. Create more healthcare facilities that are within reach

**Table 6: Physician Questionnaire Results, Question 6**

<b>What challenges do you believe poor women face in regards to receiving pre and post natal care?</b>
<ol style="list-style-type: none"> <li>1. Lack of family support and spouse cooperation</li> <li>2. Low socioeconomic status</li> <li>3. Lack of educational awareness</li> <li>4. Poor doctor/patient relationships</li> <li>5. Poor well being</li> <li>6. Large family size</li> <li>7. Pregnancy related anemia and sepsis</li> <li>8. Social myths</li> <li>9. Women are malnourished</li> <li>10. No access to healthcare (facilities are too far)</li> <li>11. Psychological issues</li> </ol>

### **T-Test Results**

There were many similarities in the survey questions asked to both the patients and physicians. Therefore, multiple t-tests were conducted in order to determine the significance between the questions asked.

**Table 7: T-test, Standard Deviation and Average Assessment Results for Patients and Physicians**

<b>Patient and Physician Questions</b>	<b>Patient and Physician Average Standard Deviation</b>	<b>Patient and Physician Average Assessment</b>	<b>T-Value</b>
<p>Patient: The hospital I receive care at always puts the patients needs first</p> <p>Physician: The hospital I deliver care at always puts patients needs first</p>	<p>Patient: 45.46</p> <p>Physician: 24.09</p>	<p>Patient: 2.84</p> <p>Physician: 2.48</p>	0.067
<p>Patient: There are many hospitals nearby that provide the same level of care as the hospital I am currently receiving care at</p> <p>Physician: There are many other hospitals</p>	<p>Patient: 1.00</p> <p>Physician: 12.12</p>	<p>Patient: 2.01</p> <p>Physician: 2.16</p>	0.427

nearby that provide the same level of care as the hospital I am employed at			
Patient: The hospital I receive care at has all the necessary equipment and medical supplies for pre and post natal care  Physician: The hospital I deliver care at has all the necessary equipment and medical supplies for pre and post natal care	Patient: 44.74  Physician: 21.20	Patient: 2.84  Physician: 2.28	0.070
Patient: There are many female physicians employed	Patient: 38.37  Physician: 45.21	Patient: 2.84  Physician: 2.79	0.078

<p>at this hospital who are available to provide pre and post natal care to woman</p> <p>Physician: There are many female physicians employed at this hospital who provide pre and post natal care to women</p>			
<p>Patient: Pre and post natal care is widely available to all patients in this hospital, regardless of income, status and wealth</p> <p>Physician: Pre and post natal care is widely available to all patients in this</p>	<p>Patient: 26.54</p> <p>Physician: 44.06</p>	<p>Patient: 2.78</p> <p>Physician: 2.58</p>	<p>0.123</p>

hospital, regardless of income, status and wealth			
<p>Patient: My family allows me to have access to healthcare</p> <p>Physician: Family support is one of the biggest hindrances when women seek medical care</p>	<p>Patient: 49.08</p> <p>Physician: 17.35</p>	<p>Patient: 2.81</p> <p>Physician: 2.37</p>	0.144
<p>Patient: Financial limitations are one of the burdens regarding my access to healthcare</p> <p>Physician: Financial limitations are burdensome to</p>	<p>Patient: 17.56</p> <p>Physician: 29.51</p>	<p>Patient: 1.86</p> <p>Physician: 2.63</p>	0.219

families seeking healthcare			
Patient: I am aware of my many healthcare seeking options (access to providers and/or services)  Physician: Most women (patients) are aware of their healthcare options (physicians and/or services)	Patient: 15.72  Physician: 13.05	Patient: 1.86  Physician: 1.88	0.367
Patient: I have received prenatal care during my pregnancy  Physician: I have provided prenatal care to patients before	Patient: 45.97  Physician: 15.72	Patient: 2.80  Physician: 2.32	0.071

Patient: I have received postnatal care after my pregnancy Physician: I have provided postnatal care to patients before	Patient: 43.41 Physician: 20.80	Patient: 2.75 Physician: 2.35	0.060
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## **Chapter 5**

### **Discussion**

#### **Patients and Physicians**

Per the results of the patient survey, most patients that received care in Pakistani hospitals were satisfied with the healthcare they received. This was surprising considering the increasing lack of quality of healthcare around the country. On the survey questions (ranked 1 to 3, from not at all true to very true) that asked participants of different aspects of their hospital stay and care, most patients replied with “very true” which stated that they were extremely satisfied with the services received. It is interesting to note that patients consistently scored higher on the questions relating to hospital stay and care than physicians who were asked similar questions.

On the scale regarding whether or not patients’ needs were put first by the doctor and hospitals, patients ranked their satisfaction with an average of 2.84. While the physicians ranked their ability to provide care with an average of 2.48. The t-test value for this question was 0.067, since it was only slightly higher than 0.05, it suggests that the difference between the two data sets could be approaching statistical significance, but most likely occurred due to chance. Considering previous research that was conducted at public hospitals in Pakistan and the increasing wait times associated with receiving care at hospitals, it is possible that this value occurred due to doctors shading their answers and not wanting to disclose the environment of the hospital that they were employed at.

Across Pakistan, there is a vast number of hospitals that provide varying levels of care. The varying levels of care provided at the hospitals are based on multiple factors. One of the questions

asked to both patients and physicians in the survey questions was if there were hospitals nearby that provided the same level of care they were either employed at or receiving care at. Patients ranked their answer with an average of 2.01. While physicians ranked the answer with an average of 2.16. The t-test value for this question was 0.427, which suggests that the data was statistically insignificant. It is possible that this occurred because patients had only ever been to the hospital that they were currently receiving care at or they weren't sure about any other hospitals in the specific area that they were visiting.

Likewise, both patient and physician respondents were asked if the hospital they received care at/worked at had all the necessary equipment and medical supplies for pre and post natal care. Patients reported an average value of 2.84, while physicians reported an average value of 2.28. The t-test value was 0.070, this value was once again only slightly higher than 0.05, which suggests that the data could be approaching statistical significance, but most likely occurred due to chance. This significance value most likely could have occurred if the patients had only ever been to this hospital before or physicians were shielding the environment and availabilities of the hospital that they were currently employed at.

This question may relate to the frequency of how many female physicians are employed at hospitals who have the ability to provide pre and post natal care to woman. Per the results of question 4 in both the patient and physician survey. Patients reported their answer with an average of 2.84. Meanwhile, physicians provided an answer with an average of 2.78. The t-test value for this question was 0.078. Since it once again close to the 0.05 significance value, it shows that the data set was approaching significance but most likely occurred due to chance. In Pakistan, there is a large need for more female doctors, which is why the results for this section of the data were quite interesting to see. It is possible that the reason why this data is skewed is because one of the

hospitals that the researcher visited was a primarily female dominated hospital (Lady Wellington) which provided only Gynae and OB GYN care. This could have potentially lead to a large number of respondents saying that females provided many patients with both pre and post natal care.

Unfortunately, in Pakistan there is a rather large divide between the rich and the poor. This can sometimes make it difficult for those that are less off to receive the care that they deserve. Question 5 of the patient and physician survey asked whether patients received the necessary care they desired regardless of income, status and wealth. The average association for patients in this question was 2.78. For physicians the average assessment was 2.58. It can be noted that the t-test value was 0.123 showing that this data set could have been a mere result of chance and the difference was not significant. This t-test value could have proved to been insignificant because a lot of the hospitals that the researcher visited were government funded and treated patients to the best of their ability.

In addition to level of care and availability of physicians at hospitals, providers and patients were also asked to rank how strongly they felt that financial reasons were a burden which limited to access of care. Average assessment for the patients who answered this question was 1.86. The average assessment for the physicians questioned was 2.63. The t-test value proved to be 0.219, which shows that the value was insignificant. This question also posed intriguing results since we saw a rather large disagreement between the physician and patient survey results. Many patients believe that finances were not a reason for lack of healthcare, while for physician's financial limitations were one of the biggest reasons for why patients never came to hospitals for treatment. This could have occurred if patients did not want the researcher to know of their current financial status.

An identical question was asked to both patients and physicians, where both groups were asked whether family allowed patients access to healthcare facilities for care. This question also provided very interesting results, as the physicians and patients had very opposing answers. The average assessment for the patients in this question was 2.88. For the physicians the average assessment was 2.37. The t-test value was 0.144, which shows once again that the data was once again statistically irrelevant. Many patients believed that their family members were supportive in regards to receiving healthcare, whereas once again physicians believed that family support is a massive cause for women not receiving proper pre and post natal healthcare. It is possible that patients were shading their answers and did not want to disclose their familial issues/relationships.

Next, patients were asked if they were aware of the various other healthcare seeking options in a hospital. Physicians were asked a similar question, dealing with women and whether they took advantage of seeking other physician services. The average assessment for patients was 1.86. For physicians the average assessment was 1.88. The t-test value for this question was 0.367, which suggests that this data was not significant. This t-test value could have been a mere result of chance or the patients did not fully understand the question that was being asked of them because both physicians and patients agreed that they were not aware of their many health care seeking options that were available to them. This could have also occurred because many patients in the healthcare facilities that were interviewed had no or low levels of education and they could have genuinely not been aware of their other options for seeking healthcare in Pakistan.

Patients and physicians were then asked a question relating to pre natal care. Patients were asked whether they had ever received pre natal care during their pregnancy, while physicians were asked whether they had every provided pre natal care. The average assessment for the patients was 2.80, while the average assessment for the physicians was 2.32. The t-test value for this question

was 0.071, which suggests that it was approaching statistical significance since it is close to 0.05. It is possible that this value most likely occurred due to chance and could have happened if patients weren't aware of what the question was asking (due to low education levels) or if they wanted to shield their personal life.

Finally, patients and physicians were asked a question relating to post natal care. Patients were asked whether they had every received post natal care after their pregnancy, while physicians were asked whether they had every provided post natal care. The average assessment for the patients was 2.75, while the average assessment for the physicians was 2.35 The t-test value for this question was 0.060, which suggests that it was approaching statistical significance since it was close to 0.05. Once again, this value could have possibly occurred due to chance and also if patients weren't aware of what the question was asking (due to low education levels) or if they wanted to shield their personal life.

### **Study Limitations**

It should be noted that several study limitations were observed in this project. Firstly, while the goal for this study was to gather approximately 100 patient participants and 50-80 physician participants from Pakistan, this was by no means a large enough representation of the women patient and physician population of the country. Secondly, the researcher only spent 2 weeks gathering research in Pakistan, which was a very limited amount of time to generate data. In addition, the researcher only conducted research at 4 hospitals, which is not nearly enough hospitals to gather research from (especially since there can be upwards of 50+ hospitals in just one city). Next, there was a small language barrier between the researcher and the patients that

were interviewed for the survey. While the researcher spoke fluent Urdu, she still had trouble communicating with certain patients who spoke other dialects of Urdu. Finally, the results of the study are prone to human error, as it was difficult to determine the accuracy of patient and physician responses to certain questions. Especially questions regarding “financial limitations” and “family support.” It was noted that most patients did not believe that these were factors that denied them care, while most physicians believed that money and family were the biggest hindrances.

### **Additional Research**

There are a significant number of areas throughout this research that should be further investigated with additional research. Some of the chief complaints of study participants were “there are too many patients and not enough doctors,” “wait times are too long, I have been here since 8 am and it is now 4 pm, the doctor has yet to see me” and finally, “sometimes doctors are rude to patients, even when we are just asking questions.” Pakistan must also focus on guaranteeing clean and functional health facilities that are well within reach of every mother and baby. The government must recruit, train (educate doctors on well treatment of patients) and retain a sufficient number of doctors, nurses and midwives, ensure that there will be equipment available in hospitals for mother and babies, and finally focus on empowering adolescent girls, mothers and families to demand and receive quality care. As of July 2018, there has been a new government regime in Pakistan (Pakistan Tehreek-e-Insaf) that aims to better the overall healthcare crisis that is currently striking the country. The hope is that in the next couple of years, Pakistan will be able

decrease the overall number of maternal and newborn deaths, as well as increase the number of healthcare units, screenings for mothers and children, and the number of women medical officers.

## **Chapter 6**

### **Conclusion**

Access to pre and post natal care is a genuine issue that is plaguing the country of Pakistan. While the country is working on bettering the healthcare system for both women and children, it will take a while before there is true improvement seen. The hopes of this study was to determine the factors that contribute to the morbidity and mortality rate for pre and post natal care in rural women of Pakistan. The data collected from both physicians and patients produced interesting results, which provided areas of further research that must be conducted.

The study operated by surveying 106 patients and 93 providers. The criteria for the patients to be eligible in the study included women who came in for gynecological issues between the ages (15-59), women who have recently given birth, and women who are currently pregnant between the ages (15-49). While the criteria for the physicians was that they must practice in OB GYN, pediatrics or family medicine. Participants were asked to rank several questions on a scale of 1 to 3 (not at all true to very true) that assessed areas such as quality, access, and cost of receiving healthcare in Pakistan. Providers were also asked to answer 6 open-ended questions on how to best improve access to pre and post natal care for women. The values from these questions were then compiled and basic statistical data was generated.

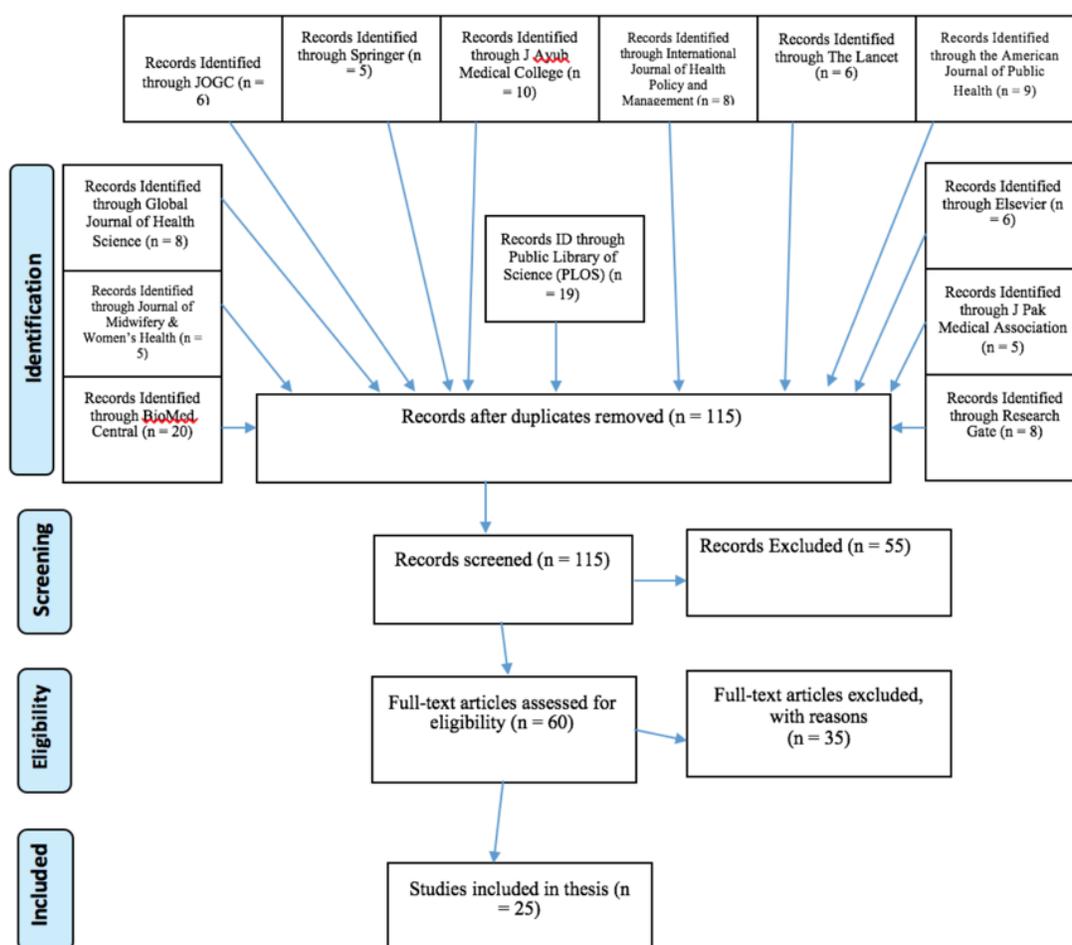
The results from this study were quite unexpected. The original hypothesis for this study was to determine how the lack of pre and post natal care in rural areas of Pakistan contributed to the morbidity and mortality rates for women. As seen in the results section of this thesis, t-tests were run for some of the questions that were similar between patients and physicians. It can be

noted that some of the data was approaching statistical significance (values were slightly above 0.05), while some of the data was statistically insignificant. There are a number of reasons for why the data could have been approaching statistical insignificance or was insignificant, but the most plausible reasons include human error and patients/physicians shading their views. One important issue to note is that throughout the data collection portion of this research many patients and physicians had opposing viewpoints for similar questions. For example, the researcher was expecting answers of “very true” from the patients when they were asked if financial burdens or family support were reasons that limited their access to healthcare, but in return got a number of “not at all true” answers. Most physicians answered “very true” when asked if financial burdens were a reason that limited patients access to healthcare. Many women and physicians who partook in this research were satisfied with the treatment that they were receiving and providing. This suggests that the initial hypothesis that was generated was incorrect since it was rather difficult to determine the reasons for high morbidity and mortality rates from the rural women in this study population. Although, results of this research were not as expected, Pakistan must still work on furthering awareness on this issue, improving overall access and quality of care in other hospitals across the country.

## Appendix A

### Prisma Flow Chart, Matrix and Tables

#### Prisma Flowchart



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009), Preferred Reporting Items for Systematic Reviews and Meta Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. Doi:10.1371/journal.pmed1000097

## Matrix Chart

Article Title	Article Focus	Limitations	Conclusions
Quality of antenatal care and household wealth as determinants of institutional delivery in Pakistan: Results of a cross-sectional household survey (2016)	This study worked to understand the relationship between the quality of antenatal care and wealth and how that effects institutional delivery	The quality of care variable is based on retrospective self-report of antenatal care services, which may not capture the actual experience of women who receive services	<p>The effects of quality of care are strong and powerful, and independent of the effects of education, wealth and other variables</p> <p>Also, quality of care appears to have a dose-response relationship with institutional delivery: the better the quality of care provided, the higher the institutional delivery rate</p> <p>The findings emphasize the importance of having a strong focus on improving quality of antenatal care services in Pakistan in order to drive rapid increases in the institutional delivery rate and improve health outcomes for women and children</p>
Access to comprehensive emergency obstetric and newborn care facilities in three rural districts of	This study attempted to assess access to comprehensive emergency obstetric and newborn care (C-EmONC) facilities and barriers		C-EmONC services in both public and private hospitals may simply be not accessible and affordable for the vast majority of poor

Sindh province, Pakistan (2015)	hampering access in Sindh		and marginalized women in targeted districts of Sindh province
Improvement of perinatal and newborn care in rural Pakistan through community-based strategies: a cluster-randomized effectiveness trial (2011)	This study aimed to evaluate the effectiveness of a community-based intervention package, principally delivered through LHWs working with traditional birth attendants and community health committees for reduction of perinatal and neonatal mortality in a rural district of Pakistan		Despite low coverage and high complexity, the intervention was associated with significant reductions in stillbirths and neonatal mortality in the rural district of Pakistan
Individual and Area Level Factors Associated with Prenatal, Delivery, and Postnatal Care in Pakistan (2015)	This study aimed to examine individual and area level factors associated with maternal health care utilization in Pakistan	Much of the data in this study was self-reported and subject to recall bias Respondents may also feel the need to provide a desirable answer, leading to an underestimation of poor health outcomes	Evidence was found to support the positive effect of individual level variables, education and wealth, on the utilization of maternal health care across all five measures  Birth order was found to have a statistically significant effects across all measures; the higher the birth order, the lower the odds of accessing prenatal, delivery or postnatal care  Women who cited distance as a barrier, had lower odds of

			receiving post natal healthcare, but still engaged in pre natal services and often had a skilled attendant present at delivery
What Works? Strategies to Increase Reproductive, Maternal and Child Health in Difficult to Access Mountainous Locations: A Systematic Literature Review (2014)	This study aims to identify strategies to address barriers to reproductive MNCH service utilization in difficult-to-reach mountainous regions in low and lower-middle income settings		<p>Delivering quality healthcare services to populations in hard to reach environments is challenging</p> <p>There are some promising strategies that can address the burden of geographical inaccessibility</p> <p>For example: task shifting, strengthened roles for CHWs and volunteers, mobile teams, incentives and removal of user fees, local awareness initiatives, and highly inclusive structured health promotion and planning forums</p>
Safe delivery and newborn care practices in Sindh, Pakistan: a community-based investigation of mothers and health workers (2012)	This study aims to determine the prevalence of specific intrapartum practices in Sindh province, Pakistan		Safe delivery and newborn practices by unskilled health workers were low and there were high levels of unsafe practices such as cord traction and insertion of hand into the vagina during delivery

			<p>Majority of mothers and other health workers reported that clean delivery kits were not used.</p> <p>Hygiene is compromised even at health facilities. Findings show that deliveries at home or primary health-care facilities attended by unskilled health workers are highly prevalent in rural areas and it will therefore be a major task to change this</p>
Maternal Health and Survival in Pakistan: Issues and Options (2009)	This study examines the factors influencing the under-utilization of maternal health services among Pakistani women, such as the lack of availability of skilled care providers and poor quality services		Even though Pakistan has one of the highest rates of maternal mortality in the South Asia region, most of the causes of maternal morbidity and mortality can be addressed by health system interventions, social sector reform, and human development
Accessibility of antenatal services at primary healthcare facilities in Punjab, Pakistan (2015)	This study evaluates the accessibility of antenatal care services in primary healthcare settings in the Punjab province of Pakistan during the period of June 2010-August 2011		<p>The availability and accessibility of health services is influenced by a number of managerial and social factors</p> <p>Managerial factors: distant location, affordability, availability of transport services</p>

			Social factors: lack of client self empowerment, health facility staff being unavailable
Coverage and Quality of Antenatal Care Provided at Primary Health Care Facilities in the 'Punjab' Province of 'Pakistan' (2014)	This study aims to assess the coverage and quality antenatal care in the primary health care facilities in 'Punjab' province of Pakistan		To improve the quality of services, health care providers should be trained to improve their technical skills for assessment, treatment and counseling of clients. Providers should get motivation and training to encourage them to follow the standard protocols for provision of quality ANC services
Equity in the use of public services for mother and newborn child health care in Pakistan: a utilization incidence analysis (2016)	This study aims to employ nationally representative household data for Pakistan for 2007-08 and 2010-11 to investigate whether benefits from publicly financed services on Mother and Newborn Child Health are effectively captured by the poor in terms of service utilization	Benefits are measured in terms of utilization of services and anyone who uses a public health service or a facility is considered a beneficiary.  Data on the utilization of health services do not capture differences in the quality of service provided	The province needs to devise a strategy on how best to mitigate these inequities in health care usage  It is recommended that there is an increase in the overall investment in health in the province and targeting them effectively towards the poor
Residual Barriers for Utilization of Maternal and Child Health Services: Community Perceptions From Rural Pakistan (2015)	This study aims to explore community barriers in accessing Maternal and Child Health (MCH) services in ten remote		In the context of remote rural areas, the traditional emphasis on continued investment in health facility infrastructure is not

	rural districts of Pakistan		likely to address poor MCH service utilization rates
Impact of community-based interventions of maternal and neonatal health indicators: Results from a community randomized trial in rural Balochistan, Pakistan (2010)	This study aims to understand why there is a delay in decision making to seek medical care during obstetric emergencies		It was concluded that providing safe motherhood educated increased the probability of pregnant women having pre natal care and utilization of health services for obstetric complications
Are community midwives addressing the inequities in access to skilled birth attendance in Punjab, Pakistan? Gender, class and social exclusion (2012)	This study aims to understand if community midwives are addressing the inequities in access to skilled birth attendance in the province of Punjab		Improvements in the delivery of maternity care for poor and socially excluded women were seen  Poor and socially excluded women were targeted for provision of maternity care
Addressing disparities in maternal health care in Pakistan: gender, class and exclusion (2012)	This study aims to understand how certain disparities lead to gaps in maternal healthcare in Pakistan		Improvement in maternal health policies and health care system practices aimed at reducing disparities in maternal care in Pakistan
Improving Maternal Health in Pakistan: Toward a Deeper Understanding of the Social Determinants of Poor Women's Access to Maternal Health Services (2014)	This study aims to understand how maternal health in Pakistan can be improved		It is noted that reducing financial obstacles to accessing services will have limited impact until there is a better understanding of the social and economic realities of poor women's lives

Qualitative exploration of facilitating factors and barriers to use of antenatal care services by pregnant women in urban and rural settings in Pakistan (2016)	This study aims to explore facilitators and barriers to use of antenatal care services in rural and urban communities of two selected districts in Pakistan	The qualitative research is not representative of all districts in Pakistan. Also, data was not collected on women in both urban and rural settings	There is a need of formulation and testing of interventions, especially in rural communities, to improve ANC services coverage
Determinants of neonatal mortality in Pakistan: secondary analysis of Pakistan Demographic and Health Survey 2006-07 (2014)	The aim of this study was to identify determinants of neonatal mortality in Pakistan	Only surviving mothers were interviewed which may have led to an underestimate of the neonatal mortality rate  Variables such as parental occupation which represented the employment status within the last 12 months, were not infant specific because they only presented the most recent conditions	To reduce neonatal mortality, there is a need to implement interventions focusing on antenatal care, effective referral system and restraining of healthcare providers to manage delivery complications and smaller than average birth size babies in resource poor communities of Pakistan
Health reform in Pakistan: a call to action (2013)	This study aimed to understand why health reform in Pakistan is necessary		Pakistan must pitch the attainment of health at the right political and institutional levels
An Audit of Morbidity and Mortality of Hospitalized Neonates in Neonatal Care Unit of A Tertiary Care Hospital in Abbottabad (2011)	This study aimed to determine the neonatal mortality in the Hazara region		Improvement in the pre natal, natal and nursery care as a whole can reduce the neonatal mortality in preterm as well as full term neonates
Perceived barriers to utilizing maternal and neonatal health	The objective of this study was to explore perceived barriers to	FGD was the only method of information	Contracting needs to be accompanied by measures for

<p>services in contracted-out versus government-managed health facilities in the rural districts of Pakistan (2015)</p>	<p>utilizing (MNH) services, in health facilities contracted out by government to NGO for service provision versus in those which are managed by government (non-contracted)</p>	<p>collection while other qualitative methods such as in-depth interviews were not applied which could have helped in triangulation</p> <p>This study was confined to rural remote setting in Pakistan and cannot be generalized to less remote low-income settings</p>	<p>transportation in remote settings, oversight on user fee charges by contractor, and strong community-based behavior change strategies</p>
<p>Midwifery Education and Maternal and Neonatal Health Issues: Challenges in Pakistan (2007)</p>	<p>This study highlights some of the challenges that midwifery, maternal and neonatal health present</p>	<p style="background-color: black; color: black;">[REDACTED]</p>	<p>Good midwifery practice outcomes have helped attract clients and positively affected reimbursement rates</p> <p>Pakistan needs to make a similar commitment and implement midwifery training and education programs, which include the development of extensive and complex skills</p> <p>A vision of the rebirth of midwifery is crucial to meet a serious health need in Pakistan. Midwives, LHVs, and nurses must have a major role in improving and impacting Pakistani women's and neonates' health</p>

<p>Factors affecting the utilization of antenatal care among women of reproductive age in Nurpur Shahan (2011)</p>	<p>This study aims to understand the factors that affect the utilization of antenatal care in Nurpur Shahan</p>		<p>Although women visited the hospital during pregnancy, many still preferred to have the delivery at home in the presence of an unqualified Dai There is a significant relation between the literacy of the husband and utilization of antenatal care</p>
<p>Social and Societal Barriers in Utilization of Maternal Health Care Services in Rural Punjab, Pakistan (2015)</p>	<p>This study explores the perspectives of rural community members about the antenatal and delivery care services utilization by the community</p>		<p>Home based antenatal and delivery services are still under utilized in the rural community  Strengthening community-based participatory programs to actively engage all stakeholders in overcoming these constraints will be beneficial</p>
<p>Low utilization of post natal care: searching the window of opportunity to save mothers and newborns lives in Islamabad capital territory, Pakistan (2015)</p>	<p>This study aims to understand why there is a low utilization of post natal care and how they can work to save lives of mother and newborns in Islamabad, Pakistan</p>		<p>More robust and culturally sensitive campaigns on importance of PNC must be thought out by the national MNCH program to inform the less literate and peri urban inhabitants of Islamabad.  Health providers ought to be sensitized and trained for</p>

			promoting PNC to save maternal and newborn lives
The community-based delivery of an innovative neonatal kit to save newborn lives in rural Pakistan: design of a cluster randomized trial (2014)	This study aims to highlight the high number of neonatal deaths and the urgent need for effective and sustainable interventions that target newborn mortality in Pakistan		<p>The delivery of the intervention through the LHW program, combined with educating caregivers on how to use the neonatal kit contents will facilitate long-term sustainability</p> <p>The findings of this trial will therefore provide empirical evidence to inform policy on the implementation of sustainable interventions in rural settings to improve neonatal mortality in Pakistan</p>
Harnessing information technology to improve women's health information: evidence from Pakistan (2014)	This study aims to understand whether or not harnessing information technology will improve the overall health of women in Pakistan	<p>Short duration of the project was a limitation</p> <p>The survey used in this study was cross-sectional in nature, therefore the researchers were unable to check whether the health information imparted through the ICC followed</p>	It was concluded that ICTs have the capacity to cross the barriers of illiteracy and can reach out to disadvantaged women living under a conservative patriarchal regime

### Types of Healthcare Facilities Found in Pakistan

<b>RHCs</b>	Rural Healthcare Center
<b>BHUs</b>	Basic Healthcare Unit
<b>B-EmONC</b>	Basic Emergency Obstetric and Newborn Care
<b>Taluka Hospital</b>	Hospital set up in the subdivision of a district in Pakistan
<b>C-EmONC</b>	Comprehensive Emergency Obstetric and Newborn Care
<b>Private Sector Hospital</b>	Smaller, more equipped to offer personalized care More Expensive
<b>Public Sector Hospital</b>	Offer care to anyone that enters their hospital More affordable
<b>PHC</b>	Primary Healthcare Facilities

**Appendix B**  
**Supporting Documents**

**Patient Survey**

Gender: \_\_\_\_\_

Age: \_\_\_\_\_

Date: \_\_\_\_\_

**PATIENT SURVEY**

This survey is anonymous. Your name, age and gender will not be given out to anyone.

---

**The first question is an example:**

I live in Pakistan.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

- 
1. The hospital I receive care at has all the necessary equipment and medical supplies for pre and post natal care.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

2. The hospital I receive care at always puts the patients needs first.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

3. There are many other hospitals nearby that provide the same level of care as the hospital I am currently receiving care at.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

4. There are many female physicians employed at this hospital who are available to provide pre and post natal care to women.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

5. Pre and post natal care is widely available to all patients in this hospital, regardless of income, status and wealth.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

6. My family allows me to have access to healthcare.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

7. My family is supportive in regards to receiving healthcare.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

8. I have a high level of education.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

9. Financial limitations are one of the burdens regarding my access to healthcare.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

10. I am aware of my many healthcare seeking options (access to providers and/or services).

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

11. I have no difficulties in reaching my nearest healthcare facility.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

12. I have received pre natal care during my pregnancy.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

13. I have received post natal care after my pregnancy.

1  
NOT AT ALL TRUE

2  
SOMEWHAT TRUE

3  
VERY TRUE

**Physician Survey**

Gender: \_\_\_\_\_

Age: \_\_\_\_\_

Date: \_\_\_\_\_

**PHYSICIAN SURVEY**This survey is anonymous. Your name, age and gender will not be given out to anyone.**The first question is an example:**

I live in Pakistan.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

1. The hospital I deliver care at has all the necessary equipment and medical supplies for pre and post natal care.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

2. The hospital I deliver care at always puts patients needs first.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

3. There are many other hospitals nearby that provide the same level of care as the hospital I am employed at.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

4. There are many female physicians employed at this hospital who provide pre and post natal care to women.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

5. Pre and post natal care is widely available to all patients in this hospital, regardless of income, status and wealth.

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

6. I have provided pre natal care to patients before

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

7. I have provided post natal care to patients before

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

8. Family support is one of the biggest hindrances when women seek medical care

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

9. Financial limitations are burdensome to families seeking healthcare

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

10. Most women (patients) are aware of their healthcare options (physicians and/or services)

1	2	3
NOT AT ALL TRUE	SOMEWHAT TRUE	VERY TRUE

## Physician Questionnaire

### For Physicians (OB GYN, Family Medicine)

1. What are some of the main barriers women in this area face when wanting pre natal care?
2. What are some of the main barriers women in this area face when wanting post natal care?
3. What are some strategies to improve pre natal access?
4. What are some strategies to improve post natal access?
5. How do you suggest we encourage more women to seek healthcare?
6. What challenges do you believe poor women face in regards to receiving pre and post natal care?

## Pakistani National Bioethics Committee (NBC) Approval Letter



### National Bioethics Committee (NBC) Pakistan



Ref: No.4-87/NBC-343/18/ 1266

Date: December 13, 2018

#### Patron

Minister of State, Ministry of National Health Services Regulations and Coordination

#### Chairperson

Secretary, Ministry of NHR&C, Government of Pakistan

Vice Chairperson, Director General, Ministry of NHR&C, Government of Pakistan

#### Secretariat

Pakistan Health Research Council

Members Ex-Officio

President, College of Physicians and Surgeons of Pakistan

President, Pakistan Medical and Dental Council, President

President, Pakistan Association of Family Physicians

Executive Director, Pakistan Health Research Council, Member/Secretary

WHO Country Representative

President, Supreme Court Bar Association

DGMS (IS)/Surgeon General Pakistan Army

Director General Health, Punjab

Director General Health, Sindh

Director General Health, Khyber Pakhtun Khwa

Director Health Services, FATA

Director General Health, Balochistan

Director General Health, AJK

Director Health Services, Gilgit Baltistan

Registrar, Pakistan Nursing Council

CEO Drug Regulatory Authority, Pakistan (DRAP)

Members

Dr. Saima Perwaiz Iqbal

(Chairperson REC)

Prof. Dr. Farhat Moazzam

(Chairperson HCEC)

Prof. Dr. Munir Akhtar Saleemi

Dr. Aamir Mustafa Jafarey

Dr. Farah Qadir

Dr. Salman Ahmed Tipu

Dr. Saima Perwaiz Iqbal

Dr. Jamshed Akhtar

Dr. Farkhanda Ghafoor

Dr. Inayatullah Memon

Dr. Manzar Anwar Khan

Mr. Abdul Ghani Sasoli

#### Zunish Saqib

The Pennsylvania State University

Old Main, State College, PA 16801

United States of America

Subject: Factors that Contribute to the Morbidity and Mortality Rate for Pre and Post Natal Care in Rural Areas of Pakistan (NBC-343).

Dear Dr. Zunish Saqib,

I am pleased to inform you that the above mentioned project has been cleared by the "Research Ethics Committee" of "National Bioethics Committee" for a period of one year.

For the continuation of project in the next years, you have to send a progress report and a formal request asking for continuation of projects (however, you do not need to submit REC application or pay any processing fee again).

Kindly keep the National Bioethics Committee, Secretariat updated about the progress of the project and submit the formal final report on completion.

Yours sincerely

(Dr. Saima Perwaiz Iqbal)  
Chairperson

NBC-Research Ethics Committee

#### NBC Secretariat:

Pakistan Health Research Council, Shahrah-e-Jamhuriat, Off Constitution Avenue, Sector G-5/2, Islamabad  
www.nbepakistan.org.pk e-mail: nbepakistan.org@gmail.com Tel: 92-51-9224325, 9216793, Fax 9216774.

## Thesis Protocol for IRB Approval



### HRP-591 - Protocol for Human Subject Research

#### Protocol Title:

[Factors that Contribute to the Morbidity and Mortality Rate for Pre and Postnatal Care in Pakistan]

#### Principal Investigator:

Name: [Zunish Saqib]

Department: [Health Policy and Administration]

Telephone: [610-554-xxxx]

E-mail Address: [Zunish.saqib22@gmail.com]

#### Version Date:

10/11/18

#### Clinicaltrials.gov Registration #:

N/A

#### Important Instructions for Using This Protocol Template:

1. Add this completed protocol template to your study in CATS IRB (<http://irb.psu.edu>) on the "Basic Information" page, item 7.
2. This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.
3. **Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.**
4. **For research being conducted at Penn State Hershey or by Penn State Hershey researchers only, delete the instructional boxes from the final version of the protocol prior to upload to CATS IRB (<http://irb.psu.edu>). For all other research, do not delete the instructional boxes from the final version of the protocol.**
5. When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the Study Submission Guide available in the Help Center in CATS IRB (<http://irb.psu.edu>) for using track changes.

#### If you need help...

<p><b>University Park and other campuses:</b>  <a href="#">Office for Research Protections Human Research Protection Program</a></p>	<p><b>College of Medicine and Hershey Medical Center:</b></p>
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<p>The 330 Building, Suite 205 University Park, PA 16802-7014 Phone: 814-865-1775 Fax: 814-863-8699 Email: <a href="mailto:irb-orp@psu.edu">irb-orp@psu.edu</a></p>	<p><a href="#">Human Subjects Protection Office</a> 90 Hope Drive, Mail Code A115, P.O. Box 855 Hershey, PA 17033 (Physical Office Location: Academic Support Building Room 1140) Phone: 717-531-5687 Fax number: 717-531-3937 Email: <a href="mailto:irb-hspo@psu.edu">irb-hspo@psu.edu</a></p>
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## 1.0 Objectives

### 1.1 Study Objectives

Describe the purpose, specific aims or objectives. State the hypotheses to be tested.

[Hypotheses: How does the lack of pre and post natal care in rural areas of Pakistan contribute to the morbidity and mortality rates for women]

[Purpose: The purpose of this study is to determine why there is a lack of pre and post natal care in Pakistan, which is a leading cause for high morbidity and mortality rates.]

### 1.2 Primary Study Endpoints

State the primary endpoints to be measured in the study. Clinical trials typically have a primary objective or endpoint. Additional objectives and endpoints are secondary. The endpoints (or outcomes), determined for each study subject, are the quantitative measurements required by the objectives. Measuring the selected endpoints is the goal of a trial (examples: response rate and survival).

[Primary End Points: What are the leading factors behind the high morbidity and mortality rates in females?]

### 1.3 Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

[Secondary End Points: How can the high morbidity and mortality rates in females be rectified?]

## 2.0 Background

### 2.1 Scientific Background and Gaps

Describe the scientific background and gaps in current knowledge.

Gaps:

- 1) Why do hospitals in Pakistan follow the “first come-first served” pattern of provision of healthcare services?
- 2) Why is it so difficult for women in Pakistan to receive proper healthcare?

Scientific Background:

Total GDP for healthcare in Pakistan = 0.9%

## 2.2 Previous Data

Describe any relevant preliminary data.

Infant mortality rate in Pakistan is 66 per 1,000 births

Life expectancy rate for women in Pakistan is 67 years

Maternal mortality rate in Pakistan is 170 per 100,000 live births

## 2.3 Study Rationale

Provide the scientific rationale for the research.

Scientific Rationale: After determining the infant mortality rate and maternal mortality rate in Pakistan for women and noticing how low it was, the principal investigator decided to determine the reasoning behind why women were dying at such a rapid rate in Pakistan and how this issue can be fixed.

## 3.0 Inclusion and Exclusion Criteria

Create a numbered list below in sections 3.1 and 3.2 of criteria subjects must meet to be eligible for study enrollment (e.g., age, gender, diagnosis, etc.). Indicate specifically whether you will include any of the following vulnerable populations: (You may not include members of these populations as subjects in your research unless you indicate this in your inclusion criteria.) Review the corresponding checklists to ensure that you have provided the necessary information.

- **Adults unable to consent**
  - Review “CHECKLIST: Cognitively Impaired Adults (HRP-417)” to ensure that you have provided sufficient information. HRP-417 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).
- **Individuals who are not yet adults (infants, children, teenagers)**
  - If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), review the “CHECKLIST: Children (HRP-416)” to ensure that you have provided sufficient information. HRP-416 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).
- **Pregnant women**
  - Review “CHECKLIST: Pregnant Women (HRP-412)” to ensure that you have provided sufficient information. HRP-412 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).
- **Prisoners**
  - Review “CHECKLIST: Prisoners (HRP-415)” to ensure that you have provided sufficient information. HRP-415 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).
- **Neonates of uncertain viability or non-viable neonates**

- Review “CHECKLIST: Neonates (HRP-413)” or “CHECKLIST: Neonates of Uncertain Viability (HRP-414)” to ensure that you have provide sufficient information. HRP-413 and HRP-414 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

### 3.1 Inclusion Criteria

List the criteria that define who will be included in your study.

[Inclusion Criteria: Women who have recently given birth, women who are currently pregnant between the (ages 18-35), Physicians (OB GYN & Family Medicine)  
[In this study: All Participants Will be Adults]

### 3.2 Exclusion Criteria

List the criteria that define who will be excluded in your study.

[Exclusion Criteria: Adults unable to consent, individuals who are not yet adults, Prisoners, Neonates of uncertain viability or non-viable neonates]

### 3.3 Early Withdrawal of Subjects

#### 3.3.1 Criteria for removal from study

Insert subject withdrawal criteria (e.g., safety reasons, failure of subject to adhere to protocol requirements, subject consent withdrawal, disease progression, etc.).

[Criteria for removal: failure of subject to adhere to protocol requirements]

#### 3.3.2 Follow-up for withdrawn subjects

Describe when and how to withdraw subjects from the study; the type and timing of the data to be collected for withdrawal of subjects; whether and how subjects are to be replaced; the follow-up for subjects withdrawn from investigational treatment.

[Follow-up: Subjects in the study are able to withdraw from the study at any point in time by asking the principal investigator if they can discontinue the study, data collected will be (survey and questionnaire style data), subjects will be replaced by asking if anyone else would like to take part in the study, subjects that have withdrawn will be asked why they withdrew and how their experience could have been better.]

## 4.0 Recruitment Methods

### 4.1 Identification of subjects

Describe the methods that will be used to identify potential subjects or the source of the subjects. If not recruiting subjects directly (e.g., database query for eligible records or samples) state what will be queried, how and by whom.

StudyFinder: If you intend to use StudyFinder (<http://studyfinder.psu.edu>) for recruitment purposes, please indicate this in section 4.1 along with any other methods for identifying subjects. Note that information provided in this protocol should be consistent with information provided on the StudyFinder page in your CATS IRB study.

For Penn State Hershey submissions using Enterprise Information Management (EIM) for recruitment, attach your EIM Design Specification form on the Basic Information page in CATS IRB (<http://irb.psu.edu>). See HRP-103 Investigator Manual, “What is appropriate for study recruitment?” for additional information.

[Methods used to identify potential subjects: Going to hospitals in Pakistan and identifying pregnant women, women that have recently given birth, talking to doctors (gynecologists and family medicine)

[The defined age group for this research is pregnant women between the ages 18-35 and women who have been recently pregnant.

Geographical location (hospitals and areas) is TBD. The hospitals will be both government and public (general) hospitals.

#### 4.2 Recruitment process

Describe how, where and when potential subjects will be recruited (e.g., approaching or providing information to potential subjects for participation in this research study).

[How: advertisements (hospital billboards), talking to doctors, talking to potential patients]

[Where: different hospitals across Pakistan (tbd)]

[When: December 2018]

[Researcher will first ask for permission to approach patients and providers by talking to hospital boards (where research is being conducted) if they are willing to allow a student to work on her thesis. If not given permission, researcher will find another hospital (there are many hospitals in Pakistan—Unfortunately, not all provide the same level of care. If given approval, researcher will begin her study.

[Patients and providers will then be kindly approached (at hospitals) by asking if they are willing to be a part of a study based on the hospital that they get care/provide care at. If they are not willing, the researcher will move on and find another subject. If they are willing, researcher will bring forth the survey and interview questions along with explaining the procedure for how the research will be conducted.]

#### 4.3 Recruitment materials

List the materials that will be used to recruit subjects. Add recruitment documents to your study in CATS IRB (<http://irb.psu.edu>) on the “Consent Forms and Recruitment Materials” page. For advertisements, upload the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.

StudyFinder: If you intend to use StudyFinder (<http://studyfinder.psu.edu>) for recruitment purposes, you do not need to upload a separate recruitment document for information placed on the StudyFinder site to your study in CATS IRB. Necessary information will be captured on the StudyFinder page in your CATS IRB study.

[Recruitment materials: Paper copy advertisements will be provided at all hospitals where research will be conducted.]

[Verbal script will be used since all potential participants will be spoken to in regards to participation in this study.]

#### 4.4 Eligibility/screening of subjects

If potential subjects will be asked eligibility questions before obtaining informed consent, describe the process. Add the script documents and a list of the eligibility questions that will be used to your study in CATS IRB (<http://irb.psu.edu>) on the “Consent Forms and Recruitment Materials” page.

StudyFinder: If you intend to use StudyFinder (<http://studyfinder.psu.edu>) for recruitment purposes, any scripts (phone, email, or other) used when contacting StudyFinder participants as well as any eligibility screening questions must be added to your study in CATS IRB (<http://irb.psu.edu>) on the “Consent Forms and Recruitment Materials” page.

[Eligibility: participants must be female, they must be 21+ and they must have been recently pregnant, currently pregnant or planning on becoming pregnant in the near future.]

## 5.0 Consent Process and Documentation

Refer to “SOP: Informed Consent Process for Research (HRP-090)”, for information about the process of obtaining informed consent from subjects. HRP-090 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

### 5.1 Consent Process

#### 5.1.1 Obtaining Informed Consent

##### 5.1.1.1 Timing and Location of Consent

*Describe where and when the consent process will take place.*

[Consent will take place in the hospital (December 2018) right before study begins]

#### **5.1.1.2 Coercion or Undue Influence during Consent**

Describe the steps that will be taken to minimize the possibility of coercion or undue influence in the consent process.

[Participants will be asked to participate in the study, if they do not want to participate, they will not be forced to. A new participant will be asked to take part in the study.]

#### **5.1.2 Waiver or alteration of the informed consent requirement**

If you are requesting a waiver or alteration of consent (consent will not be obtained, required information will not be disclosed, or the research involves deception), describe the rationale for the request in this section. If the alteration is because of deception or incomplete disclosure, explain whether and how subjects will be debriefed. Add any debriefing materials or document(s) to your study in CATS IRB (<http://irb.psu.edu>) on the “Supporting Documents” page. NOTE: Review the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” to ensure you have provided sufficient information for the IRB to make these determinations. HRP-410 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

[N/A]

### **5.2 Consent Documentation**

#### **5.2.1 Written Documentation of Consent**

Refer to “SOP: Written Documentation of Consent (HRP-091)” for information about the process to document the informed consent process in writing. HRP-091 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

If you will document consent in writing, describe how consent of the subject will be documented in writing. Add the consent document(s) to your study in CATS IRB (<http://irb.psu.edu>) on the “Consent Forms and Recruitment Materials” page. Links to Penn State’s consent templates are available in the same location where they are uploaded and their use is required.

[N/A]

#### **5.2.2 Waiver of Documentation of Consent (Implied consent, Verbal consent, etc.)**

If you will obtain consent (verbal or implied), but not document consent in writing, describe how consent will be obtained. Add the consent script(s) and/or

information sheet(s) to your study in CATS IRB (<http://irb.psu.edu>) on the “Consent Forms and Recruitment Materials” page. Links to Penn State’s consent templates are available in the same location where they are uploaded and their use is required. Review “CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)” to ensure that you have provided sufficient information. HRP-411 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.

[Consent will be verbal by asking participants if they would like to take part in the study.]

Consent will disclose the following:

- a. Name and contact information for the researcher (the researcher identifies herself as a Penn State researcher) and advisor;
- b. That the activities involve research;
- c. A description of the procedures to be performed by subjects;
- d. The individual’s participation is voluntary and they may end participation at any time;
- e. The study involves surveys or questionnaires, therefore subjects may choose not to answer specific questions;
- f. The extent, if any, to which confidentiality of records identifying the subject will be maintained.

[This study is minimal risk, as the only thing participants have to do is answer survey questions and questions that the researcher may ask. No identifiers will be associated with the data.]

[Participants will receive a copy of the consent form.]

### 5.3 Consent – Other Considerations

#### 5.3.1 Non-English Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Indicate whether the consent process will be documented in writing with the long form of the consent documentation or with the short form of the consent documentation. Review the “SOP: Written Documentation of Consent (HRP-091)” and the “Investigator Manual (HRP-103)” to ensure that you have provided sufficient information. HRP-091 and HRP-103 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

[Urdu and Punjabi – Principal investigator speaks fluent Urdu, but will request a translator for any participant who speaks Punjabi]

### 5.3.2 Cognitively Impaired Adults

Refer to “CHECKLIST: Cognitively Impaired Adults (HRP-417)” for information about research involving cognitively impaired adults as subjects. HRP-417 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

#### 5.3.2.1 Capability of Providing Consent

Describe the process to determine whether an individual is capable of consent.

[N/A]

#### 5.3.2.2 Adults Unable To Consent

Describe whether and how informed consent will be obtained from the legally authorized representative. Describe who will be allowed to provide informed consent. Describe the process used to determine these individual’s authority to consent to research.

For research conducted in the state, review “SOP: Legally Authorized Representatives, Children and Guardians (HRP-013)” to be aware of which individuals in the state meet the definition of “legally authorized representative”. HRP-013 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).” HRP-013 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

[N/A]

**5.3.2.3 Assent of Adults Unable to Consent**

Describe the process for assent of the subjects. Indicate whether assent will be required of all, some or none of the subjects. If some, indicate which subjects will be required to assent and which will not.

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

[N/A]

**5.3.3 Subjects who are not yet adults (infants, children, teenagers)****5.3.3.1 Parental Permission**

Describe whether and how parental permission will be obtained. If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission. Describe the process used to determine these individual's authority to consent to each child's general medical care.

For research conducted in the state, review "SOP: Legally Authorized Representatives, Children and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children". HRP-013 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." HRP-013 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

[N/A]

**5.3.3.2 Assent of subjects who are not yet adults**

Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.

[N/A]

**6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization**

This section is about the access, use or disclosure of Protected Health Information (PHI). PHI is individually identifiable health information (i.e., health information containing one or more 18 identifiers) that is transmitted or maintained in any form or medium by a Covered Entity or its Business Associate. A Covered Entity is a health plan, a health care clearinghouse or health care provider who transmits health information in electronic form. See the “Investigator Manual (HRP-103)” for a list of the 18 identifiers. HRP-103 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

If requesting a waiver/alteration of HIPAA authorization, complete sections 6.2 and 6.3 in addition to section 6.1. The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions. Include only information that will be accessed with the waiver/alteration.

**6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI**

Check all that apply:

- Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study. [Mark all parts of sections 6.2 and 6.3 as not applicable]**
- Authorization will be obtained and documented as part of the consent process. [If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]**
- Partial waiver is requested for recruitment purposes only (Check this box if patients’ medical records will be accessed to determine eligibility before consent/authorization has been obtained). [Complete all parts of sections 6.2 and 6.3]**
- Full waiver is requested for entire research study (e.g., medical record review studies). [Complete all parts of sections 6.2 and 6.3]**
- Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained). [Complete all parts of sections 6.2 and 6.3]**

## 6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

### 6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

#### 6.2.1.1 Plan to protect PHI from improper use or disclosure

N/A

Information is included in the “Confidentiality, Privacy and Data Management” section of this protocol.

#### 6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed. If identifiers will be retained, provide the legal, health or research justification for retaining the identifiers.

[N/A]

### 6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Provide an explanation for why the research could not practicably be conducted without access to and use of PHI.

[N/A]

### 6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Provide an explanation for why the research could not practicably be conducted without the waiver or alteration of authorization.

[N/A]

## 6.3 Waiver or alteration of authorization statements of agreement

N/A

Protected health information obtained as part of this research will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other permitted uses and disclosures according to federal regulations.

The research team will collect only information essential to the study and in accord with the 'Minimum Necessary' standard (information reasonably necessary to accomplish the objectives of the research) per federal regulations.

Access to the information will be limited, to the greatest extent possible, within the research team. All disclosures or releases of identifiable information granted under this waiver will be accounted for and documented.

## 7.0 Study Design and Procedures

### 7.1 Study Design

Describe and explain the study design.

[The proposed research design for this thesis is a literature review that evaluates pre existing research and also examines new research. This literature review will be organized through a number of methods. A detailed search on any pre-existing literature focused on women and their access to care in Pakistan will first be done. Once preliminary research of pre-existing literature is completed, the researcher will conduct her own research by traveling to Pakistan in December 2018 to determine the quality of healthcare for women in hospitals across a number of rural cities in the country. This will be done by visiting hospitals and interviewing physicians and patients about the quality of healthcare that they are either delivering or receiving.]

### 7.2 Study Procedures

Provide a description of all research procedures being performed and when they are being performed (broken out by visit, if applicable), including procedures being performed to monitor subjects for safety or minimize risks. Include any long-term follow-up procedures and data collection, if applicable.

Describe where or how you will be obtaining information about subjects (e.g., medical records, school records, surveys, interview questions, focus group topics, audio or video recordings, data collection forms, and collection of specimens through invasive or non-invasive procedures to include the amount to be collected and how often). Add any data collection instruments that will be seen by subjects to your study in CATS IRB (<http://irb.psu.edu>) in the "Supporting Documents" page.

#### 7.2.1 EXAMPLE: Visit 1 or Day 1 or Pre-test, etc. (format accordingly)

Provide a description as defined above and format accordingly.

[Visit 1: Volunteers will be provided with verbal consent along with a paper copy of consent and [if they approve], they will be asked questions relating to the research study. Information will be obtained via surveys and interview questions. All volunteers will participate in both the survey and interviews. The surveys will be administered by paper. Finally, the interviews will not be recorded, as the answers to each question will be written down on paper. ]

**7.2.2 EXAMPLE: Visit 2 or Day 2 or Post-test, etc. (format accordingly)**

Provide a description as defined above and format accordingly.

[N/A]

**7.3 Duration of Participation**

30 minutes – 1 visit

**8.0 Subject Numbers and Statistical Plan****8.1 Number of Subjects**

Indicate the total number of subjects to be accrued.

If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

[100-150 subjects are to accrued for this study]

**8.2 Sample size determination**

If applicable, provide a justification of the sample size outlined in section 8.1 – to include reflections on, or calculations of, the power of the study.

[In order for the research to be viable, multiple subjects will need to be tested. This is why the principal investigator chose to sample around 100-150 subjects.]

**8.3 Statistical methods**

Describe the statistical methods (or non-statistical methods of analysis) that will be employed.

[Information gathered from the surveys will be displayed in a table in the researcher's thesis based on the questions answered on a scale of 1-5 (least to most likely). This will show how many patients and providers agreed and disagreed to the questions asked. It is possible that the researcher will use STATA to further analyze the data received by professionals, pregnant, soon to be pregnant and recently pregnant women]

[Interview questions/answers will be incorporated in the "new literature/findings" section of the researcher's thesis. This will allow any readers of the paper to see where access to care for women in Pakistan and care provided by physicians is either lacking or improving.]

**9.0 Confidentiality, Privacy and Data Management**

**For research being conducted at Penn State Hershey or by Penn State Hershey researchers only**, the research data security and integrity plan is submitted using "HRP-598 – Research Data

Plan Review Form Application Supplement”, which is available in the Library in CATS IRB (<http://irb.psu.edu>). Refer to Penn State College of Medicine IRB’s “Standard Operating Procedure Addendum: Security and Integrity of Human Research Data”, which is available on the IRB’s website. **In order to avoid redundancy, for this section state “See the Research Data Plan Review Form” in section 9.0 if you are conducting Penn State Hershey research and move on to section 10.**

**For all other research**, in the sections below, describe the steps that will be taken to secure the data during storage, use and transmission.

## 9.1 Confidentiality

### 9.1.1 Identifiers associated with data and/or specimens

List the identifiers that will be included or associated with the data and/or specimens in any way (e.g., names, addresses, telephone/fax numbers, email addresses, dates (date of birth, admission/discharge dates, etc.), medical record numbers, social security numbers, health plan beneficiary numbers, etc.).

If no identifiers will be included or associated with the data in any way, whether directly or indirectly, please indicate this instead.

[none]

#### 9.1.1.1 Use of Codes, Master List

If identifiers will be associated with the data and/or specimens (as indicated in section 9.1.1 above), describe whether a master record or list containing a code (i.e., code number, pseudonyms) will be used to separate the data collected from identifiable information, where that master code list will be stored, who will have access to the master code list, and when it will be destroyed.

If identifiers are included or associated with the data as described in section 9.1.1 above, but no master record or list containing a code will be used, it will be assumed by the IRB that the investigator plans to directly link the identifiers with the data.

[none]

### 9.1.2 Storage of Data and/or Specimens

Describe where, how and for how long the data (hardcopy (paper) and/or electronic data) and/or specimens will be stored. NOTE: Data can include paper files, data on the internet or websites, computer files, audio/video files, photographs, etc. and should be considered in the responses. Refer to the “Investigator Manual (HRP-103)” for information about how long research

records must be stored following the completion of the research prior to completing this section. HRP-103 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

Please review [Penn State's Data Categorization Project](#) for detailed information regarding the appropriate and allowable storage of research data collected according to [Penn State Policy AD71](#). Although the IRB can impose greater confidentiality/security requirements (particularly for sensitive data), the IRB cannot approve storage of research data in any way or using any service that is not permissible by [Penn State Policy AD71](#).

[The data gathered will be stored on the investigators laptop (as electronic data). Any paper data collected will be stored in a locked file cabinet. The computer is password protected and the files with surveys and interview questions will also be password protected/stored for safe keeping.]

[After the thesis is completed, the data will be deleted within the 3 years minimum requirement for the study to be completely closed.]

### 9.1.3 Access to Data and/or Specimens

Identify who will have access to the data and/or specimens. This information should not conflict with information provided in section 9.1.1.1 regarding who has access to identifiable information, if applicable.

[Data will only be accessible to the principal investigator and advisor]

### 9.1.4 Transferring Data and/or Specimens

If the data and/or specimens will be transferred to and/or from outside collaborators, identify the collaborator to whom the data and/or specimens will be transferred and how the data and/or specimens will be transferred. This information should not conflict with information provided in section 9.1.1.1 regarding who has access to identifiable information, if applicable.

[N/A]

## 9.2 Subject Privacy

This section must address subject privacy and NOT data confidentiality.

Indicate how the research team is permitted to access any sources of information about the subjects.

Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact with or to whom they provide personal information.

Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

[Research Team only consists of Primary Investigator. Subject's privacy will be kept in a locked personal file on the investigators personal laptop and in a locked safe.]

The research procedures and interviews will be in a private setting. Prior to conducting the research, the PI will request a private room in the hospital where the door can close and no windows are present. This will ensure that the research procedures cannot be heard, seen or observed by outsiders.

[Researcher will slowly ask questions as the survey process is going on. They will ensure that the interviewee is at ease with all questions asked and answered.]

## 10.0 Data and Safety Monitoring Plan

**This section is required when research involves more than Minimal Risk to subjects.** As defined in "SOP: Definitions (HRP-001)", available in the Library in CATS IRB (<http://irb.psu.edu>), Minimal Risk is defined as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. **Please complete the sections below if the research involves more than minimal risk to subjects OR indicate as not applicable.**

### 10.1 Periodic evaluation of data

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

[N/A]

### 10.2 Data that are reviewed

Describe the data that are reviewed, including safety data, untoward events, and efficacy data.

[N/A]

### 10.3 Method of collection of safety information

Describe the method by which the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls and with subjects).

[N/A]

#### 10.4 Frequency of data collection

Describe the frequency of data collection, including when safety data collection starts.

[N/A]

#### 10.5 Individuals reviewing the data

Identify the individuals who will review the data. The plan might include establishing a data and safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

[N/A]

#### 10.6 Frequency of review of cumulative data

Describe the frequency or periodicity of review of cumulative data.

[N/A]

#### 10.7 Statistical tests

Describe the statistical tests for analyzing the safety data to determine whether harms are occurring.

[N/A]

#### 10.8 Suspension of research

Describe any conditions that trigger an immediate suspension of research.

[N/A]

### 11.0 Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. For each potential risk, describe the probability, magnitude, duration, and reversibility. Consider all types of risk including physical, psychological, social, legal, and economic risks. If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant. If applicable, describe risks to others who are not subjects.

Please keep in mind that loss of confidentiality is a potential risk when conducting human subject research and should be addressed as such.

\*Note: Since identifiers will not be collected in this research, these are all PROBABLE risks of participating in this research

It is possible that a patient might feel a sensed invasion of privacy, anxiety, shame or embarrassment from the questions asked in the survey or interview questions. This is because these questions and their answers can tend to get a bit private (especially since home life situations and pregnancy will be discussed). Once again, the PI will remind the participants that they do not have to answer every question and their participation in the research can be ended at any time. Hopefully, this will help to ensure that all risks are minimized while conducting this research.

Any risks in this research will also be minimized by the following: maintaining confidentiality of responses, ensuring data security (password protected computer and locked paper files), limiting access to data records (only primary investigator and advisor will have access). Finally, direct quotes of interview question responses will not be used. Snippets of responses will be included in the new literature/findings section of the researchers thesis.]

## 12.0 Potential Benefits to Subjects and Others

### 12.1 Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. If there is no direct benefit to subjects, indicate as such. Compensation is not considered a benefit. Compensation should be addressed in section 14.0.

[Subjects can help to determine how hospitals in Pakistan need to better the pre and post natal care that patients are receiving. This can help to decrease the morbidity and mortality rates of new mothers.]

### 12.2 Potential Benefits to Others

Include benefits to society or others.

[Future mothers will have less concerns about any pre and postnatal dangers they might face since they are receiving proper treatment.]

## 13.0 Sharing Results with Subjects

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared.

[N/A]

## 14.0 Subject Stipend (Compensation) and/or Travel Reimbursements

Describe the amount and timing of any subject stipend/payment or travel reimbursement here. If there is no subject stipend/payment or travel reimbursement, indicate as not applicable.

If course credit or extra credit is offered to subjects, describe the amount of credit and the available alternatives. Alternatives should be equal in time and effort to the amount of course or extra credit offered.

If an existing, approved student subject pool will be used to enroll subjects, please indicate as such and indicate that course credit will be given and alternatives will be offered as per the approved subject pool procedures.

[N/A]

## 15.0 Economic Burden to Subjects

### 15.1 Costs

Describe any costs that subjects may be responsible for because of participation in the research.

[N/A]

### 15.2 Compensation for research-related injury

**If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.**

**If there is no sponsor agreement that addresses compensation for medical care for research subjects with a research-related injury, include the following text as written - DO NOT ALTER OR DELETE:**

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

**For sponsored research studies with a research agreement with the sponsor that addresses compensation for medical care for research-related injuries, include the following text as written - DO NOT ALTER OR DELETE:**

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

[N/A]

## 16.0 Resources Available

### 16.1 Facilities and locations

Identify and describe the facilities, sites and locations where recruitment and study procedures will be performed.

If research will be conducted outside the United States, describe site-specific regulations or customs affecting the research, and describe the process for obtaining local ethical review. Also, describe the principal investigator's experience conducting research at these locations and familiarity with local culture.

[Research will be conducted in various hospitals across Pakistan (hospitals apart of the research are to be determined within the next couple of months (at least 1 month prior to research).]

[Research is to be approved by the National Bioethics Committee in Pakistan. Approval is in process and should be granted in the next couple of weeks.]

[There are not any customs (that the researcher is aware of) affecting the research, local ethical review will take place in the hospitals where the research will take place by asking administration if research can be conducted.]

[The researcher does not have any experience conducting prior research at these locations, but is very familiar with the local culture. The PI herself is Pakistani and has been visiting the country every year since she was a young kid. The PI is very familiar with the local customs and languages spoken in the country for this reason.]

### 16.2 Feasibility of recruiting the required number of subjects

Indicate the number of potential subjects to which the study team has access. Indicate the percentage of those potential subjects needed for recruitment.

[100-150 potential subjects, approximately 90% of those potential subjects are needed for recruitment.]

### 16.3 PI Time devoted to conducting the research

Describe how the PI will ensure that a sufficient amount of time will be devoted to conducting and completing the research. Please consider outside responsibilities as well as other on-going research for which the PI is responsible.

[The researcher will dedicate 2 weeks of time to study and interview potential subjects for this research. The PI will only focus on gathering data during these 2 weeks to ensure that proper time has been devoted to conducting and completing the research.]

### 16.4 Availability of medical or psychological resources

Describe the availability of medical or psychological resources that subject might need as a result of their participation in the study, if applicable.

[N/A]

#### 16.5 Process for informing Study Team

Describe the training plans to ensure members of the research team are informed about the protocol and their duties, if applicable.

[A copy of this protocol will be sent to the advisor, as soon as it is submitted to the IRB.]

### 17.0 Other Approvals

#### 17.1 Other Approvals from External Entities

Describe any approvals that will be obtained prior to commencing the research (e.g., from cooperating institutions, community leaders, schools, external sites, funding agencies).

[Approval will be needed from hospitals where research is conducted prior to commencing the research. Approval will also be needed from the National Bioethics Committee in Pakistan] Approval will be obtained from the Pakistan National Bioethics Committee-Research Ethics Committee prior to beginning this research.

#### 17.2 Internal PSU Committee Approvals

##### Check all that apply:

- Anatomic Pathology – Hershey only – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of HRP-902 - Human Tissue For Research Form on the “Supporting Documents” page in CATS IRB. This form is available in the CATS IRB Library.
- Animal Care and Use – All campuses – Human research involves animals and humans or the use of human tissues in animals
- Biosafety – All campuses – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).
- Clinical Laboratories – Hershey only – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes, but are no longer needed for clinical use. Upload a copy of HRP-901 - Human Body Fluids for Research Form on the “Supporting Documents” page in CATS IRB. This form is available in the CATS IRB Library.
- Clinical Research Center (CRC) Advisory Committee – All campuses – Research involves the use of CRC services in any way.

- Conflict of Interest Review – All campuses – Research has one or more of study team members indicated as having a financial interest.
- Radiation Safety – Hershey only – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of HRP-903 - Radiation Review Form on the “Supporting Documents” page in CATS IRB. This form is available in the CATS IRB Library.
- IND/IDE Audit – All campuses – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.
- Scientific Review – Hershey only – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Hershey Cancer Institute Scientific Review Committee is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website at:  
<http://www.pennstatehershey.org/web/irb/home/resources/investigator>

## 18.0 Multi-Site Research

If this is a multi-site study (i.e., the study will be conducted at other institutions each with its own principal investigator) and you are the lead investigator, describe the processes to ensure communication among sites in the sections below.

### 18.1 Communication Plans

Describe the plan for regular communication between the overall study director and the other sites to ensure that all sites have the most current version of the protocol, consent document, etc. Describe the process to ensure all modifications have been communicated to sites. Describe the process to ensure that all required approvals have been obtained at each site (including approval by the site’s IRB of record). Describe the process for communication of problems with the research, interim results and closure of the study.

[N/A]

### 18.2 Data Submission and Security Plan

Describe the process and schedule for data submission and provide the data security plan for data collected from other sites. Describe the process to ensure all engaged participating sites will safeguard data as required by local information security policies.

[N/A]

**18.3 Subject Enrollment**

Describe the procedures for coordination of subject enrollment and randomization for the overall project.

[N/A]

**18.4 Reporting of Adverse Events and New Information**

Describe how adverse events and other information will be reported from the clinical sites to the overall study director. Provide the timeframe for this reporting.

[N/A]

**18.5 Audit and Monitoring Plans**

Describe the process to ensure all local site investigators conduct the study appropriately. Describe any on-site auditing and monitoring plans for the study.

[N/A]

**19.0 Adverse Event Reporting****19.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB**

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

**20.0 Study Monitoring, Auditing and Inspecting****20.1 Auditing and Inspecting**

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure

the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

## **21.0 Future Undetermined Research: Data and Specimen Banking**

If this study is collecting identifiable data and/or specimens that will be banked for future undetermined research, please describe this process in the sections below. This information should not conflict with information provided in section 9.1.1 regarding whether or not data and/or specimens will be associated with identifiers (directly or indirectly).

### **21.1 Data and/or specimens being stored**

Identify what data and/or specimens will be stored and the data associated with each specimen.

[N/A]

### **21.2 Location of storage**

Identify the location where the data and/or specimens will be stored.

[N/A]

### **21.3 Duration of storage**

Identify how long the data and/or specimens will be stored.

[N/A]

### **21.4 Access to data and/or specimens**

Identify who will have access to the data and/or specimens.

[N/A]

### **21.5 Procedures to release data or specimens**

Describe the procedures to release the data and/or specimens, including: the process to request a release, approvals required for release, who can obtain data and/or specimens, and the data to be provided with the specimens.

[N/A]

### **21.6 Process for returning results**

Describe the process for returning results about the use of the data and/or specimens.

[N/A]

## **22.0 References**

List relevant references in the literature which highlight methods, controversies, and study outcomes.

[N/A]

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## ACADEMIC VITA

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Zunish Saqib  
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### Education

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**The Pennsylvania State University**  
*College of Health and Human Development*  
Bachelor of Science in Health Policy and Administration

**State College, PA**  
*Class of 2019*

**Schreyer Honors College**  
*Honors Degree (B.Sc.) in Health Policy and Administration*

*Class of 2019*

### Research Experience

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**The Pennsylvania State University**  
*Lead Researcher*

**Center Valley, PA**  
*August 2016 – May 2017*

The Effects of a Collagen I Substrate on the Phenotypic Switching and Morphology of A-10 Cells: Analysis of Co-expression of  $\alpha$ -smooth muscle actin and Myosin Light Chain Kinase in A-10 Cells

- Studied the phenotypic switching in smooth muscle cell specific proteins
- Determined that placing A-10 cells in a more *in vivo* like environment did not have influence on morphology
- Found that the use of collagen I coverslips may influence a greater number of cells to express  $\alpha$ -smooth muscle actin
- Refined and harnessed the following hand skills: titration, cell counting, pipette, media preparation, and glass staining

**The Pennsylvania State University**  
*Lead Researcher – Schreyer Honors College*

**State College, PA**  
*August 2018-Present*

Factors that Contribute to the Morbidity and Mortality Rate for Pre and Post Natal Care in Rural Women of Pakistan

- Studied the factors that contribute to morbidity and mortality rates in pre natal and post natal care for rural women of Pakistan
- Talked to patients, physicians and government officials in the department of health in Pakistan to determine reasoning behind high morbidity and mortality rates
- Determined that lack of education, lack of financial stability and limited hospital resources are the reason for lack of care

### Volunteer and Professional Experience

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**Outreach360**  
*Volunteer*

**Monte Cristi, DR**  
*March 2018*

- Taught elementary and middle school aged children English in a local elementary school and the Outreach360 learning center
- Worked with a group of Penn State Pre-dental students to create lessons plans for students

**Red Cross Blood Drives**  
*Student Volunteer*

**State College, PA**  
*August 2017 – Present*

- Worked multiple blood drives across the Penn State Campus
- Volunteered at the Canteen station where I ensured that donors were hydrated and fed after donating blood
- Also volunteered as a recruiter and interacted with students to convince them to donate blood

**Mid State Literary Council**  
*Student Volunteer*

**State College, PA**  
*January 2019 – Present*

- Worked with a local Portuguese student in the State College area to better her English
- Worked with the student to teach her how to tell time, how to differentiate between certain alphabets and common contraction words

**Indian Valley Elementary School**  
*Student Volunteer*

**Reedsville, PA**  
*February 2018 & 2019*

- Worked with children to reinforce the importance of good oral hygiene
- Educated the children by teaching them about good and bad foods for the oral cavity

**Hamilton Dental Designs**  
*Pre-dental Intern*

**Allentown, PA**  
*May 2018-June 2018*

- Assisted and observed various procedures i.e. composite filling, implant placement, extractions, etc.
- Built and refined rapport with patients to improve interpersonal skills
- Learned and discussed the business aspects of dentistry
- Learned the basics of how to read an x-ray radiography
- Learned how to treatment plan for a variety of different patients

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### **Leadership Roles**

**Health and Human Services Society**  
*Founder, President*

**Center Valley, PA**  
*August 2016 – May 2017*

- Led monthly meetings regarding the changing health care system for 25 members
- Organized key speakers (i.e. dentist, physicians, nurse practitioners) to discuss their experiences
- Negotiated with Student Government Association for club financing and establishing a future
- Fundraised \$3,000 total for trips to Mutter Museum (in Philadelphia) and Smithsonian (in Washington, D.C.)

**Health Policy Administration Society**  
*Event Coordinator*

**Center Valley, PA**  
*January 2016 – May 2017*

- Networked with major hospital systems to invite administrators to speak to groups of students
- Planned how to further educate administrators and established mentorship opportunities for students in the Lehigh Valley Area
- Held resume, networking, and other social events to further refine skills for all students

**Outreach360**  
*Trip Leader*

**Monte Cristi, DR**  
*March 2018*

- Organized important travel documents and meetings for the trip to the Dominican Republic
- Assisted in creating fundraisers to help pay for Outreach360 program

**Outreach360 at PSU**  
*Founder, President*

**State College, PA**  
*March 2018 – Present*

- Worked with student affairs at Penn State to write a constitution
- Helped to organize club affairs to refine application process and preserve the future of the club
- Worked with fellow board members to organize and fundraise for the spring 2019 trip to the DR

**Pre-Dental Society**  
*Outreach360 Chair*

**State College, PA**  
*August 2018 – Present*

- Worked with fellow board members to organize and fundraise for the spring 2019 trip to the DR
- Assisted in setting up club meetings and activities for pre-dental students

**American Student Dental Association (ASDA) at PSU**  
*President*

**State College, PA**  
*August 2018 – Present*

- Worked with student affairs at Penn State in order to run a successful club
- Worked with fellow board members to organize volunteering and fundraising events for ASDA

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## Organizational Involvement

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### **Business Society**

*Student Member*

**Center Valley, PA**

*August 2015 – May 2017*

- Assisted in fundraising \$1,000 for a NYC trip via bake sales and various business seminars
- Attended a variety of meetings with an emphasis on leadership to increase interpersonal skills

### **Pre-Dental Society**

*Student Member*

**State College, PA**

*August 2017 – Present*

- Networked with local dentists to further gain insights in the dental field
- Attended a variety of meetings to understand the dental school process

### **Alpha Epsilon Delta**

*National Inductee*

**State College, PA**

*April 2018 – Present*

- Volunteered at the Red Cross Student Club to assist during blood drives
- Attended pre-health meetings to prepare for standardized exams, and networking with other healthcare professionals

### **National Society of Leadership and Success**

*National Inductee*

**State College, PA**

*February 2018 – Present*

- Attended leadership training programs
- Conducted SNT's (success networking teams) to build long lasting relationships and support groups

### **The Honor Society of Phi Kappa Phi**

*National Inductee*

**State College, PA**

*January 2019 – Present*

- Networked with fellow inductees and learned the benefits of joining Phi Kappa Phi

### **American Student Dental Association**

*Student Member*

**Chicago, IL**

*March 2018 – Present*

- Attended a variety of online seminars which emphasized how to do well and study for the DAT

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## Various Skills and Accolades

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**Language Proficiency:** Full proficiency in English, Urdu & Hindi

**Accolades:** Penn State Dean's List (2015 – Present), NSLS National Inductee (2017 – Present), Penn State Schreyer Scholar (2017 – Present), Awarded First place at the Penn State Lehigh Valley Undergraduate Research Symposium (April 2017), Alpha Epsilon Delta National Inductee (April 2018-Present), The Honor Society of Phi Kappa Phi (January 2019 – Present), Upsilon Phi Delta (April 2019 – Present)