Dr Moazzam Ali

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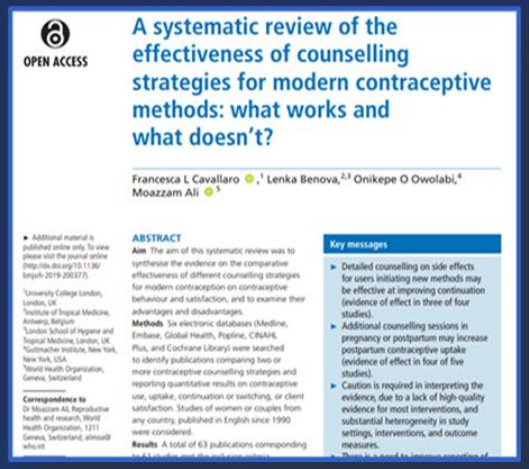
Dr Moazzam Ali is an experienced public health professional and medical practitioner with over twenty years of global expertise in reproductive health/ family planning, health systems strengthening, and policy development. His career encompasses the design and evaluation of national health systems, leadership in clinical trials, and capacity-building initiatives in low- and middle-income countries. Holding dual master's degrees, a postgraduate diploma, and a PhD in International Health, Dr Ali currently serves as an Epidemiologist/Medical Officer with the Department of Life course, Health and Research at the WHO in Geneva, where he provides leadership in clinical and implementation research. His work primarily focuses on advancing health equity, quality, coverage, and the sustainability of health services. A well-published author, Dr. Ali has also made critical contributions to key WHO guidelines, shaping global policies and improving access to quality reproductive health care.



OPEN ACCESS

A systematic review of the effectiveness of counselling strategies for modern contraceptive methods: what works and what doesn't?

Francesca L Cavallaro ,[1] Lenka Benova,[2,3] Onikepe O Owolabi,[4] Moazzam Ali [5]

ABSTRACT

Key messages

- Detailed counselling on side effects for users initiating new methods may be effective at improving continuation (evidence of effect in three of four studies).
- Additional counselling sessions in pregnancy or postpartum may increase postpartum contraceptive uptake (evidence of effect in four of five studies).
- Caution is required in interpreting the evidence, due to a lack of high-quality evidence for most interventions, and substantial heterogeneity in study settings, interventions, and outcome measures.

The art of scientific publishing: Strategies for successful publication

ICFP, Bogota 2025

Moazzam Ali MBBS, PhD, MPH

World Health Organization

human reproduction programme hrp

research for impact

UNDP·UNFPA·UNICEF·WHO·WORLD BANK

Topics covered in this lecture

- What makes a great paper (essential criteria)
- Elements of writing style
- Titles and abstracts
- Data presentation
- Results and discussion
- Closing out

Your readers have 4 key questions

What did you do?

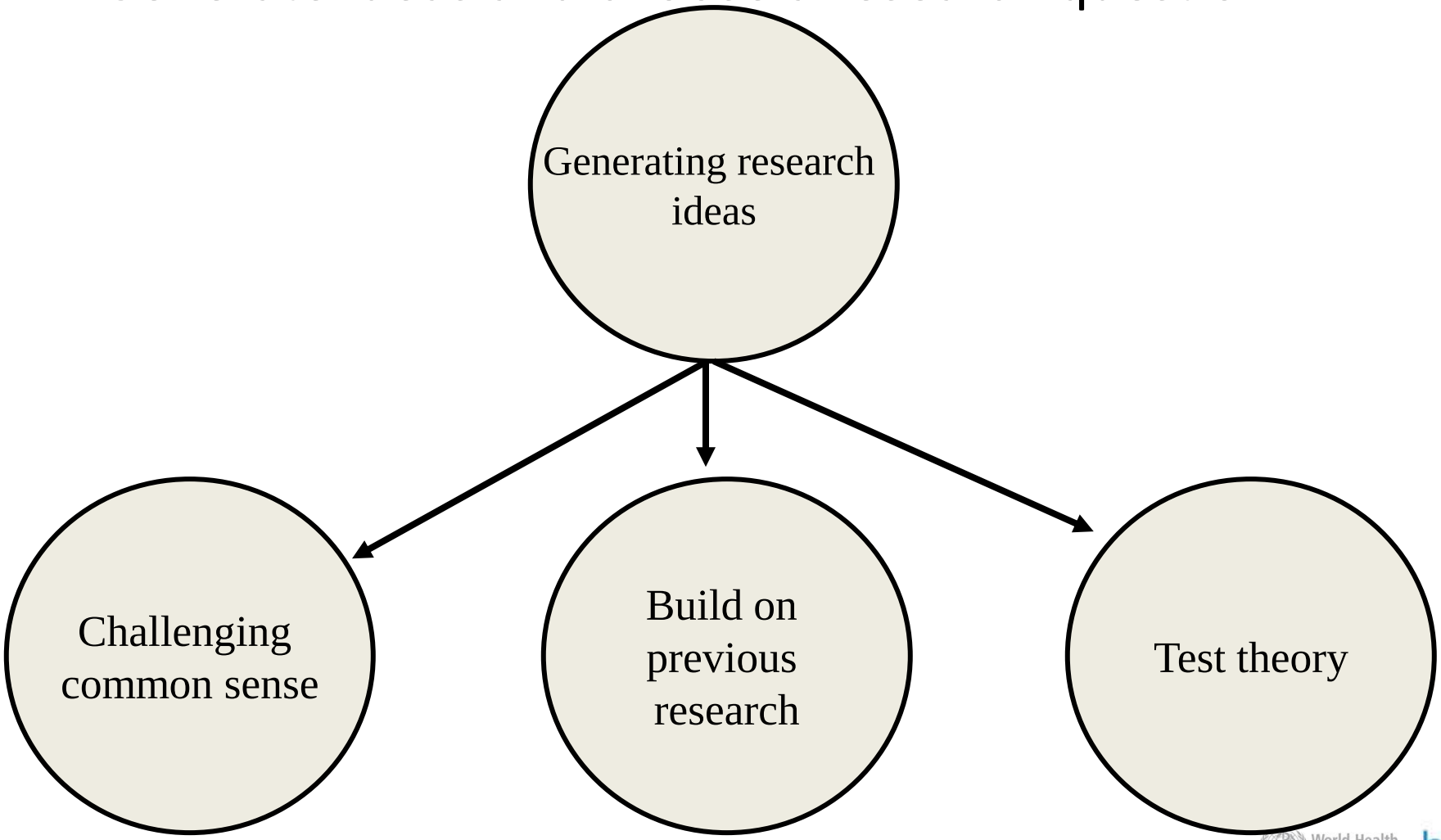
What did you find?

Why did you do the study?

How does the study advance the field?

Generating a research question

- Generate ideas and choose a research question



How to generate a research question

- **Safety ?**
- **Efficacy ?**
- **Effectiveness ?**
- **Extended use of implant ?**

Human Reproduction, Vol.31, No.11 pp. 2491–2498, 2016
Advanced Access publication on September 26, 2016 doi:10.1093/humrep/dew222

human reproduction **ORIGINAL ARTICLE** ***Fertility control***

Extended use up to 5 years of the etonogestrel-releasing subdermal contraceptive implant: comparison to levonorgestrel-releasing subdermal implant

Moazzam Ali[1,*], Ayse Akin[2], Luis Bahamondes[3], Vivian Brache[4], Ndema Habib[1], Sihem Landoulsi[1], and David Hubacher[5]; for the WHO study group on subdermal contraceptive implants for women†

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Submitted on May 7, 2016; resubmitted on July 28, 2016; accepted on August 9, 2016

STUDY QUESTION: Is it possible to extend the use of the 3-year one-rod etonogestrel (ENG)-releasing subdermal contraceptive implant to 5 years?

SUMMARY ANSWER: The extended use of the one-rod ENG-releasing subdermal contraceptive implant showed 100% efficacy in years 4 and 5.

WHAT IS KNOWN ALREADY: The initial regulated trials on the ENG-releasing subdermal contraceptive implant conducted in the 1990 s were designed to measure cumulative 3-year efficacy. The ENG-implant has both well established safety and efficacy for up to 3 years. Pharmacokinetic data on ENG show high levels at 3 years and some previous clinical research confirms efficacy beyond the current approved duration of 3 years. Today, many women, because the labeled duration has been reached, have the ENG implant removed at 3 years, increasing costs, inconvenience and risks.

STUDY DESIGN SIZE, DURATION: For the first 3 years, this study was an open-label, multi-centre randomized trial comparing the 3-year ENG implant to the 5-year levonorgestrel (LNG)-releasing implant. After 3 years, a subset of 390 ENG participants, consented to extended use. We compared efficacy, side effects and removal procedures of both implants. We used Kaplan–Meier (K–M) analysis. We included an observational cohort of copper intrauterine device (IUD) users as non-users of hormonal contraceptive method for comparative purposes.

PARTICIPANTS/MATERIALS, SETTING, METHODS: The study took place in family planning clinics in seven countries worldwide. Women were enlisted after an eligibility check and informed consent, and 1328 women were enrolled: 390, 522 and 416 in the ENG-implant, LNG-implant and IUD groups, respectively.

MAIN RESULTS AND THE ROLE OF CHANCE: Over 200 women used the ENG implant for at least 5 years. No pregnancies occurred during the additional 2 years of follow up in the ENG or LNG implant group. The overall 5-year K–M cumulative pregnancy rates for ENG- and LNG- implants were 0.6 per 100 women-years (W-Y) [95% confidence interval (CI): 0.2–1.8] and 0.8 per 100 W-Y [95% CI: 0.2–2.3], respectively. Complaints of bleeding changes were similar; however, ENG-users were more likely than LNG-users to experience heavy bleeding ($p < 0.05$). The median duration of the implant removal procedure was 64 seconds shorter for the one-rod ENG-implant

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Introduction and methods sections

Introduction

The etonogestrel (ENG)-releasing subdermal contraceptive implant was developed in the 1980s and the first regulatory trials were conducted in the 1990s. Scientists involved in the early development of the product suspected that high contraceptive efficacy would extend beyond 3 years; however, the industry-sponsored trials were not designed to go past 3 years. Thus, the product was approved worldwide with a 3-year indication.

The existing data suggested that an ENG concentration >90 pg/ml is necessary to effectively prevent ovulation (Diaz *et al.*, 1991). In normal-weight women (i.e. BMI = 18.5–24.9 kg/m^2), the average ENG concentrations at 2 and 3 years post-insertion are 194 and 156 pg/ml, respectively. The ENG subdermal contraceptive implant is a device consisting of 68 mg of ENG as the active ingredient with an average release rate of 60–70 µg/day in weeks 5–6, decreasing to ~35–45 µg/day by the end of the first year, 30–40 µg/day by year 2, and then to 25–30 µg/day at the end of the third year (Implanon, 2016). The bioavailability remains constant and close to 100%, and the elimination half-life of the parent compound is around 25 h (Huber and Wenzl, 1998). Pharmacokinetic (PK) analysis showed at the end of the life-span of the ENG implant (i.e. 3 years) the serum levels are above the threshold for effective contraception (Wenzl *et al.*, 1998; Zheng *et al.*, 1999).

Although the ENG-implant is approved for use up to 3 years, some reports demonstrate effectiveness beyond that. Two studies did not report any pregnancies through the fourth year of use (Kiriwat *et al.*, 1998; McNicholas *et al.*, 2015). The extended use of the ENG-implant could reduce the frequency of removal/insertion procedures, and consequently improve implant cost-effectiveness, while improving convenience for women.

Subdermal implants have grown in popularity in resource-poor countries over the past decade, particularly in sub-Saharan Africa. In 2005, international donor agencies purchased approximately 84 000 subdermal implants for the region; since then, the annual number of units increased steadily and peaked in 2015 when 7.4 million were purchased (Reproductive Health Supplies Coalition, 2015). Approximately 50% of implants were ENG-products; thus, extended use of the ENG-implant would have tremendous global impact.

This article reports results for extended use up to 5 years after insertion of the ENG-implant and compares the results to the 5-year levonorgestrel (LNG)-releasing implant, with a focus on contraceptive performance, side effects and reasons for method discontinuation. Also, we compare the performance with a non-randomized group of women who received a TCu380A intrauterine device (IUD) as users of a non-hormonal contraceptive method.

Materials and methods

The original 3-year design of this study was a randomized open parallel group trial of the 1-rod ENG (Implanon®, Merck & Co., Inc., Whitehouse Station, NJ, USA) and the 2-rod LNG subdermal contraceptive implants (Jadelle®, Bayer Healthcare, Berlin, Germany) with a 1:1 allocation ratio, and a non-randomized control group of women using the TCu380A IUD (Pregna®, Pregna International, Mumbai, India) (Bahamondes *et al.*, 2015). The trial was registered as ISRCTN33378571. The study was approved by the Scientific and Ethical Review Group at Development and Research Training in Human Reproduction (HRP/the World Health Organization (WHO), WHO Secretariat Committee on Research Involving Human Subjects, and by the Ethical Committees of all participating centres.

The study took place in family planning clinics (centres) in: Campinas, Brazil; Santiago, Chile; Santo Domingo, Dominican Republic; Szeged, Hungary; Bangkok, Thailand; Ankara,Turkey; Harare, Zimbabwe. The

Introduction section

- ✓ Emphasis on literature review
  - ✓ Use published literature
  - ✓ Grey literature ? Probably not
- ✓ Past work and status of knowledge
- ✓ Focus needs to be clear

It needs to be around 500-700 words

Methods section

It should include the following:

- ✓ Declare type of study design, in line with the objectives
- ✓ Geographic location – one district, multicenter trial?
- ✓ Timeline
- ✓ Target population – children under 5; women, adolescents
- ✓ Describe tools used for data collection
- ✓ Data management - how did you do it. Telephonic interviews, field visits etc.
- ✓ Analysis/Statistics plan
- ✓ Ethics approval ?

It should be around 400-500 words

Methods: What do your readers need to know?

Who/what was used in the study

Samples or participants

Materials (where purchased)

How you conducted the study

Methodology and techniques

Discuss specific conditions and controls

How you analyzed your data

Quantification methods/software

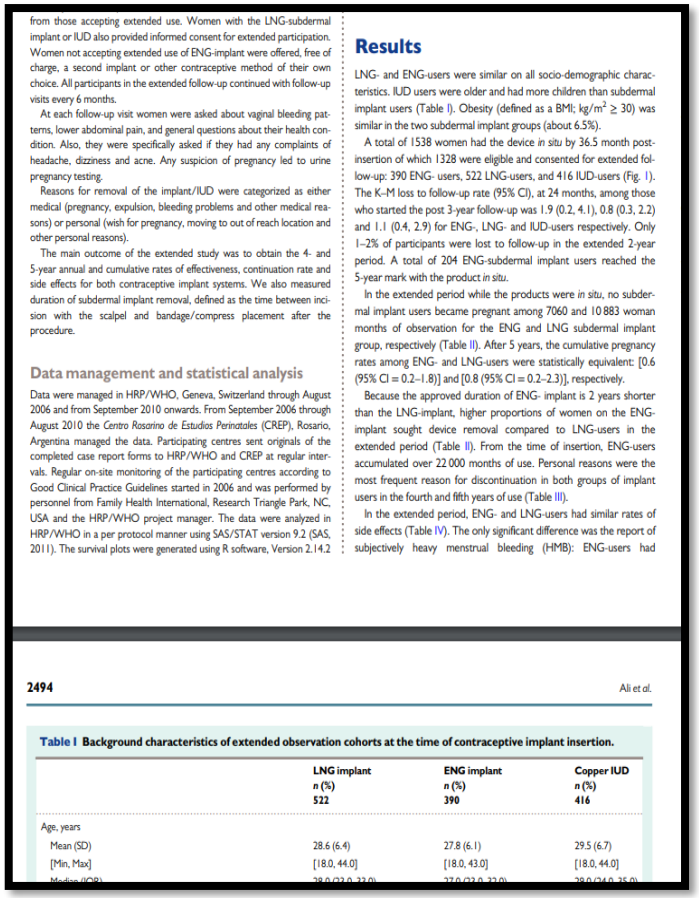
Statistical tests (consult a statistician)

Results section – what did you find

Initial observation

Characterization

Application



from those accepting extended use. Women with the LNG-subdermal implant or IUD also provided informed consent for extended participation. Women not accepting extended use of ENG-implant were offered, free of charge, a second implant or other contraceptive method of their own choice. All participants in the extended follow-up continued with follow-up visits every 6 months.

At each follow-up visit women were asked about vaginal bleeding patterns, lower abdominal pain, and general questions about their health condition. Also, they were specifically asked if they had any complaints of headache, dizziness and acne. Any suspicion of pregnancy led to urine pregnancy testing.

Reasons for removal of the implant/IUD were categorized as either medical (pregnancy, expulsion, bleeding problems and other medical reasons) or personal (wish for pregnancy, moving to out of reach location and other personal reasons).

The main outcome of the extended study was to obtain the 4- and 5-year annual and cumulative rates of effectiveness, continuation rate and side effects for both contraceptive implant systems. We also measured duration of subdermal implant removal, defined as the time between incision with the scalpel and bandage/compress placement after the procedure.

Data management and statistical analysis

Data were managed in HRP/WHO, Geneva, Switzerland through August 2006 and from September 2010 onwards. From September 2006 through August 2010 the *Centro Rosarino de Estudios Perinatales* (CREP), Rosario, Argentina managed the data. Participating centres sent originals of the completed case report forms to HRP/WHO and CREP at regular intervals. Regular on-site monitoring of the participating centres according to Good Clinical Practice Guidelines started in 2006 and was performed by personnel from Family Health International, Research Triangle Park, NC, USA and the HRP/WHO project manager. The data were analyzed in HRP/WHO in a per protocol manner using SAS/STAT version 9.2 (SAS, 2011). The survival plots were generated using R software, Version 2.14.2

Results

LNG- and ENG-users were similar on all socio-demographic characteristics. IUD users were older and had more children than subdermal implant users (Table I). Obesity (defined as a BMI; kg/m^2 ≥ 30) was similar in the two subdermal implant groups (about 6.5%).

A total of 1538 women had the device *in situ* by 36.5 month post-insertion of which 1328 were eligible and consented for extended follow-up: 390 ENG- users, 522 LNG-users, and 416 IUD-users (Fig. 1). The K–M loss to follow-up rate (95% CI), at 24 months, among those who started the post 3-year follow-up was 1.9 (0.2, 4.1), 0.8 (0.3, 2.2) and 1.1 (0.4, 2.9) for ENG-, LNG- and IUD-users respectively. Only 1–2% of participants were lost to follow-up in the extended 2-year period. A total of 204 ENG-subdermal implant users reached the 5-year mark with the product *in situ*.

In the extended period while the products were *in situ*, no subdermal implant users became pregnant among 7060 and 10 883 woman months of observation for the ENG and LNG subdermal implant group, respectively (Table II). After 5 years, the cumulative pregnancy rates among ENG- and LNG-users were statistically equivalent: [0.6 (95% CI = 0.2–1.8)] and [0.8 (95% CI = 0.2–2.3)], respectively.

Because the approved duration of ENG- implant is 2 years shorter than the LNG-implant, higher proportions of women on the ENG-implant sought device removal compared to LNG-users in the extended period (Table II). From the time of insertion, ENG-users accumulated over 22 000 months of use. Personal reasons were the most frequent reason for discontinuation in both groups of implant users in the fourth and fifth years of use (Table III).

In the extended period, ENG- and LNG-users had similar rates of side effects (Table IV). The only significant difference was the report of subjectively heavy menstrual bleeding (HMB): ENG-users had

Table I Background characteristics of extended observation cohorts at the time of contraceptive implant insertion.

	LNG implant *n* (%) 522	ENG implant *n* (%) 390	Copper IUD *n* (%) 416
Age, years			
Mean (SD)	28.6 (6.4)	27.8 (6.1)	29.5 (6.7)
[Min, Max]	[18.0, 44.0]	[18.0, 43.0]	[18.0, 44.0]
Median (IQR)	28.0 (23.0, 33.0)	27.0 (23.0, 33.0)	28.0 (24.0, 35.0)

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Results section

It should focus on:

- ✓ **Summary of your key findings** arranged in a logical sequence that generally follows your methodology section.

- ✓ Inclusion of non-textual elements, such as, **figures, charts, photos, maps, tables,** etc. to further illustrate the findings, if appropriate. Do not repeat things

- ✓ In the text, a **systematic description of your results**, highlighting for the reader observations that are most relevant to the topic under investigation.

- ✓ Use of the **past tense** when referring to your results.

It should be around 800-1000 words

Discussion section

was still low (only 12%).

Implant removal information for the full 5 years of the study was available for 332 and 444 ENG- and LNG-users, respectively (Table V). The median time required for the removal procedure was 1 min for the ENG- and 2 min for the LNG-implant. For about 2 and 9% of ENG- and LNG-implants, respectively, removals were deemed slightly difficult or difficult.

Discussion

This study examined contraceptive efficacy of the ENG-subdermal implant beyond its approved duration of 3 years and up to 5 years. Of

became pregnant in the fourth and fifth years under observation. Although attrition reduced the amount of efficacy data, over 200 women used the product for at least 5 years.

Others are also examining extended use of the ENG-implant. In the US-based contraceptive CHOICE study, investigators have data on 123 women completing 4 years of use and 34 users completing 5 years of use; zero pregnancies have occurred after 229 W-Y of extended use (McNicholas *et al.*, 2015). Median levels of ENG in serum were 188 and 177 pg/ml at 3 and 3 years, respectively. The investigators are expecting to enroll a total of 550 ENG-implant users and currently have 287 (personal communication, Dr. Colleen McNicholas, November 12, 2015). A study of 47 Thai women (Kiriwat *et al.*, 1998)

Discussion section

- ✓ **Summary**: brief recap of your key results/ findings
- ✓ **Interpretations**: What do your results mean? And how do they compare with existing knowledge?
- ✓ **Implications**: Why do your results matter? What novelty does the study brings in? how will it influence:
  - ✓ Policy
  - ✓ Current practices
  - ✓ Program implementation etc.
- ✓ **Limitations**: What can't your results tell us?
- ✓ **Recommendations**: Is the data sufficient to understand and describe phenomenon under study? Do we need to do further research to understand it better (better design, large sample size, multi-country study?)
- ✓ *It should be around 1000-1200 words*

Discussion section

Summarize what you did

Begin with research problem. Key findings

Interpret your findings

- Similarities and differences

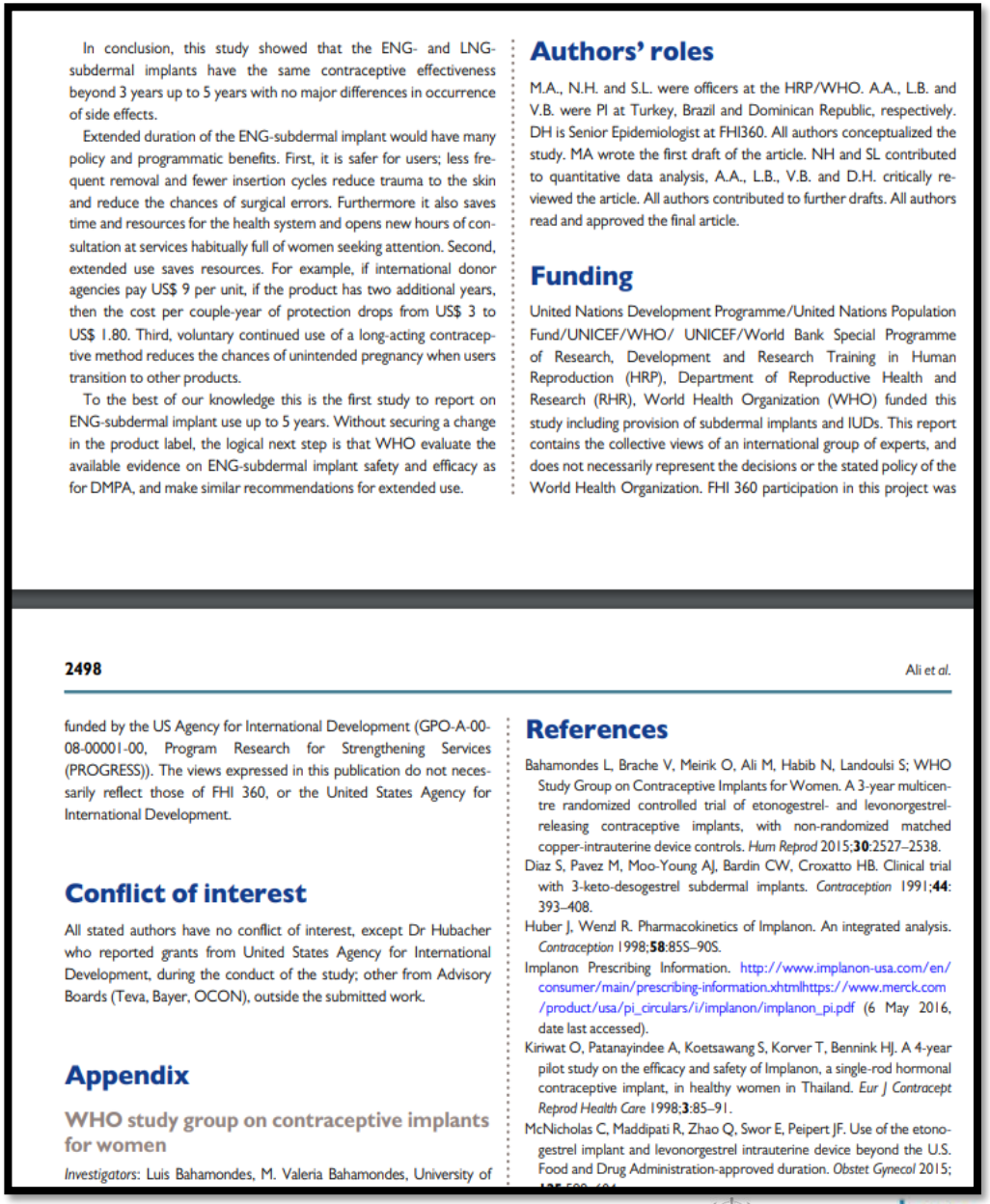
Why important to the field

Main conclusions. Implications

Before closing out

…

Title, abstract, references, figure and tables, submission to journal



In conclusion, this study showed that the ENG- and LNG-subdermal implants have the same contraceptive effectiveness beyond 3 years up to 5 years with no major differences in occurrence of side effects.

Extended duration of the ENG-subdermal implant would have many policy and programmatic benefits. First, it is safer for users; less frequent removal and fewer insertion cycles reduce trauma to the skin and reduce the chances of surgical errors. Furthermore it also saves time and resources for the health system and opens new hours of consultation at services habitually full of women seeking attention. Second, extended use saves resources. For example, if international donor agencies pay US$ 9 per unit, if the product has two additional years, then the cost per couple-year of protection drops from US$ 3 to US$ 1.80. Third, voluntary continued use of a long-acting contraceptive method reduces the chances of unintended pregnancy when users transition to other products.

To the best of our knowledge this is the first study to report on ENG-subdermal implant use up to 5 years. Without securing a change in the product label, the logical next step is that WHO evaluate the available evidence on ENG-subdermal implant safety and efficacy as for DMPA, and make similar recommendations for extended use.

Authors' roles

M.A., N.H. and S.L. were officers at the HRP/WHO. A.A., L.B. and V.B. were PI at Turkey, Brazil and Dominican Republic, respectively. DH is Senior Epidemiologist at FHI360. All authors conceptualized the study. MA wrote the first draft of the article. NH and SL contributed to quantitative data analysis, A.A., L.B., V.B. and D.H. critically reviewed the article. All authors contributed to further drafts. All authors read and approved the final article.

Funding

United Nations Development Programme/United Nations Population Fund/UNICEF/WHO/ UNICEF/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), Department of Reproductive Health and Research (RHR), World Health Organization (WHO) funded this study including provision of subdermal implants and IUDs. This report contains the collective views of an international group of experts, and does not necessarily represent the decisions or the stated policy of the World Health Organization. FHI 360 participation in this project was

funded by the US Agency for International Development (GPO-A-00-08-00001-00, Program Research for Strengthening Services (PROGRESS)). The views expressed in this publication do not necessarily reflect those of FHI 360, or the United States Agency for International Development.

Conflict of interest

All stated authors have no conflict of interest, except Dr Hubacher who reported grants from United States Agency for International Development, during the conduct of the study; other from Advisory Boards (Teva, Bayer, OCON), outside the submitted work.

Appendix

WHO study group on contraceptive implants for women

Investigators: Luis Bahamondes, M. Valeria Bahamondes, University of

References

Bahamondes L, Brache V, Meirik O, Ali M, Habib N, Landoulsi S; WHO Study Group on Contraceptive Implants for Women. A 3-year multicentre randomized controlled trial of etonogestrel- and levonorgestrel-releasing contraceptive implants, with non-randomized matched copper-intrauterine device controls. *Hum Reprod* 2015;**30**:2527–2538.

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Huber J, Wenzl R. Pharmacokinetics of Implanon. An integrated analysis. *Contraception* 1998;**58**:85S–90S.

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Kiriwat O, Patanayindee A, Koetsawang S, Korver T, Bennink HJ. A 4-year pilot study on the efficacy and safety of Implanon, a single-rod hormonal contraceptive implant, in healthy women in Thailand. *Eur J Contracept Reprod Health Care* 1998;**3**:85–91.

McNicholas C, Maddipati R, Zhao Q, Swor E, Peipert JF. Use of the etonogestrel implant and levonorgestrel intrauterine device beyond the U.S. Food and Drug Administration-approved duration. *Obstet Gynecol* 2015;

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Abstract –

First impression of the paper

Abstract

Introduction This study aimed to provide an overview of the research landscape and to identify research gaps linking climate change events and sexual and reproductive health and rights (SRHR) in low-income and middle-income countries (LMICs), where the negative impacts of climate change are most severe.

Methods We conducted a scoping review to map research studies that link climate change events or factors and SRHR aspects in LMICs. We performed a structured literature search across six databases to identify relevant peer-reviewed publications between January 1994 and 6 September 2023. The literature search yielded 14 674 peer-reviewed articles. After screening, 75 articles were included, spanning 99 countries across the globe.

Results Climate change events such as extreme temperatures, drought, rainfall shocks, cyclones and floods were found to be associated with negative maternal and newborn health outcomes ranging from reduced or low birth weight, preterm births and low Apgar scores, to lack of pregnancy care, pregnancy complications, stillbirths, and newborn and maternal deaths. Associations were also found between climate-related events and increased gender-based violence and HIV prevalence, as well as fertility decisions and harmful practices such as female genital mutilations and early and forced marriages. About two-thirds (48/75) of the articles were from the African or Western Pacific regions. The main research gaps on climate change-related events and SRHR included abortion, reproductive cancers and contraception use.

Conclusion Complementing existing evidence with targeted research to fill these knowledge gaps could enhance mitigation programmes and policies.

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Referencing

- Howard style (Alphabetical)
- APA (American Psychological Association)
- Vancouver (numbering)

Software for referencing:

- Endnote.
  - Endnote Basic https://endnote.com/product-details/basic/
- Reference manager
- Mendeley
- Zotero

Figures and Tables

A well-designed data plot includes:

- clear and concise legend and caption
- axes labels
- clear units for quantities
- curves and data sets are labelled
- all elements found in the figure are identified in the caption.
- font type and size are legible

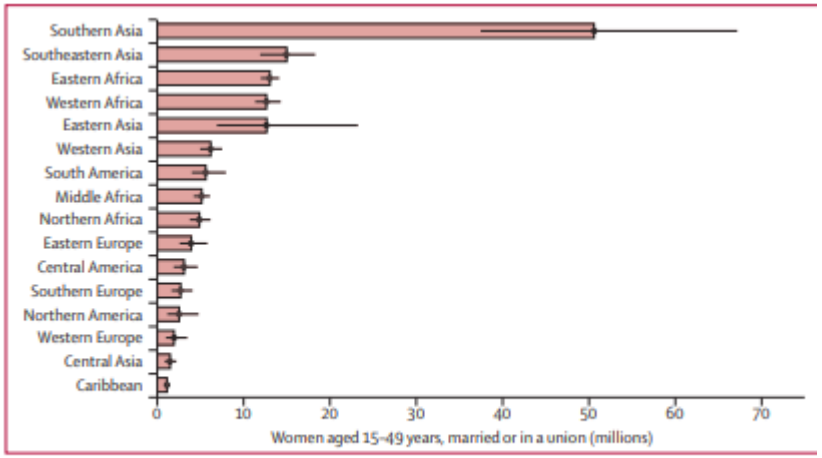

Figure 2: **Number of women aged 15–49 years who were married or in a union with an unmet need for family planning in 2010, by subregion**

A well-designed table includes:

- clear and concise legend and caption
- data divided into categories for clarity
- sufficient spacing around columns and rows
- clear units for quantities
- font type and size are legible

Table 2 Results of meta-analysis on the impact of FP interventions on secondary outcomes

Outcome	Number of studies	Odds Ratio (95% CI)	Heterogeneity	
			Chi^2 p-value	I^2 (%)
All Contraceptive method use	12	1.73 (1.51–1.98)	0.00001	83
Total unmet need	3	0.86 (0.78–0.94)	0.14	50
Current use of				
Pills*	11	1.38 (1.06–1.79)	0.00001	75
Condom*	11	1.32 (1.0, 1.77)	0.00001	93
Injectable	8	0.92 (0.67–1.27)	0.00001	88
Male sterilization	4	1.22 (0.73–2.05)	0.16	37
Female Sterilization	9	0.91 (0.71–1.15)	0.001	82
Intra-Uterine Device*	11	1.62 (1.05–2.50)	0.001	91
Implants	4	1.76 (0.86–3.61)	0.11	44
Knowledge				
Condom*	7	2.03 (1.19–3.47)	0.001	98
Pills	8	1.45 (1.01–2.08)	0.001	95
Injectable	6	1.55 (1.03–2.33)	0.001	97
Male sterilization	6	1.63 (0.81–3.29)	0.001	99
Female Sterilization	6	1.59 (1.03, 2.45)	0.001	97
Intra-Uterine Device	6	1.53 (0.79–2.95)	0.001	99
Implants	3	2.86 (1.16–7.06)	0.001	97
ECP use	3	1.31 (0.65–2.67)	0.001	91

*are the outcome variables with P-value of random-effect model is < 0.05

Submission of manuscript – an example

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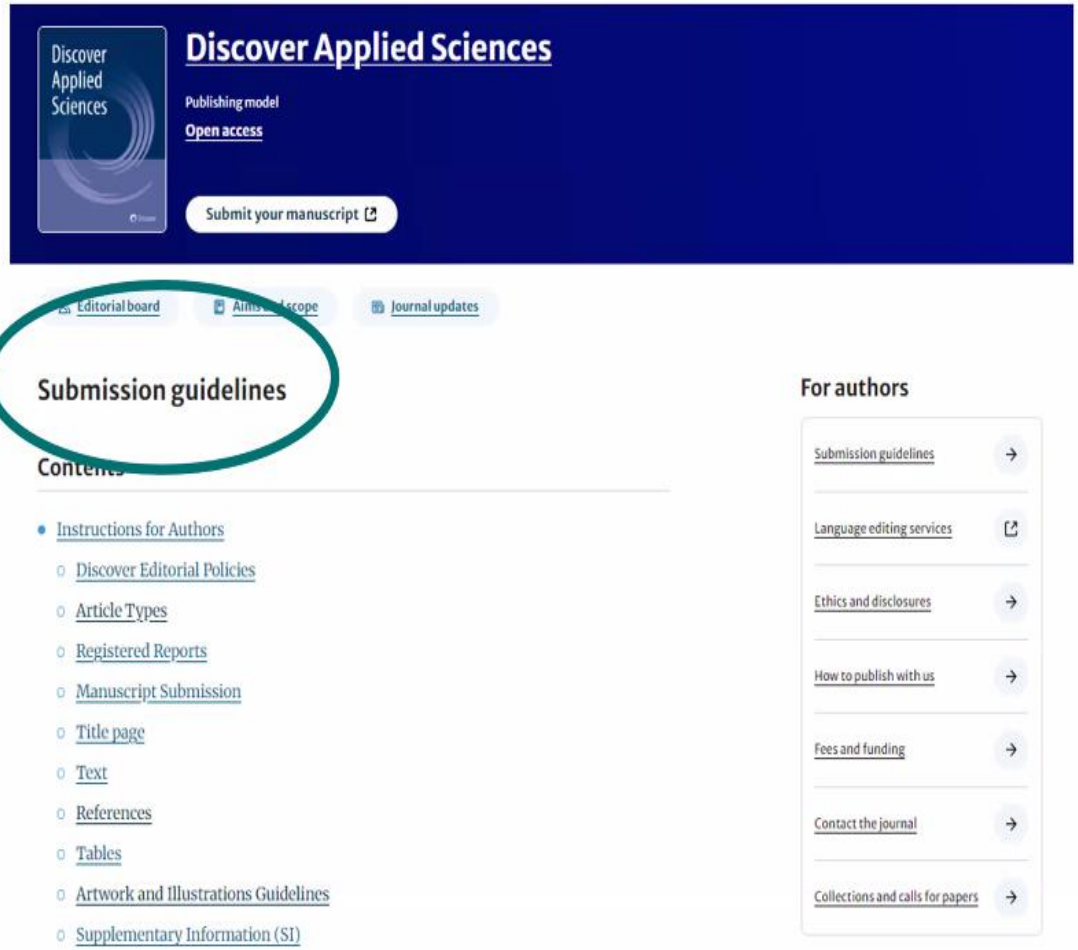

Thank you and good luck with publishing your research

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