WHO Improving Program Implementation through Embedded Research (iPIER)-2014

"The Breastfeeding Code": Overcoming Implementation Barriers in Pakistan

Final Report
by

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Research Team

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Introduction

Malnutrition accounts for the majority of child deaths globally[i]. Breastfeeding has been proven as one of the most effective interventions for infant and child health[vi,vii]. Infants not breastfed are 15 times more likely to die from pneumonia and 11 times more likely to die of diarrhea than those who are exclusively breastfed for the first six months[viii,ix]. In Pakistan, there is steady decline in mean duration of breastfeeding since last three decades. Although a law for protection of breast-feeding, known as "the Breastfeeding Code", was passed in 2002 in Pakistan, its implementation remained a problem[xvii]. The most important reason for lack of implementation is the absence of an accountability mechanism. In the absence of an effective accountability mechanism, health care providers are not complying by the code. Given that there are incentives in place for prescribing formula milk, the health care providers may consider themselves disincentivised, by complying with the code.

Objectives

The overall aim of this research was to explore reasons and factors leading to ineffective implementation of the breastfeeding code in Pakistan. The objective of the study was to explore and analyse stakeholders' perceptions about reasons and factors leading to lack of accountability with reference to compliance with the breastfeeding code. It also explored options for developing accountability and monitoring mechanism for proper implementation of breastfeeding code in Pakistan.

Methodology

A qualitative study with primary data collected through in-depth interviews of key stakeholders in federal, provincial and district levels of Pakistan were undertaken.

Key stakeholders working at three levels of implementation (associated with maternal, neonatal and child health services and/or nutrition) at federal, provincial and district level, were included in the study. Respondents who had less than six months' experience were excluded. Study respondents included health care administrators, general medical practitioners, civil society activists and community key informants. In total 75 in-depth interviews were conducted across Pakistan. For the literature review, online reports and documents were searched to retrieve information related to various initiatives and interventions for breastfeeding promotion in Pakistan. Secondary data was collected using, a data extraction tool was developed and used to get information from available surveys, studies and previous research done on the topic.

Findings

There is poor implementation of the Breast feeding (BF) code in Pakistan with little demand and understanding of the importance of the BF code and hence the poor indicators of breastfeeding. There is lack of dissemination of the information about the code, non existent check and balance system and a disconnection between central and peripheral level implementing bodies. Federal level is interacting with international partners in devising methodologies for proper implementation but there is limited demand and a huge role and goal conflict with the peripheral offices.

Conclusion

The lack of coordination among key stakeholders, the absence of organizational structures and improper dissemination of relevant information about the code has resulted in challenges in implementation. There is a need to foster ownership and stakeholders engagement at all tiers from the central to the peripheral levels.

Improving Program Implementation through Embedded Research Process

An implementation strategy based on the evidence generated by the research project is proposed with the specific objective to enhance the accountability mechanisms pertaining to the implementation of the BF Code. In this regard, the agenda of the code is to be steered through the other national initiatives for maternal and and neonatal health and nutrition. The provinces are to ensure

compliance through strengthening the organizational structure and governance to enforce the BF code through infant feeding boards. The nutrition wing of the Ministry is to activate the Infant feeding Boards to include the BF code implementation in its agenda. Awareness campaigns to improve understanding of the families and health care providers training about the code and its implications by the academia will be a pivotal part of the strategy.

Background

Globally, the number of children dying in a year has come down to 7.6 million in 2010 from 12 million as reported in 1990, at an average annual reduction rate of 1.8%.[i] Although child mortality is declining in various countries yet there is room for improvement in terms of better health outcomes. Approximately 90% of these deaths occur in Sub-Saharan Africa and South Asia. Five countries with highest number of child deaths are India, Pakistan, Nigeria, Democratic Republic of Congo and Ethiopia.[ii] Malnutrition, a risk factor in child mortality, is responsible for more than 50% of under-five deaths in developing countries.[iii,iv] Over two-thirds of child deaths occur in first year of life, which are often associated with inappropriate feeding practices. According to an estimation 830,000 deaths can be avoided worldwide if every baby is breast fed within its first hour of life. About 22% of new-born deaths can be prevented if breast-feeding is initiated within first hour after birth, and 16% if breast feeding is started within the first 24 hours. Babies who are given breast milk within an hour after birth are three times more likely to survive than the ones breastfed a day later. Infants who are not breastfed are 15 times more likely to die from pneumonia and 11 times more likely to die of diarrhoea than those who are exclusively breastfed for the first six months of life.[v] Infants 6-11 months, who are not breastfed, have higher risk of death.[vi,vii]

Although, breast milk is readily available soon after birth of the newborn, lack of awareness among mothers and families on importance of exclusive breast feeding, unethical involvements of health staff in prescription of breast milk substitutes as well as engagement of manufacturers and distributors in unlawful promotion of breast milk substitutes have influenced the attitude, practices and the decision making process thus jeopardizing initiation, continuation and promotion of breast feeding in general and exclusive breast feeding in particular. The importance of exclusive breastfeeding in terms of growth and development of infants and young children and the protection from infections is widely accepted globally.[viii,ix]

Pakistan is one of the countries where reduction in child mortality has been slow. It is ranked third among five countries, which account for half of deaths in children under five worldwide.[x].[xi] Pakistan's under-five mortality witnessed decrease from 117 per 1000 live births in 1991 to 94 per 1000 in 2007. Similarly infant mortality

rate declined from 91 per 1000 to 78 per 1000 live births from 1991 to 2007.[xii,xiii] In Pakistan, the breastfeeding rates are low, with only 37% mothers exclusively breastfeeding their children up to six months. Promotion campaigns by formula milk companies, are supported by practicing doctors that further increase prevalence of bottle-feeding. Various studies have shown that doctors support idea of receiving gifts, promotion material and donations from formula milk/feeding bottle manufacturers. [xiv, xv] The bottle-feeding rate has increased from 21.8% in 1990, to 34.1% in 2007.[xvi]

Implementation challenge that you were trying to address with this research

Pakistan was among 118 countries which voted in favour of adopting International Code of Marketing of Breast-milk Substitutes during World Health Assembly in May 1981, but legislation came very late in Pakistan. "The Protection of Breast-Feeding and Child Nutrition Ordinance, 2002" (XCIII Of 2002) commonly labelled as "The Code" was passed on 26th October 2002. However, implementation of this law in Pakistan has remained a huge challenge. A large population based survey conducted by Save the Children in 2012 across Pakistan showed that many violations of the breastfeeding code exist.[xvii] The survey reports that many mothers are advised formula milk by doctors. Not only do the doctors recommend formula milk, they also recommend some specific brands of formula milk. It highlighted the lack of implementation of national level legislation and highlighted the need for proper implementation of the breastfeeding code in Pakistan. It was stressed that developing proper accountability mechanisms for ensuring compliance to the breastfeeding code can mitigate problems of implementation.

Since the promulgation of the breastfeeding code in Pakistan in 2002, not much progress has been made for in its implementation. Although mothers are advised exclusive breastfeeding and weaning by health provides, they are also advised to bottle feed the infant. Most mothers are aware of early initiation of breastfeeding, and have knowledge of duration of exclusive breastfeeding, yet the amount of mothers actually practicing it are low[xxi].

Many doctors have been visited by representatives of formula milk companies for product information and have recieved gifts and free samples from companies. Many health providers are unaware of Breastfeeding Code and its rules. Most health providers consider that this law does not carry forceful penalty in case of violation, and also there is no monitoring system in place for proper enforcement of the Code. Aggressive marketing campaign and unethical promotional strategies by the formula milk industry has increased the community demand for milk substitutes and health providers are also promoting their products and violating the Code. There is a huge private health sector in Pakistan, which is largely unregulated and operates for profit and is mostly influenced by the formula milk industry. Another important dimension is the lack of awareness among stakeholders and health care providers about various articles of the breastfeeding code.[xxi]

The systems failures may be multiple, but mostly they are related to the lack of proper implementation and enforcement of the breastfeeding code and its rules. Most important reason for this component of system failure is the absence of accountability mechanism.[xxi] In the absence of effective accountability mechanism, health care providers are not complying by the code. Given that there are incentives in place for prescribing formula milk, the health care poviders may consider disincentivised, by complying with the code.

It is envisaged that developing proper accountability mechanisms for ensuring compliance to the breastfeeding code may mitigate the problems in implementation of the Code. In order to develop such mechanisms, there is a need to understand reasons of lack of accountability mechanisms as well to conduct a stakeholder analysis for developing means and options for better accountability. The study was undertaken to provide insight into the reason for absence of accountability mechanisms as well as help inform decision making for better and effective implementation of the Code in Pakistan. The current study was undertaken to explore and analyse stakeholders' perceptions about reasons and factors leading to lack of accountability with reference to compliance with the breastfeeding code. It also explored options for developing accountability and monitoring mechanism for proper implementation of breastfeeding code in Pakistan.

Methodology

A qualitative content analysis was undertaken based on a priori Walt and Gilson Model[xviii]. The foundation of this framework is a multi-disciplinary approach to public policy that aims to explain the interaction between institutions, interests and ideas in the policy process. The relevance of this framework for the current study was evident since it is useful in understanding past policy failures and successes and to help plan for future policy implementation[xix]. The actors involved in the adoption of the breastfeeding code, policy-making and implementation process, and the power they exercised in influencing the policy content was examined. In addition, contextual factors that influenced the policy as incorporation of systemic /environmental factors, local contextual factors (like the culture and traditions); influence of international and exogenous factors affecting implementation of the Breastfeeding code were reviewed. Execution of the program policy process included agenda building, planning, implementation, monitoring and evaluation. The content of the program policy, including the constituent parts, implementation modalities, beneficiaries and intended outcomes, were examined.

Data Collection Procedure and Analysis

Following the literature review, key stakeholders were identified. Primary data was collected through in-depth interviews (IDI) of stakeholders at three levels of implementation; namely; Federal, Provincial and District. In addition, other stakeholders as health service providers and community key informants were included in the study. The respondents included government health and nutrition officials at the federal, provincial and district level. Doctors in public sector as well as private sector practice and key informants (as political leaders, religious leaders, teachers, social workers and media representatives) were interviewed. A purposive sampling was undertaken. Key informants were then identified at the district level and interviews continued till saturation was used. Five health and nutrition officials were interviewed at the federal and provincial levels. Key informants were then identified at the district level and interviews continued till saturation was used .Five

districts were selected from each of the provinces with two from the largest province of Punjab; 5 interviews with doctors were done in each of the district. Similarly, 5 key informant interviews were conducted in each of the districts. Altogether 75 interviews were conducted across Pakistan.

An interview guide was developed. After preparation of the guide in English it was translated into the Urdu language for easy understanding by interviewers and respondents in field. In order to test the authenticity of the translation, back-translation in English was done. Both English and Urdu translated interview guides were carried by the data collection team. The interview guide was pre-tested to detect any possible problems in the translations or flow of the questions, and the time required for the interviews. The instruments were pre-tested in Rawalpindi district with three respondents of the target population. Following the feedback of pretesting, minor adjustments mostly related to the flow of questions were done. Probing was done around relevant areas as well as new areas of possible investigation that opened up as a result of the inquiry. Respondents were assured of the confidential nature of the inquiry and that no real names were to be recorded (i.e. coded respondent data, date and location of interview were to be used). Each interview lasted between 20 - 40 minutes and was conducted in Urdu. The interview notes were transcribed verbatim for future translation. Field notes were taken concurrently and referred to at the time of analysis to understand the context. Interviewers were trained by the Principal Investigator and Co-Investigator and supervised. The data collectors were trained how to conduct an in-depth interview and to avoid leading questions and probe where needed. All notes from IDIs were translated into English to ensure equivalence of concepts for data analysis. The information collected from key informants was compiled and read multiple times by the research team to get an insight about the implementation. The research team comprised of public health professionals who had experience of working in the public sector and had been involved in various policy level interventions. The data were tabulated using MS Office software for each question to help identify differences and similarities. Using the Gibson and Walt Model, themes were identified. Data and investigator triangulation ensured the trustworthiness of the

data. Validation of the findings was sought from the key stakeholders at the federal level for further modification and amendment.

For this study ethical clearance was granted by Institutional Review Committee of Health Services Academy, Islamabad, Pakistan and ratified by the WHO/EMRO Ethical Review Committee.

Findings

Secondary data sources showed that Pakistan voted in favour of adopting International Code of Marketing of Breast-milk Substitutes during World Health Assembly in May 1981 World Health Assembly "The Protection of Breast-Feeding and Child Nutrition Ordinance, 2002" (XCIII Of 2002). However, implementation rules as late as the *Protection of Breast-feeding Rules 2009, notified through the Ministry of Health S.R.O on 2nd November, 2009.* Although The Protection of Breast-Feeding and Child Nutrition Ordinance 2002 also stressed on formation of a National Infant Feeding Board (NIFB) to monitor implementation of the said Ordinance, this NIFB came into existence on 5th July 2010. On 30th June 2011, 18th Constitutional Amendment abolished 17 Federal Ministries including health, and health became completely a Provincial subject in Pakistan. After devolution, Provinces were authorized to make legislations pertaining to all matters in health including provincial level health policy and strategies. Punjab introduced legislation on breastfeeding and child nutrition in 2012, by adopting Protection of Breast-Feeding and Child Nutrition Ordinance 2002. In 2013, Sindh Assembly also unanimously passed the Sindh Protection of Breastfeeding and Child Nutrition Act-2013 on 13th February 2013 which was similar to the Federal law and implementation modalities.

Further exploration was undertaken with in-depth interviews with stakeholders. Altogether 75 in-depth interviews were conducted (Table 1).

Table 1: Respondents' Profile

Total Number of Respondents	75
Male	60
Female	15
Age Range	26 to 64 Years (Mean 44)
Federal Level	8
Provincial Level	25
District level	42
Public Sector	52
General Practitioner	12
Community KII	11

The main theme identified was "Breast Feeding code enactment to fulfil international commitment with little domestic demand". Three sub-themes underlying the main theme were; Lack of dissemination of relevant information about the BF code, Absence of check and balance system and Disconnect between Policy makers and implementers.

The data are presented starting with the main theme, sub-themes and their relation to the categories of analysis (Table 3) hereunder:

Table 3: Analysis Table Main theme to Categories

MAIN THEME BF code enactment to fulfil international commitment with little domestic demand		
SUB-THEME I Lack of dissemination of relevant information about the BF code	**SUB-THEME II** Absence of check and balance system	**SUB-THEME III** Disconnection between policy makers and implementers
Category I Lack of awareness of the code **Category II** Absence of organizational structure for enforcement of code **Category III** Malpractices of formula milk companies **Category IV** Families' misperceptions about benefits of formula milk **Category V** Corporate sector intent of profit making	**Category I** Poor governance within public sector **Category II** Absence of SOPs for regulation **Category III** Repeated health sector reforms with little stability and sustainability **Category IV** Unregulated corporate sector market **Category V** Provider dis-incentivized	**Category I** Lack of formal coordinating mechanism from federal to district level **Category II** Conflicting interests (goal & role conflicts) among federal, provincial and district (peripheral) actors

Breast Feeding code enactment to fulfil international commitment with little domestic demand

The main theme "Breast Feeding code enactment to fulfil international commitment with little domestic demand" illustrates lack of stakeholders' commitment to complete the envisaged call to action. This is evident through the chronology of events where after ratification in 1981, the law was enacted in 2002, and its operationalization was initiated in 2009. Comprehensive enforcement of the code remains pending to date.

> "*Pakistan promotion and protection of breast feeding ordinance was passed in 2002. Breast feeding Rules for implementation and monitoring of that ordinance were formulated in 2009 after 9 years …….. A structure was proposed to oversee, monitor and review the implementation of Breast Feeding Code, but it is yet to be realized. All the initiatives were at the central level with little coordination or coordination with the peripheral stakeholders……..Based on the National Breast Feeding Rules, all types of promotion and advertisement of Breast Feeding Substituted is prohibited at media, hospitals or health services delivery points. But you do not see it being enforced".* (Policy Maker)

The three sub-themes contributing to the main theme are elaborated further.

1. ***Lack of dissemination of relevant information about the BF code***

The responsiveness to the stakeholders' needs was found lacking. The information pertaining to the details of the operational plan for long term benefits implicit in the code was never communicated to the peripheral offices by the central office.

a. <u>Lack of awareness of the code</u>

The lack of awareness about the BF code details was apparent at peripheral levels. Practicing physicians when asked to share their knowledge about the code, a few reported having heard about it whereas others indicated that they had 'no idea about it'. The physicians' knowledge was more about benefits of breast feeding taught in medical schools than that related to the code. Counselling on Breast feeding was done in most of the health facilities routinely.

However, none of the health professionals knew about the details of the code. No steps had been taken by the health facilities to enforce it either.

b. Absence of organizational structure for enforcement of code

There was an absence of any organizational structure for enforcement of code. BF counselling was being offered by the health professionals was largely driven by the hospital/ health care providers' own initiatives and efforts. However, none of the respondents at the district level were familiar with the code or what their role was in its implementation.

> *"According to my knowledge there is a national breast feeding steering committee but I am not sure about any district committee, whether it exists or not. National committee seems to be non-functional too."*

c. Malpractices of the formula milk company

The formula milk companies were found to be largely unregulated. Their representatives reached the families through the media and handed promotion material to the doctors in the private and public sector.

d. Families' misperceptions about benefits of formula milk

Due to the advertisements on television and displays of such products in public places and hospitals, the families especially the mothers associated formula milk as a means to promote health in infants. The same was resonated by the healthcare provides too when they stated that the demand was in fact from the families to advise formula milk.

> "*The doctors advise mothers to breast feed their children but many a times families demand recommending milk substitutes so that the babies may put on weight. "*

e. Corporate sector intent of profit making

The respondents reported that there is a huge business of formula milk companies which thrives on the creation of demand for their milk and they do lot of marketing for this purpose. They agreed that these businesses were not in control of health department. Even though there was a ban on company representatives to visit the public sector hospitals, they still did so after office hours in private clinics and interacted with doctors.

2. ***Absence of check and balance system***

Various lapses in the check and balance system were identified by the respondents.

a. Poor governance within public sector

Multiple issues of governance within public sector were identified. This was reflected in the responses of the administrators especially. Resource and capacity constraints for most offices to ensure implementation of code was pointed out and the need for continuous monitoring emphasized.

b. Absence of SOPs for regulation

The respondents agreed that currently procedural clarity what lacking on how to proceed with the violations of this code. Authority and responsibility at the local peripheral levels are not clear.

c. Repeated health sector reforms with little stability and sustainability

The public and civil society respondents reported the introduction of many reforms in last two decades. It was also pointed out that most local offices did not understand the dynamics of the BF code and their roles and how to sustain them.

d. Unregulated corporate sector market

The doctors and policy makers shared existence of the huge market for formula milk industry targeting doctors and mothers. The difficulty was in regulating these companies which was beyond the scope of Health Departments with minimal coordination with concerned line of authority/authorities.

e. Provider dis-incentivized

Doctors reported that there were incentives offered by the formula companies such as attending conferences abroad, free samples and dinners. They were not aware of any restrictions/limitations by law.

3. Disconnection between Policy makers and implementers

Policy makers understood the code but there was lack of translation and coordination of the code to the peripheral level offices, which are the key players for implementation.

a. Lack of formal coordinating mechanism from federal to district level

After the 18th Amendment, the federal government officials reported that they are still struggling to redefine the mechanisms and linkages with peripheral offices.

> *"We are fully aware of the code but cannot implement directly at the district level. We have communicated to the provinces but it depends upon them to communicate at the district as well as transfer authority to the district offices."*

b. Conflicting interests (goal & role conflicts) among federal, provincial and district (peripheral) actors

Respondents reported that federal government is responsible for ensuring compliance to international commitments and treaties. However, the provinces and the district neither owned such commitments nor were interested to comply. They felt that the peripheral offices did not come in the mainstream of international collaborations and hence were not interested.

Discussion

Implementation research seeks to understand the "real world", paying particular attention to the audience that will use the research, the context in which implementation occurs, and the factors that influence implementation [xx]. The main finding of the current study was lack of information about the details of the code at peripheral level. This may be due to lack of communication by the central government to the implementing authorities in the wake of devolution in the country. Policy makers at the federal level were clear about the code and understood its implications but had no control over its translation at the provincial level. The coordination mechanisms pertaining to the implementation of the code and delegation of authority to the district level was to be undertaken at the provincial level, which was largely ignored. The key players in implementation at the district level were not aware of their roles and responsibilities. Even if the knowledge about the code was there at some offices, there was absence of organizational structure for enforcement of code. On the other hand, the formula milk companies were reported to be active in private and public sector. Due to the advertisements on television and displays of such products in public places and hospitals, the families especially the mothers associated formula milk as a means to promote health in infants.[xvii] The respondents shared that there was huge business of formula milk companies which thrived on the creation of demand for their milk through marketing strategies. The corporate sector is beyond the control of the health department, therefore thriving. Even though there is a ban on company representatives visiting the public sector hospitals, they visited after office hours in private clinics for marketing.[xv] This was not seen as a violation of any legislation by the respondents.

This study has identified various lapses in the check and balance system, which are generic and not just specific to this law. Given the resource and capacity constraints of most offices it is difficult to ensure implementation of this rule. There is also a need for procedural clarity on how to proceed with violations of this code, and most local offices as the study revealed, did not understand their role and responsibility in this regard. Another difficulty was in regulating formula companies, which is beyond the scope of Health Departments with minimal coordination with concerned line of

authority. Although federal government is responsible for international commitments, the peripheral health offices did not come in mainstream after 18th amendment, so federal government struggles to redefine mechanisms and linkages with peripheral health offices.

Conclusion

There is little understanding of the BF code by the stakeholders especially at the periphery resulting in lack of commitment to contribute to the envisaged call for action to oversee, monitor and review the implementation of the code. This was mainly due to the lack of dissemination of the relevant information pertaining to the code to the peripheral offices by the central office. The organizational structure to enforce the code was never undertaken. Whatever little that was undertaken to promote breastfeeding was driven by the providers' own initiatives. Since the roles were not clearly defined and accountability mechanisms absent, translation of the code had not been realized resulting in an unregulated corporate sector market. In this scenario the disconnect between the policy makers and the implementers resulted in poor implementation of the code in true essence.

Implementation Strategy

Objective: To provide strategic direction to address the BF Code Implementation aligned with evidence generated through research for a detailed plan of action.

The specific objectives are to:

1. Enhance health outcomes in the provinces and regions by improving accountability mechanisms for BF Code
2. Enhance stewardship role of DOH for steering the BF Code implementation and activation of the Infant feeding boards
3. Harmonize the strategy plan with national policies and international commitments pertaining to the BF code
4. Provide a Monitoring and Evaluation Framework for the monitoring of the BF code implementation and reporting to line departments.

The guiding principles for the strategies are:

- Provincial-demand driven and addressing provincial context
- Building on appropriate existing provincial/regional processes and experience
- Improve equity by maximizing benefits to disadvantaged population
- Sectoral vision encompassing both public and private sector
- Inter Sectoral action to enhance healthy public policy through implementation of the BF Code
- Strong element of monitoring and accountability

Based on the findings of the study the main requirement was seen to be creation of an accountability mechanism for the implementation of the code, which is aligned with the ongoing initiatives at the national level. Such initiatives include the maternal neonatal child health and nutrition, family planning and extended program on immunization. The National MNCH Steering Committee is to own the BF code implementation and promote breast feeding using role models in BCC campaigns under these initiatives. The provinces must be obligated to ensure compliance while keeping their stakeholders at the district level on board to foster ownership of the BF Code at periphery levels and ensuring functional accountability mechanisms. This

will be concurrently facilitated through the strong role of politicians and celebrities for initiating advocacy against unethical formula marketing.

Opportunity for change

There is a political will for newborn and child health in Pakistan. Law for the enforcement of the BF code is already in place. Federal government has shown commitment and ownership. Ministry of National Health Services Regulations & Coordination (MoNHSR&C), in light of the Pakistan Vision 2025 (pillar 1), identified top priority areas for RMNCH. This National Vision for Coordinated priority actions to address challenges of reproductive, maternal, neonatal, child and adolescent health and nutrition (2016-2025) was endorsed by all provinces and regions in May 2015. The focus is on improving the access and quality of MNCH community based primary care services, overcoming financial barriers, investing in nutrition, family planning, adolescents and generating political will to support MNCH as a key priority within the Sustainable Development Goals. The agenda for implementation of the BF code as a step to improve the neonatal and maternal health can be incorporated within the national vision. In addition, civil society movements exist for promotion of the BF and international partners presence stands increased in provinces after devolution.

The key players identified to take the BF Code agenda forward include policy makers and implementer listed hereunder:

- Policy Makers
    - Federal: Directorate of Health to
        - Strengthen the organizational structure, governance to enforce BF code through infant feeding boards
    - Nutrition Division to
        - Revitalize Health Steering Committee to oversee BF code implementation
        - Conduct consultative meetings at the Federal and Provincial level and follow up meetings to define the accountability mechanisms
        - Raise awareness of the code – Improve families' misperceptions about benefits of formula milk through role models and celebrities

- Academia and HSA (Member of HSSAIU)
    - Train Healthcare providers and Implementers on the details of the Code
- Implementers
    - District Offices of Health (MNCH/Nutrition/LHW Program/EPI) - regular supervisory visits, checklist, reporting
    - Coordination with Line Departments - Committee formulation and coordination with Health, District Administration and Law enforcement agencies

The implementation strategy is detailed in table 1.

Table 1 : Action plan for implementation strategy

PROPOSED STRATEGY	KEY IMPLEMENTATION STEPS	KEY PLAYERS	LEAD AUTHORITIES	TIMELINE
Strengthening the organizational structure, governance to enforce BF code through infant feeding boards	1. Define organizational structure in the context of the BF Code 2. Inclusion of the BF Code in the agenda of the Infant feeding board. 3. Clearly defining the reporting line	Directorate of Health	Directorate of Health	6 months
Revitalizing Health Steering Committee to oversee the BF code implementation	1. Establish linkages of Breast feeding board with other initiatives under MNCH/Nutrition and FP 2. Steering Committee to take up the BF code agenda and prioritize it 3. Consultative meetings at the Federal and Provincial level. And Follow up meetings	Provincial Health Departments	Nutrition Wing	1 year
Awareness of the code - Families' misperceptions about benefits of formula milk	1. Campaigns on MNCH to include BF promotion and code awareness			
Training Healthcare providers and Implementers on the details of the Code	Providers to be trained and made aware of the BF Code	Health Services Academy	Academia Health Departments	2 years

SECTON II:

Part II: Reporting on the iPIER process

How research findings helped inform changes in health policies and programs

The study has identified that there is little demand and understanding of the importance of BF code resulting in lack of implementation and poor indicators of BF. Disconnect between central and peripheral level implementing bodies in Pakistan hampers further progress in this regard. Federal level is interacting with international partners in devising methodologies for proper implementation but there is a huge role and goal conflict with peripheral offices. There is dire need to engage all stakeholders to foster ownership at all tiers.

Cognizant of the disconnect between the centre and the periphery, the Government of Pakistan has taken the initiative to develop a vision 2025 for the country by taking all stakeholders on board. Health is one primary element that is addressed in the vision. The Ministry of National Health Services Regulation and Coordination in this regard, in collaboration with the provinces has defined a National Vision for Health. The agenda of implementation of the BF code under the maternal child health and nutrition vision can therefore can be taken forward. This will help maximize the efforts to improve the health of the mothers and children in harmony with the international and national commitments and in response to the contextual needs in the periphery.

Collaboration (positive and negative aspects) between the implementer and the researcher(s)

Health Services Academy being an autonomous institution under the Ministry of National Health Services and Regulations is duly recognized by the Ministry as an institution for capacity building of the health professionals and for generating evidence. Another role is policy advice. Being a member of the Health System Strengthening Policy Unit of MoNHSR&C, it is well placed to forward the research findings of the project to the other programs at the national level to promote evidence base for policy development, planning for health systems strengthening at federal, provincial and district level.

Please describe the collaboration/support (positive and negative aspects) provided by Birzeit ICPH and EMRO?

The support from Birziet ICPH and EMRO was much appreciated during the project period. Periodic reminders from both the offices helped the project team to maintain timelines. However, there was delay in the release of funds at the institutional level which resulted in interruption in data collection and made the researchers work against tight timelines. However, seeing the varied responses from other teams since the timelines were extended by EMRO the team managed project completion within the revised timeframe.

Since this project was being run concurrently with other institutional work and commitments, the coordination by the Birzeit ICPH, their timely reminders and response to the queries raised by different teams kept everyone informed of other teams' progress and maintained the momentum for project completion. The additional seminars arranged by Birzeit ICPH and EMRO provided a learning environment and generated discussion between teams. Through the small grants, problem identified in implementation (and substantiated with evidence collected in a scientific manner) was brought to the notice of the relevant authorities. A seminar was arranged for the students of HSA on Breast Feeding Day and the project was introduced to them. The team hopes to disseminate the findings of the study in HAS's national conference this year.

What if any, challenges have you experienced during this period?

The main challenge was at the federal level and as all the key stakeholders were extremely busy people and they could not be interviewed with our data collection team. PI or Co-I had to schedule interviews with them. Data collection teams were trained in the provinces and PI and Co-I travelled to train and supervise the data collection. With the other commitments at the Ministry these visits had to be scheduled accordingly. It was necessary for the PI and Co-I to lead the initiative as the authorities in the provinces had to be explained the objectives of the project by a senior person and to attain clearance from the departments which at times took longer than expected.

Tools

IDI GUIDE FOR iPIER RESEARCH

Date: ____/_____/____ Address: _____

Start time: _____ District: _____

Finish time: _____

Place of Interview: specify: _____

Facilitator's Name: _____

(For office use only)

Reviewed by: _____

Date of review: _____/_____/_____

Date of data entry: ____/____/_____

Data entered by: _____

Instructions for the Interviewer:

Before the interview:

Make an appointment with the respondent explaining him/her the objective of this Implementation Research and the reason for doing the interview.

At the time of interview:

a) Felicitate the respondent and introduce yourself. Clearly explain the objective of the study and the reason for doing the interview with him/her.

b) Explain why he/she was selected for the interview. Also, request enough time for conducting the interview highlighting the importance of the views expressed by the respondent.

c) Discourage prompting by other people in the room if their presence there is unavoidable.

d) Ask the questions one by one and note down the replies clearly. If the respondent seems to not have clearly understood the question, explain it further but avoid putting any leading question that suggests the answer in itself.

e) Facilitate discussion, if any, to remain within the context of the interview. If you are not clear about the answer provided to you, request the respondent to repeat his view on that particular question.

f) Before ending the interview session, reconfirm that all questions have been asked.

g) Thank the respondent at the end of the session.

After the interview:

Organize the answers according to the questions.

Collate all other views expressed by the respondent that do not fall directly under any question in a separate section.

Prepare a summary of the interview session with each respondent.

Section A: Respondent Information

ID Num: _____

Current Position: _____

Organization/Institution: _____

Department: _____

Duration of current service position: _____

Total Working Experience: _____

Total Relevant Experience: _____

Section B- Administration

1- What organizational structure is available for implementation of Code? If so what do you know about it ----- (when possible, probe for)
    a. *Composition*
    b. *Characteristics*
    c. *Terms of Reference*
    d. *Powers and Authority*
    e. *Coordination*
    f. *Functions and Roles & responsibilities*
    g. *Quorum of meetings and resolutions passed for the Implementation and Follow up*
    h. *Administrative, Technical and Financial Support available and required*
    i. *Declaration of No Conflict of Interest*

2- What are the functions of any implementation mechanism available at Federal, Provincial or District level? (Probe for)
    i. *Reporting on performance*
        a. *Coordination with line departments and legislative authorities*
        b. *Monitoring mechanisms for violation of Code*
        c. *Reporting Mechanisms for violation of Code*
        d. *Number/Type of action taken on violation of Code*
        e. *Record of formal requests made for donations in cash or in kind including breast milk substitutes*
        f. *Record of Consultative meetings held with experts and advocates of nutrition, civil society, manufacturers and distributors of BMS and other ministries, line departments, religious leaders and teachers*
    ii. *Development of national, provincial and district level strategies for promotion of breast feeding*
    iii. *Development/Adaptation of information and education material for infant and young child feeding*

iv. *Involvement in public awareness programs on breastfeeding and young child feeding at community level*

3- What are the capacity building measures in place for strengthening the roles of any Committees and Inspectors at district level?

4- Can you provide us some evidence on inspection measures taken by the Inspectors under patronage of Health Ministry? (Probe for)

   a. *ToRs for inspection*
   b. *Roles and responsibilities of inspectors, educational qualification, trainings and technical capability*
   c. *Schedule of inspections*
   d. *Availability of Checklists/tools/ Log frames for inspections covering quality assurance, expiry, manufacturing, labelling, packaging and nutritional compatibility at*
      i. *Plant*
      ii. *Markets*
      iii. *Health facilities*
   e. *Reports generated*
   f. *Reporting channels*
   g. *Actions taken*

5- What are the written protocols for initiating an investigation process and what kind of legal support is available for implementation of investigation process. (Probe for)

   a. *Initiation*
   b. *Filing of case*
   c. *Types of cases registered or in process*
   d. *Technical capacity of Board for the legal proceedings*

6- What are the major issues and challenges the Health Ministry and Committees face after 18th amendment in implementation of the Code?

<u>Section C- Promulgation, Public Awareness and Prohibitions</u>

1- What are the measures taken by the government for Promulgation (of Code/ordinance and Rule) by province and districts? (Probe for)

a. *Awareness among end users i.e. pregnant and lactating mothers*
b. *Awareness among health professionals*
c. *Awareness among allied health staff*
d. *Awareness among general public*
e. *Awareness among management staff at provincial and district level*

2- What is the total number of health professionals who completed training, or orientations on Code/Ordinance/Rule in your organization? (Probe for record)
3- What kind of arrangements exist at your organization/institution for orientation of mothers/care givers on Code/Ordinance/Rule? Can you please share record?
4- How do you ensure that companies of formula milk conduct trainings for their distributors and salesman on Code/Ordinance/Rule?
5- Do you think that healthcare workers are involved in promotion of formula milk? If yes how do you ensure that healthcare workers are not involved in promotion of designated products including the distribution of designated products among women and children? If no, why do you say that?
6- What is the reporting mechanism at healthcare settings in case of violation of Ordinance and Int Code and what are the actions taken?
7- What are the trainings/orientations conducted for the implementers including the focal persons for nutrition and district health administration?
8- Please provide us information on the availability and functions of Work force/Task force with-
    a. Assignments/roles and responsibilities to check violations in desired specification in terms of sale, products, packaging, promotions and labelling
    b. Assignments for Assessment of conformity with desired standards
        i. Essential messages related to breast feeding
        ii. Nutritional facts
        iii. Preparation Methods
        iv. Disadvantages and consequences
        v. Benefits
        vi. Labelling

Section D- Information and Material

1. Where do manufacturers and promoters of BMS submit the information and material for approval with the board and committees and what is the current status? (of approval or disapproval)
2. How do you assess the availability of protocols, guidelines and tools with manufacturers and distributors for compliance with Int Code of marketing, Ordinance and Rule in I&M produced by the companies.
3. Do you have material for promulgation of the ordinance and prohibitions at provincial and district level? What is the situation of availability of material at health facilities and maternity wards?
4. What is the situation related to availability and appropriate display of Code/ Rule/Ordinance at health facilities and information and guidelines and policy frameworks and awareness on such material in settings (private and public) where health service providers are working?
5. How do you ensure the Promotion of Breast Feeding? (Probe here for)
    a. *Availability of material for Breast Feeding Promotion for health workforce,*
    b. *Breastfeeding corners,*
    c. *IEC for parents at health facilities and information and guidelines*
    d. *Breastfeeding techniques and procedures and guidelines for health workforce*
    e. *Policy frameworks and awareness on such material in settings (private and public) where health service providers are working*.
6. What are the follow-up mechanisms for the implementation of breastfeeding policy, breastfeeding Ordinance and Rule and 10 steps of breastfeeding in hospitals?
7. How do you conduct the in-house training/orientations on promotion of breastfeeding and how is the funding for these capacity building workshops ensured? Who provides the material for trainings?
8. Can you please provide us with the details of donated material in maternal and paediatric wards, OPD, nursery and NICUs? (Probe here if possible for)

were these provided on request or for the sake of promotion and expected favour from healthcare workers for sale of BMS?

Section E- Violations

1. Do you think this institution has appropriate measures to ensure early initiation of breast feeding, counselling for exclusive breastfeeding and complementary feeding? If yes how? If no why?

2. What is your opinion on failure of early initiation and exclusive breast feeding?

3. Do you think that health workers including the specialists, medical officers, nurses and dai are involved in violation of breastfeeding rights of newborn? If yes why do they do so? What do they mostly recommend in case they want the baby to be fed on formula milk? Why?

4. Do representatives from manufacturers and promoters of formula milk visit you? If yes, why? if not, why? Which companies visit you most frequently and why? What impact do they have on breastfeeding initiation and exclusive breastfeeding in particular and infant and young child feeding in general?

5. Do they visit on their own or you or other staff member request them for it?

6. How do they promote their products? (Probe only for mothers if required? Like messages on charts, pictures, advertisements in magazines, newspapers, radio, TV; Literature in doctors' LHVs' DAI' NURSES' rooms

or direct discussion of promoters with mothers or attendants soon after birth of baby)

7. Do they give you or other staff members something during or after the visit? If yes what they give and why? If no why? (inform the respondent that other studies have shown gifts being given to health workers and allied staff include pens, writing pads, calendars/ posters, medicines, cloths, stationary, medical equipments, umbrella, refrigerators, air conditioners etc)? Can you please show us the gifted item?

8. Do you receive donations from BMS? If yes, what kind of donation including in kind material? Why do you receive such donated material? (probe for donation of material including the medical and surgical equipment used in maternity like suction machines, weighing machines, growth charts and height measuring scales, infant milk etc. in addition to the ones mentioned above.)

9. Why do or any other staff members at this organization/ institution receive free samples or low cost supplies? What are the reasons that the hospital/organization/institution does not prohibit such practices?

SECTION F- OBSERVATION (for Violations)

1- Inspection for display of material directly or indirectly promoting the formula and other foods. Note all violations and if possible take photographs with permission from the head of organization.

2- Assessment/ observation of Products for quality assurance and compliance with Rules 2009 and CODEX ALIMENTARIUS COMMISSION AND THE CODEX CODE OF HYGIENIC PRACTICE FOR FOODS FOR INFANTS AND CHILDREN FOR

a. Labelling

i. *Availability of Message(s) for promotion of breast feeding local language*
ii. *Message on Importance of Mothers Milk*
iii. *Do not show words like "Humanized" or "Materialized"*
iv. *Do not show comparison with mothers' milk*
v. *Do not show Graphics, Drawing or pictures of child, bottles to promote its use*
vi. *Correct method of preparation of milk*
vii. *Nutritional facts, composition and ingredients in Urdu*
viii. *Batch Number, Expiry date and Storage conditions*
ix. *Disadvantages and consequences*
x. *Benefits*

b. **WARNING**

Infant Formula Milk, Complementary Food and Milk Products, Bottle Feeding (Rule 10-1 a, b, c,d,e,f, 11-1, 11-2)

3- Violations, Penalties and Prosecutions

1- Assessment of official correspondence made to the manufacturers and distributors by the board and the committees or otherwise by the Federal or provincial governments.
2- Record of Penalties imposed?????
3- Stay Orders against verdicts/ penalties???
4- Record on Gifts, contribution, sponsorship, financial assistance, non-financial incentives given to health workers
5- Assessment of Information and Education Material in health facilities with and without visible messages on
    i. *Superiority of breast feeding*
    ii. *The preparation for and maintenance of breast feeding and its importance*
    iii. *The negative effects of both BMS on breastfeeding and introduction of bottle feeding*

iv. *The difficulty of reversing to breastfeeding once breastfeeding starts*
v. *Health hazards of bottle feeding*
vi. *The social and financial implications of feeding with a product*
vii. *The health hazards of improper feeding/ unnecessary feeding with breast milk substitutes*
viii. *How to feed with cup and spoon*
ix. *The health hazards of complementary feed in early stages*
x. *Promotion of home-made complementary foods and importance*
xi. *Age limits (above 06 months)*
xii. *Presence of graphics, pictures and drawings which may allure the caregivers and mothers for BMS use*
xiii. *No logos should be present*
xiv. *Language-should be in simple, easy to understand Urdu*

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