A Qualitative Investigation of Policy Barriers to Injectable Contraceptives in India

Courtney E. Henderson, MPH[1], Anne Berg Villumsen[2], Malcolm Potts, MB, FRCOG[1], Jenna Johnson-Hanks, PhD[3]

[1] Bixby Center for Population, Health, and Sustainability, School of Public Health, University of California, Berkeley
[2] Department of Public Health, University of Copenhagen
[3] Department of Demography, University of California, Berkeley

Corresponding Author:
Courtney E. Henderson, MPH
Bixby Center for Population, Health, and Sustainability
School of Public Health, 17 University Hall
University of California, Berkeley
Berkeley, CA 94720
Email: Courtney_Henderson@berkeley.edu

Abstract
India's National Population Policy highlights expanding voluntary family planning options. However, injectable contraceptives remain excluded from the Indian National Family Planning Program. The lack of access to injectables through this program results in fewer contraceptive choices for economically marginalized women who cannot access private sector options. This research uses Social Ecological Model and Political Economy as its theoretical frameworks, and employs qualitative methods, including media content analysis and in-depth interviews (n=31), to investigate key opinion leaders' positions on injectable contraceptives' role in the National Family Planning Program. Understanding why those leaders support or oppose the inclusion of injectable contraceptives and how they influence contraceptive policy is critical to the development of family planning programs and policies. This research will inform efforts to minimize policy barriers to injectable contraceptives. Such information may be useful beyond the scope of family planning, extending to other reproductive health services and policies in India.

Introduction
In 1951, India became the first country in the developing world to adopt a state-sponsored family planning program (Visaria L, Jejeebhoy S, & Merrick T, 1999). Following the International Conference on Population and Development in 1994, India shifted its family planning program to focus on improving women's reproductive health within a broader human rights framework (World Bank, 1997). Despite this paradigm shift and more than six decades of family planning promotion, reproductive health outcomes, particularly in the Northern regions of the country, remain poor (Indian Ministry of Health, 2012).

Non-permanent contraceptive methods that are used to space births, such as condoms, oral contraceptive pills, injectable contraceptives, and intra-uterine devices, are particularly important for improving infant and maternal health. Children are more likely to survive when subsequent pregnancies occur at least 24 months after a birth, and indeed, this is the birth spacing interval recommended by the World Health Organization (World Health Organization, 2005). Studies have found that short spacing pregnancy intervals are associated with higher risks of poor infant health outcomes, including pre-term birth, low birth weight and small for gestational age (Conde-Agudelo et al, 2006). Additional studies have found that increases in pregnancy spacing are associated with improvements in maternal health (Razzaque et al, 2005). Moreover, the ability to determine when one has children through the use of modern contraceptive methods has potential to lead to reductions in poverty and improvement in women's educational status (Cleland, 2006).

India's current National Population Policy highlights the importance of expanding choices for voluntary family planning within a broader rights framework (India National Commission on Population, 2000). However, injectable contraceptives remain excluded from the Government program. Injectable contraceptives were approved by India's Drug Controller in 1994, are manufactured in India, and are available through the private sector. In 2004, the Indian Government, UNFPA, and the Packard Foundation organized a workshop to expand contraceptive choices with the inclusion of injectable contraceptives in the Indian Government's

National Family Planning Program. More than 40 Indian health groups responded to that workshop by signing a memorandum against injectable contraceptives that was submitted to the Indian Union Health Minister (Sudhir and Malarcher, 2010).

There is little research documenting the reasons why key opinion leaders support or oppose injectable contraceptives. Understanding these reasons, in addition to how key opinion leaders influence national contraceptive policy, is critical to the development of effective family planning programs and policies. Media framing is one technique through which social problems are constructed. Frames define problems, identify causes, and suggest solutions (Entman, 1995). The literature has demonstrated that media framing has an impact on public health in the domain of health policy formation (Dorfman, 2005). Thus, this research included both a media content analysis and in-depth interviews with key opinion leaders to explore discourses surrounding injectable contraceptives in India, the role that key opinion leaders play in shaping these discourses, and how key opinion leaders influence national policy that determines access to injectable contraceptives. It is expected that this research will inform efforts to minimize policy barriers to injectable contraceptives for economically marginalized women. Such information will likely be useful beyond the scope of family planning, extending to other reproductive health services and policies in India.

The Social Ecological Theory (Stokols, 1996) provides a currently unutilized lens for a multifaceted understanding of the viewpoints of key opinion leaders in regards to injectable contraceptives. This model focuses on numerous physical, social, and cultural factors that influence the adoption of a health behavior (or in this case, contraceptive technology). Similar to Social Ecology Theory, Political Economy stresses the importance of viewing health problems in terms of their relationship to other facets of society and environment. This framework adds to Social Ecological Theory by specifically, "suggesting that such problems must also be viewed in broad historical relief" (Minkler, Wallace & MacDonald, 1994). This is critical given the long history of family planning promotion in India. The attention to the dynamics of class and gender, and how these interact to effect the lives of individuals and broader social groups, also makes Political Economy a useful framework for this research.

Research Design and Methods

The research approach integrated media content analysis and in-depth interviews with study participants. The content analysis was completed during July-October 2012. Semi-structured in-depth interviews (n=31) were conducted with key opinion leaders from both Indian and international organizations. Interviews were conducted in India during June-August 2012 and May-July 2013. This research was approved by the University of California, Berkeley Institutional Review Board (protocol # 2012-02-4053).

Media Content Analysis Design

Indian newspapers were sampled for relevant content, both because they are easily accessible and because newspapers typically set the agenda for other media, including television and blogs (Pew Research Center, 2013). An extensive set of keywords (i.e., injectable, contraceptive, family planning, DMPA) was used to sample newspaper articles that appeared between 2004-2006 and 2011-2012 in the database *Access World News*. The earlier time frame was chosen because the debate over injectable contraceptives was at its peak in 2004, following the injectable contraceptive workshop. The latter time frame was chosen to collect current data relevant to the issue of injectable contraceptives in India. Individual paragraphs, instead of entire news stories, were coded. In addition to identifying supportive and oppositional frames, paragraphs were also coded to identify individuals or groups receiving coverage.

In-Depth Interviews Design

Development of Interview Guide

A semi-structured interview guide was developed and included open-ended and probing questions to explore stakeholder's attitudes and perceptions toward non-permanent contraceptive methods. Areas for inquiry were theoretically constructed based upon questionnaires that have been used to assess knowledge and attitudes toward contraception among key opinion leaders (Sharma & Sharma, 1996). Questions were also included to specifically explore stakeholder views of injectable contraceptives, and their reasons for supporting or opposing this method's inclusion in the National Family Planning Program.

The interview guide was written in English, the predominant language spoken by individuals who belong to the identified stakeholder groups. Consistent with the iterative nature of qualitative research (Denzin, 1978), the original interview guide was modified over time as preliminary analysis of initial interviews suggested new lines of inquiry and the need for more detailed information on particular topics.

Sampling and Recruitment

The first set of study participants were selected based on results from the media content analysis. Intensity driven purposive sampling was used, in which information rich "cases" were sampled based upon strongly manifesting the phenomena of interest, namely support or opposition to injectable contraceptives (Patton, 1990.) Snowball sampling techniques were then used to identify additional key opinion leaders for participation in this study. These participants were only included if at least two other key opinion leaders had identified them. This sampling strategy was purposefully non-random, as the research team was attempting to gain access to key opinion leaders who have publicly expressed opinions on injectable contraceptives.

Interview Procedures

All study participants were asked to provide written informed consent for interviews conducted in-person and verbal informed consent for interviews conducted via phone. Interviews were conducted in English, were digitally recorded, and lasted between 1-2 hours. All interviews were conducted in the private offices of study participants in order to maintain privacy of participants or via phone. The interviewer recorded non-verbal cues and observational data during the interview. Interviews were stopped immediately if there was any intrusion by another person, or risk of being overheard. Interviews were not re-started until privacy had been re-established, and the study participant was specifically asked if he or she was comfortable continuing the interview. Interviewers prepared short memos following every interview. In addition, the study team debriefed following every interview. This served as an assessment of quality and consistency of interviews and allowed the study team to constantly evaluate research activities in the field as they occurred. Participants did not receive financial incentives for participation in this research.

Coding and Analysis of Interview Data

Interviews were transcribed in English. Preliminary coding was done while the researchers were in the field in order to develop a broad understanding of the data, and to identify additional areas of inquiry. Text files of all interviews, observational data, and memos will be imported into NVivo for coding and analysis. Multiple forms of coding are being used to examine the data. The methodology for data analysis is rooted in concepts of grounded theory and constant comparison (Glaser and Strauss, 1967; Strauss and Corbin, 1998; Charmaz, 2006). All data is first reviewed to develop a broad understanding of the content as it relates to the study's specific aims. Short memos are prepared to identify, name, describe, and categorize phenomena in the text. During this step, the boundaries of specific codes, including inclusion and exclusion criteria for codes, are defined. Next, materials from memos, interviews, and observational data re coded to produce data into analyzable units. Segments of text from a few words to several paragraphs are coded. Two types of coding are being utilized: open coding to identify emergent themes and a priori coding, based on themes from the interview guide. Finally, axial coding is used to connect codes to one another. A complete list of codes (codebook) is currently being developed, which includes six basic components: the code, a brief definition, a full definition, guidelines for when to use the code, guidelines for when not to use the code, and examples.

Two coders are responsible for coding all data. Inter-coder agreement in application of codes will be assessed. Both coders independently code the same section of text. The results of their coding are then compared for consistency of text segmentation and code application (MacQueen et al, 1998). If the results are acceptable and consistent, coding continues with periodic checks for inter-coder agreement. Inconsistent results are reviewed to determine if the inconsistencies re due to codebook guidelines or coder error (i.e., misunderstanding of terminology).

Preliminary Results - Content Analysis

A total of 67 articles were identified. Of these, 22 were relevant to the research question. In an attempt to identify additional news articles, search criteria were expanded to include the entire region of Asia. Of 94 articles, only three additional articles were relevant to this analysis. One of these three articles was only tangentially related, but was included, since one of its paragraphs specifically mentioned deterrents to use of injectable contraceptives in India. Of 157 total paragraphs analyzed, 75 were directly oppositional or critical to

the inclusion of injectable contraceptives in the Indian Government's National Family Planning Program, while 80 were directly supportive, or supportive of family planning efforts more generally. Two paragraphs were neither oppositional nor supportive.

Oppositional Frames

Within the paragraphs analyzed, 33 different oppositional frames were identified. These frames were collapsed into six categories, including: (1) side effects; (2) inadequate health system; (3) coercive governmental policies; (4) ethics and Western power; (5) provider-controlled method; and (6) additional frames. The risk of hazardous side effects was the oppositional frame used most often, appearing 58 times. General side effects, damaging effects to women's health, increased risk of bone loss, increased risk of HIV infection, and interruptions to the menstrual cycle were all cited frequently within the side effects category. Frames for the inadequate health system, coercive governmental policies, ethics and Western power, and provider-controlled methods appeared nine, eight, eight, and four times, respectively. Six additional frames appeared, though these were used infrequently. The oppositional frames intersected to form an overall message that injectable contraceptives are dangerous, cannot be implemented safely given the Government's ill-equipped healthcare personnel and infrastructure, and are being used by Western powers (including the World Bank and big pharmaceutical companies) and the Indian Government to control populations coercively.

Supportive Frames

Forty-one different frames were identified in support of including injectable contraceptives in the Indian Government's National Family Planning Program. These frames were collapsed into six categories: (1) effective method; (2) prevention; (3) world-wide acceptance; (4) improved choice; (5) adequate health system; and (6) additional frames. Within the effective method category, frames focused on effectiveness, convenience, and safety. These frames were used most often, appearing 24 times. Frames for prevention, world-wide acceptance, improved choice, and adequacy of the health system appeared 11, nine, nine, and four times, respectively. Twenty-three additional frames appeared, though the frequency for each of these frames was no more than two times. Frames that focus on overarching values – namely, choice and access for all women - were invoked in frames supporting improved choice. However, these frames were only the fourth most common type of frame used, after effective method, prevention, and world-wide acceptance frames.

Who is Included in Coverage

The fact that 75 paragraphs were oppositional, while 80 were supportive, would suggest that the news coverage of this issue is relatively balanced. However, an analysis of whose voice is actually included in the news articles provided additional detail. Opponents to the inclusion of injectable contraceptives in the Government's National Family Planning Program were quoted 59 different times. By comparison, supporters to the inclusion of injectable contraceptives were quoted approximately half as often (31 times). Among the opposition, those quoted most frequently were women's groups (though names of specific women's groups were often omitted), followed by Brinda Karat, a member of Parliament, the Marxist Party of India, and the All-India Democratic Women's Association. Public health experts and groups were also cited, but specific names of individuals or groups were largely omitted. Among supporters, the Federation of Obstetric and Gynecological Societies of India (FOGSI) was quoted most frequently, followed by Douglas Huber, a consultant at Management Sciences for Health in Boston, Massachusetts. Other supportive voices that were quoted include the Health Ministry, various non-governmental organizations (i.e., Packard Foundation), and local organizations. However, the frequency of quoted material from these other supportive voices was minimal. Interestingly, the one voice that might be most important in this controversy includes the women who are the end-users of injectable contraceptives. Not a single quote from end-users was identified.

Preliminary Results - In-Depth Interviews

A total of 31 in-depth interviews were conducted with key opinion leaders from both Indian organizations and international non-governmental organizations. The results presented below are preliminary, as analysis is still being conducted. Final results will include analysis of all 31 interview transcripts.

Preliminary analysis of interview data suggests that many of the frames identified in the media content analysis align with the discourses that key opinion leaders employ in discussing injectable contraceptives. Key themes that have emerged thus far in support of the inclusion of injectable contraceptives in the Indian Government's National Family Planning Program include: (1) expanded choice; (2) it is a woman's right to make decisions

about taking injectable contraceptives; not the government's right; and (3) injectable contraceptives give women more control over their bodies and fertility. Key themes that have emerged in opposition to the inclusion of injectable contraceptives in the National Family Planning Program include: (1) potential for coercion or abuse against women with injectable contraceptives; (2) injectable contraceptives are unsafe; and (3) injectable contraceptives are a provider-controlled method that is inappropriate for use in India.

Additional themes that were not present in the content analysis have emerged from the in-depth interview data. These themes include: (1) inability of the Government to provide injectable contraceptives, even if the method was included in policy; (2) continued focus on sterilization and use of incentives; (3) caveats to inclusion of injectable contraceptives in the Government Program; and (4) invoking rights-based discourses.

Inability of Government to Provide Method, Even if In Policy

Whether key opinion leaders fundamentally believed that injectable contraceptives should or should not be included in the National Family Planning Program, many discussed the inability of the Government to actually provide this method, even if it was included in policy. Indeed, many interviewees discussed the Government's failure to provide the contraceptive methods that are already included in its' family planning policy. As stated by one key opinion leader who supported the inclusion of injectable contraceptives in the Indian government program, "*the basket of choice in India is an empty basket*."

Continued Focus on Sterilization and Use of Incentives

In addition, a theme emerged among key opinion leaders regarding the Indian Government's continued focus on female sterilization with little access to non-permanent contraceptive methods. One key opinion leader who was opposed to the inclusion of injectable contraceptives in the Indian Government's program discussed how the Government uses politically-correct language grounded in rights, but the reality on the ground is a continued focus on population control: "*In rhetoric, the state continues to say that this (family planning) is for the health of women…and they will be empowered and they can take care of themselves, but ultimately, the state's obsession and...you know, thing with population hasn't gone away at all."* As stated by one key opinion leader who supported the inclusion of injectable contraceptives in the Indian government program, "*See government's priority and actions are both two different things. Government's priorities are actually providing choices and stabilizing population…all their services indicates that there is high unmet need both for spacing and permanent contraception and government objective is to actually meet them. But when you look at the ground, their objective…is to provide only permanent methods of contraception*."

A complementary theme focused on the continued use of incentives to encourage young couples to adopt female sterilization. As stated by one key opinion leader who opposed the inclusion of injectable contraceptives in the Government's program, "*Increasingly there has been the state that has been pushing for permanent in the sense…has been used to give incentives and has been giving incentives for permanent sterilization*."

Caveats to Inclusion of Injectable Contraceptives in the Indian Government Program

Key opinion leaders who were generally supportive of the inclusion of injectable contraceptives in the Indian Government program also expressed caveats for that inclusion. The need for increased counseling emerged as a common theme. As expressed by one key opinion leader when queried about any negative factors related to injectable contraceptives, "*Only negative thing is that if you don't provide a good quality service for injectables…then it's a problem if you don't counsel the women regarding the natural changes that she's likely to get…So you need to counsel and that's part of the quality service."*

Invoking a Rights Discourse

Interestingly, key opinion leaders who both supported and opposed the inclusion of injectable contraceptives in the Indian Government's National Family Planning Program invoked rights-based discourses grounded in the concept of choice. One interviewee, who was supportive of injectable contraceptives, stated that, "*You know, some women really like it (injectable contraceptives). Some women don't like it. So it's not for us to judge what they like and don't like. It's the choice they have.*" Another proponent of injectable contraceptives said, "*…if you can't get that (injectable contraceptives) into the system then are we really ever going to be offering choices to women beyond what we have or beyond what we were lucky to get into the government program back in the '70s and '80s."* An interviewee who was opposed to injectable contraceptives discussed how

women can't make informed choices about injectable contraceptives without proper information: "*The whole information transaction…access to information is very, very limited or low or…does not exist…And situation is largely towards coercion and I don't think it is about choice at all*."

Strengths and Limitations

There are several strengths to this research. By its nature, qualitative methodologies, and in particular, in-depth interviewing, allow one to analyze a given phenomenon while taking into account social, cultural, and political factors. This accords well with the theoretical framework employed in this research. Interviewing methodologies allowed for an in-depth exploration of key opinion leaders' experiences with injectable contraceptives.

There are limitations to this research. The media content analysis was conducted among English-language newspapers only. However, given that the issue of injectable contraceptives has been covered at the national level (as a potential national policy), this strategy seemed appropriate. Additionally, there is an entire body of literature of interviews as social interactions, which describes both how participants might respond to the interviewer, but also how the interviewer might interpret the data. It is important to acknowledge that, as the study authors are not native to India, in-depth interview participants may have structured their responses accordingly. Similarly, study authors may interpret data based upon their own lived experiences.

Implications

Understanding the reasons why different key opinion leaders support or oppose the inclusion of injectable contraceptives in the Indian Government's National Family Planning Program is critical in the development of new family planning programs and policies. These groups hold strong political appeal and are highly influential in determining policy decisions regarding making new family planning technologies accessible to women through the public (government) sector in India. The information gained from this research will likely be useful beyond the scope of family planning, extending to other reproductive health services and policies in India.

Acknowledgements

The authors would like to thank the Bixby Center for Population, Health, and Sustainability at University of California, Berkeley and the Center for Global Public Health at University of California, Berkeley for their financial support, and all the individuals who so generously offered to share their time and experiences with us.

References

1. Charmaz K. (2006). Constructing grounded theory: a practical guide through qualitative analysis. Thousand Oaks, CA: Sage Publications.
2. Cleland J, Bernstein S, Ezeh A, Faundes A, Glasier A, & Innis J. (2006). Family planning: the unfinished agenda. *Lancet*, 368(9542), 1810-27.
3. Conde-Agudelo A, Rosas-Bermudez A, Kafury-Goeta A. (2006). Birth spacing and risk of adverse perinatal outcomes: a meta-analysis. *JAMA*, 295(15), 1809-1823.
4. Denzin NK. (1978). The logic of naturalistic inquiry, in Sociological Methods. Thousand Oaks, CA: Sage Publications.
5. Dorfman L, Wallack L, & Woodruff K. (2005). More than a message: framing public health advocacy to change corporate practices. *Health Education and Behavior*, 32: 320-326.
6. Entman R. (1995). Framing: toward clarification of a fractured paradigm. *Journal of Communication*, 43: 51-58.
7. Glaser BG, Strauss AL. (1967). The discovery of grounded theory: strategies for qualitative research. New York: Aldine de Gruyter.
8. India National Commission on Population. (2000). National Population Policy. Available at: http://populationcommission.nic.in/. Last accessed 21 September 2013.
9. Indian Ministry of Health and Family Welfare. Profile of Uttar Pradesh. Available at: http://mofw.nic.in. Last accessed 10 March 2013.
10. MacQueen K, McLellan E, Kay K, & Milstein B. (1998). Codebook development for team-based qualitative analysis. *Cultural Anthropology Methods*, 10(2), 31-36.
11. Minkler M, Wallace S & McDonald M. (1994). The political economy of health: a useful theoretical tool for health education practice. *International Quarterly of Community Health Education*, 15(2): 111-125.
12. Patton, MQ. (1990). Qualitative evaluation and research methods, 2nd ed. Newbury Park, CA: Sage Publications.)
13. Pew Research Center's Project for Excellence in Journalism. (2010). New Media, Old Media: the Blogosphere. Available at: http://www.journalism.org/analysis_report/blogosphere. Last accessed 19 February 2013.
14. Razzaque A, DaVanzo J, Rahman M, Gausia K, Hale L, Khan M, & Mustafa A. (2005). Pregnancy spacing and maternal morbidity in Matlab, Bangaldesh. *International Journal of Gynecology and Obstetrics*, 89, S41-S49.
15. Stokols D. (1996). Translating social ecological theory into guidelines for community health promotion. *American Journal of Public Health*, 10(4), 282-98.
16. Strauss AL, & Corbin JM. (1998). Basics of qualitative research techniques and procedures for developing grounded theory, 4th ed. Thousand Oaks, CA: Sage Publications.
17. Sudhir M, Malarcher S. (2010). Injectable contraceptives in India: past, present, and future. New Delhi, India: USAID.
18. Visaria L, Jejeebhoy S, & Merrick T. (1999). From family planning to reproductive health: challenges facing India. *International Family Planning Perspectives*, 25(Suppl), S44-49.
19. World Bank. (1997). India-Reproductive and Child Health Project. Report no. PIC2555. Washington, DC. Available at: http://documents.worldbank.org/curated/en/1997/09/694363/india-reproductive-child-health. Last accessed 10 March 2013.
20. World Health Organization. (2005). Report of a WHO technical consultation on birth spacing. Geneva, Switzerland. 13-15 June 2005. Available at: http://www.who.int/maternal_child_adolescent/documents/birth_spacing.pdf. Last accessed 10 March 2013.