

Medintim

Caya Diaphragm Specialist Survey Report Germany

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Report: Caya Diaphragm Specialist Survey Germany

Introduction:

Today, women and couples seeking to avoid pregnancy can choose from a range of contraceptive options that have different characteristics. Some offer short-term protection while others provide long-term protection. Some are hormonal and others nonhormonal. Some are under the control of the woman and used only at the time of sex; others require a clinic visit for a provider to insert an IUD, contraceptive implant or provide an injectable contraceptive.

Women choose their contraceptive method based on personal needs and preferences which can change over the stages of her life and relationships. Since hormonal contraception became available, hormonal methods—specifically oral contraceptive pills—have become the most widely used method in Germany. A smaller portion of women in Germany use other hormonal methods including the hormonal IUD, vaginal ring, injectable and patch.

Before hormonal methods became widely available, many women used the diaphragm. Over time, diaphragm use fell off and fewer providers were trained in how to provide this method.

We know from research and clinical practice that not all women can use or want to use hormonal methods, or an IUD, or condoms. For some of those women, a nonhormonal barrier method—like the diaphragm—could help meet their needs. The Caya contoured diaphragm was developed to help address the needs of women who want a nonhormonal, user-initiated option.

Caya Diaphragm was first marketed in Germany in 2013 and more than 150,000 Caya had been sold to women in this market as of December 2022. While Caya is available without prescription (over the counter), family planning providers are trusted sources of information, and many women consult their provider to discuss contraception. Medintim GmbH (the Caya manufacturer) conducts surveys annually to explore Caya users' experiences using this nonhormonal barrier method. This is the first survey among providers to explore their perceptions about Caya diaphragm and their perceptions about their clients' experience using Caya. This report primarily focuses results from the provider survey but also includes findings from the consumer surveys where those data help interpret provider responses.

Optimal contraception should be very safe, have as few side effects as possible, not interfere with the natural cycle or rhythm, be flexible and easy to use as well as to remove and strengthen the partnership; the Caya diaphragm finally combines all these desirable characteristics.

Method:

In 2023, Medintim sent email invitations to 133 FP providers in Germany who voluntarily signed up to be registered in a database of qualified Caya providers and agreed to be contacted for issues related to Caya provision. The providers represented both FP clinics and OB/GYN specialists. FP clinics were represented by non-profit organization Profamilia who is a member association of IPPF (International Planned Parenthood Federation) which exhibit a huge client base. The OB/Gyn represented both private and public practices. After agreeing to participate, providers were sent a link via e-mail to an online survey comprised of 13 questions that they filled out individually and submitted. They had the option to submit anonymously (8%) or to provide contact information (92%).

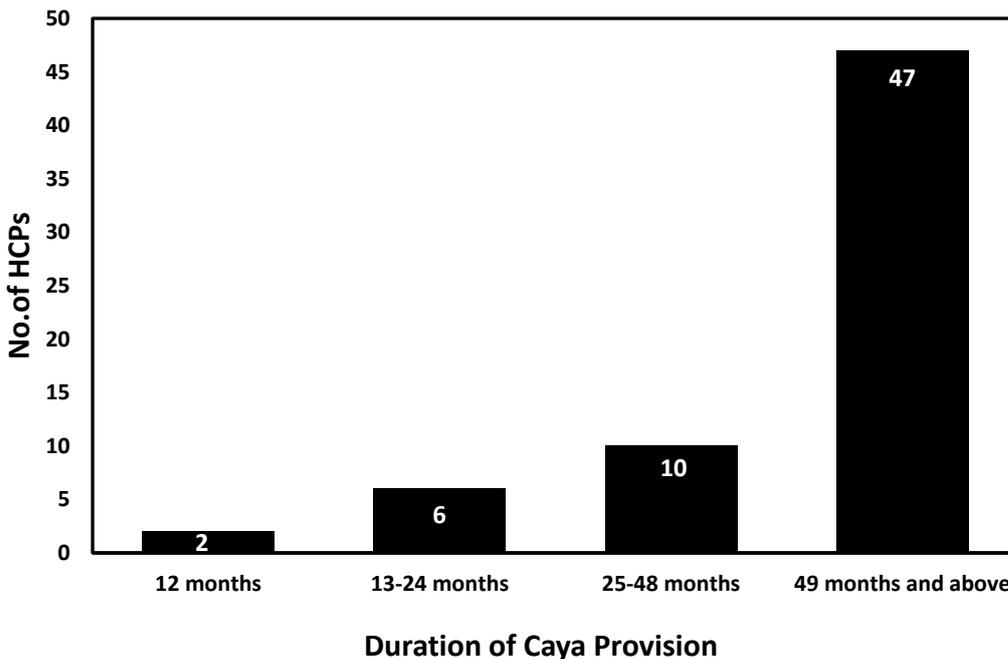
Survey Results

In total, 65 providers responded to the online survey over the 2 months that the survey was open (July-September 2023), representing a 49% response rate.

We asked providers to estimate the number of clients who were using Caya diaphragm. In total, across the 65 health care providers, they estimated nearly 3000 clients were using Caya diaphragm (N=-2895).

Key results from the survey questionnaire are presented below.

Q. About how long have you been providing Caya diaphragms in your practice?

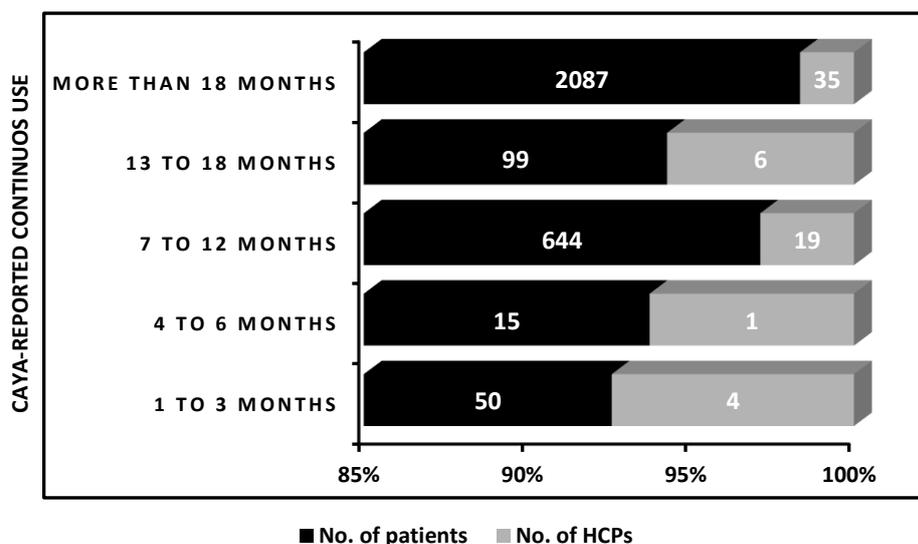


Caya Provider Survey

Of the survey respondents, 72% (47/65) reported they had been providing Caya diaphragm for 4+ years (49 months and above).

About 15% of providers (10/65) reported they had been providing Caya for 2-4 years (25-48 months) and 12% (8/65) had provided Caya for 2 or fewer years (24 months or less).

Q. How long have been your patients using the Caya diaphragm permanently (estimated number)?

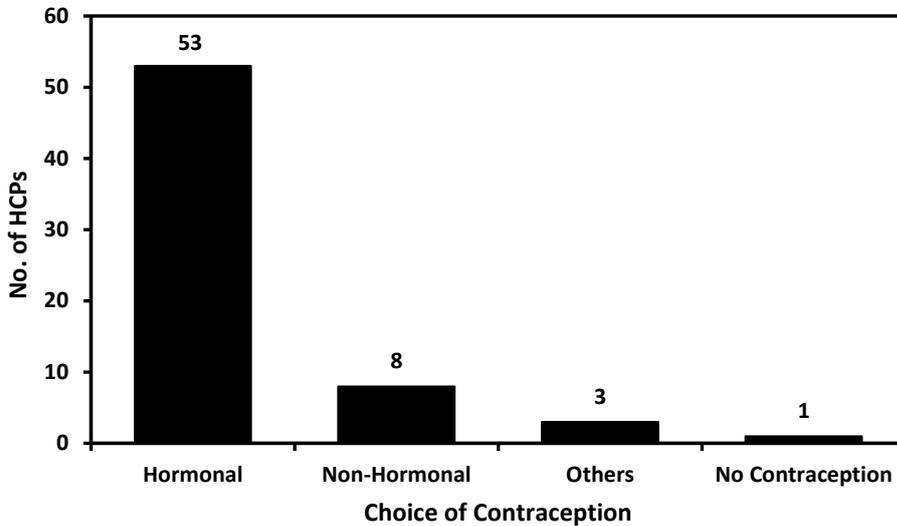


54% of providers (35/65) reported that most of their clients (72%; 2087/2895) had been using Caya diaphragm longer than 18 months.

37% of providers (24/65) reported their Caya clients had been using Caya 12 months or less. These providers clients represent about 25% (709/2895) of the Caya users whose experience is characterized in this survey.

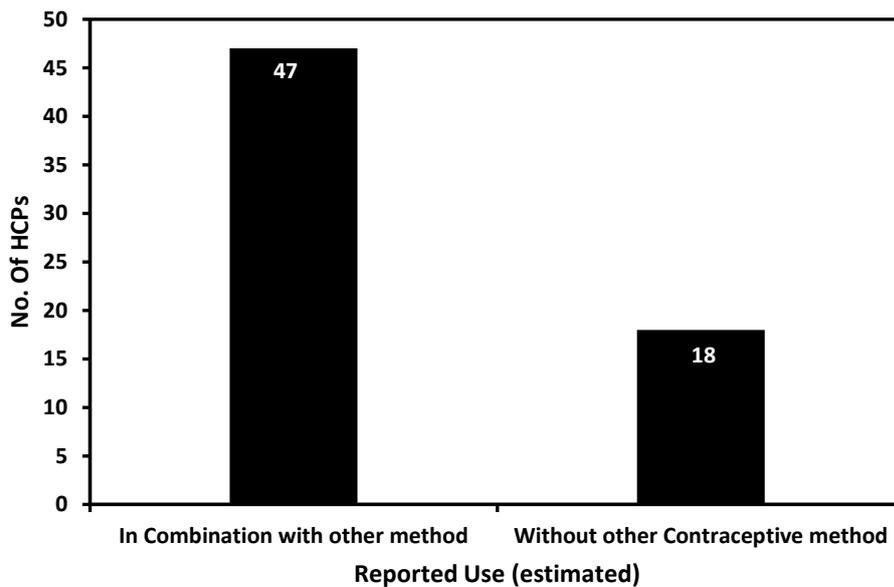
Thus, providers to this survey represented both a combination of experienced and fairly new providers. Most providers responding reported having clients who had used the Caya diaphragm for 18 months or longer.

Q. Which contraceptive method(s) did your patients most commonly use before switching to Caya diaphragm?



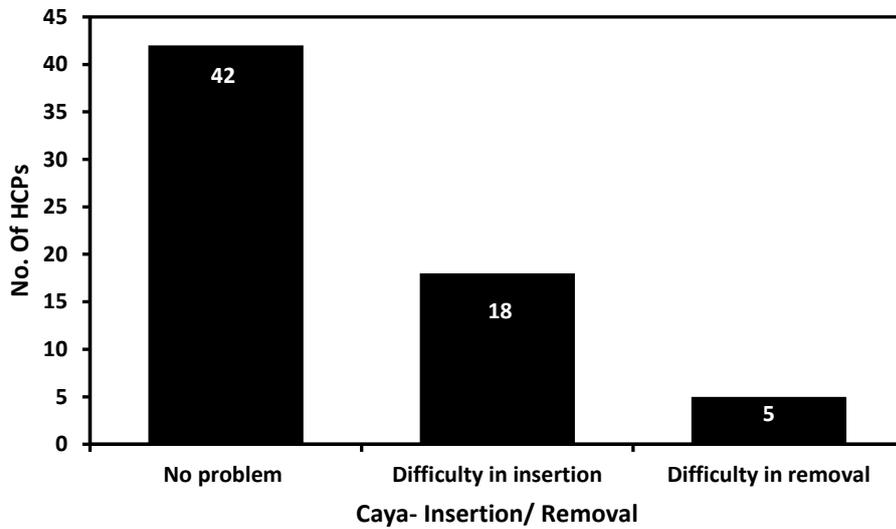
Of the 65 providers who responded to the survey, 82% (53/65) indicated their clients chose Caya diaphragm after having previously used some type of hormonal contraception. 18% (12/65) of the providers stated previous non- hormonal contraception, other contraceptive methods or no contraception were used by their clients before switching to the diaphragm.

Q. Do your patients use the diaphragm in combination with other contraceptive methods?



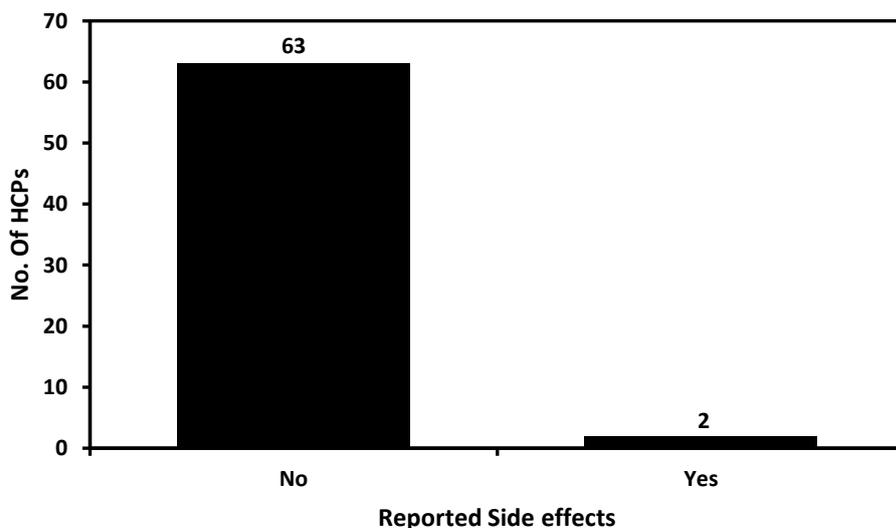
72% of providers (47/65) responded their clients use Caya with other contraceptive methods. This could be alternating various methods or dual methods use.

Q. Did your patients report any difficulty inserting or removing the diaphragm?



65% of providers (42/65) reported their clients did not have trouble inserting or removing Caya. Of the 35% of providers (23/65) who indicated their clients had some difficulty with Caya, most providers indicated clients had difficulty with insertion. (Depending on interpretation of the question, this could also mean ensuring correct fit/placement of Caya.) A small number of providers indicated their clients had difficulty with removal. We don't know how challenging these difficulties were, whether providers were able to help the client overcome these difficulties with a bit of additional coaching and practice, or whether these difficulties were so challenging that clients decided not to use Caya.

Q. Did your patients report any side effects of using Caya diaphragm?

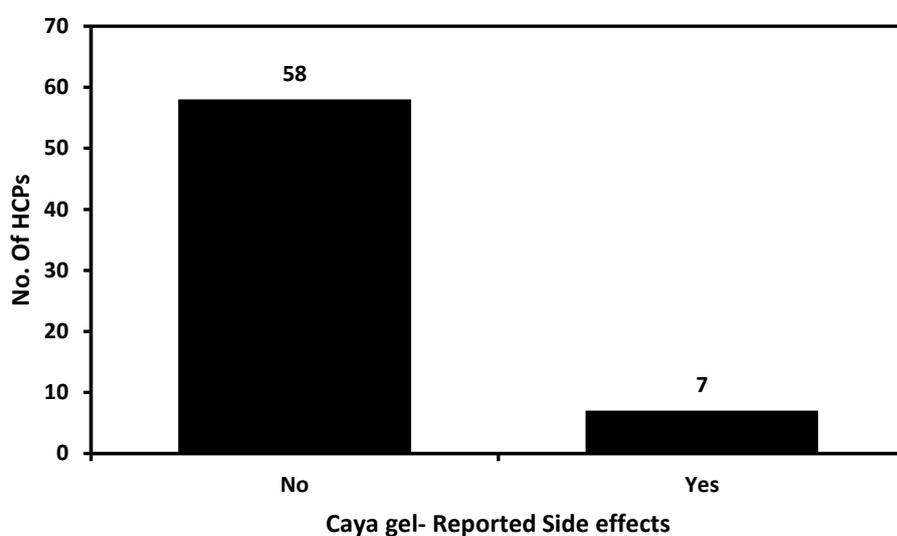


Caya Provider Survey

97% of providers (63/65) reported clients did not report experiencing side effects of using Caya diaphragm. Only 3% of providers (2/65) indicated clients had reported side effects. Side effects included conditions such as vaginal irritation or urinary tract infections. In these women previous health status was unknown in context with this survey.

Note: This was a multiple-choice question listing several potential side effects. It is not known how many clients or what percentage of clients reported any side effect or whether side effects meant the woman stopped using Caya diaphragm.

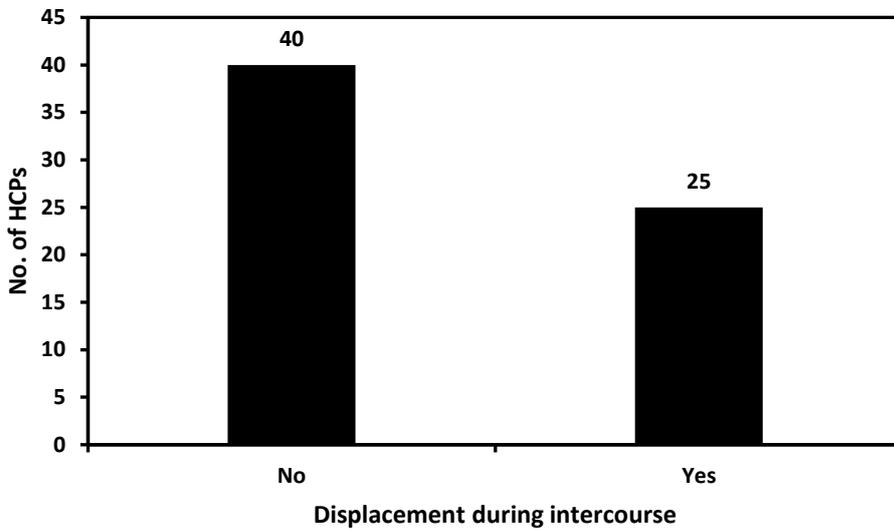
Q. Did your patients report any side effects using Caya Gel / Contragel with Caya diaphragm?



89% of respondents (58/65) indicated clients had not reported side effects using Caya gel / Contragel with diaphragm, whereas 11% of providers (7/65) indicated some knowledge that clients reported side effects such as burning sensation, vaginal irritation, or vaginal discharge. Previous health status of the women exhibiting these side effects was unknown in context to this survey.

Note: This was a multiple-choice question that listed several potential side effects. It is not known how many or what percentage of clients in a clinic practice reported these side effects or whether side effects meant the woman stopped using Caya diaphragm gel or Contragel.

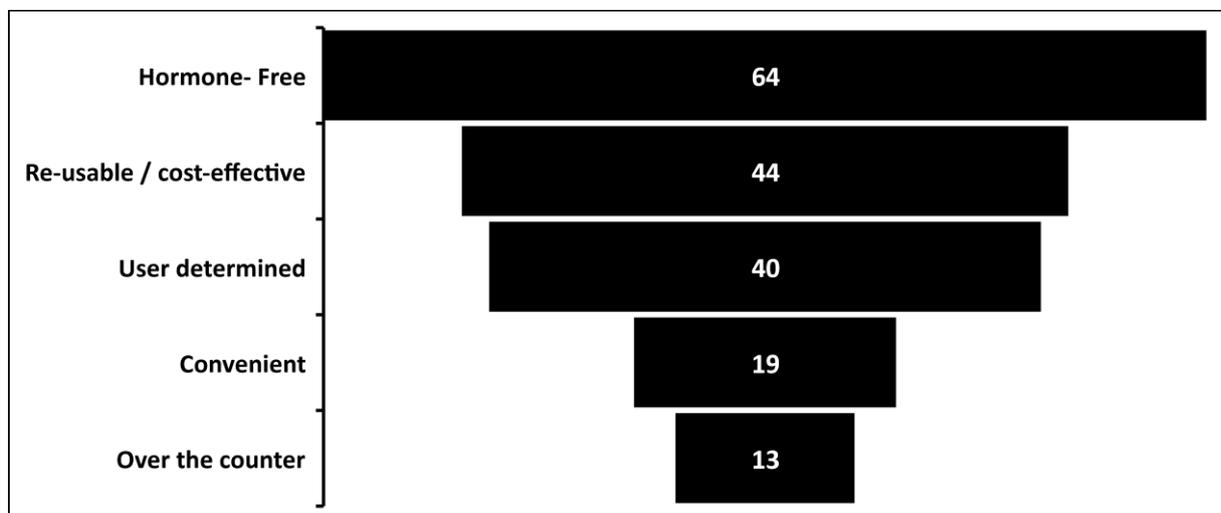
Q. Did your patients report displacement of Caya diaphragm during intercourse?



Almost 61% (40/65) of Caya diaphragm providers indicated that they didn't receive/hear any reports of Caya displacement during intercourse from their clients, whereas 39% (25/65) indicated they received reports of displacement during intercourse.

Note: It is not known how many clients in a clinic practice reported displacement during intercourse or if this led to the client to stop using Caya diaphragm. As some providers mentioned that their clients reported displacement during intercourse, this might be due to first time use, incorrect use, discontinuous use, or other factors. Further, the displacement of Caya diaphragm during intercourse led to discontinuous use of this method in these women is unknown. It is also possible that these women could address and solve this issue on their own or after consultation with their HCPS.

Q. Of your patients who continue using Caya, what do you think are the primary reasons they like this method?

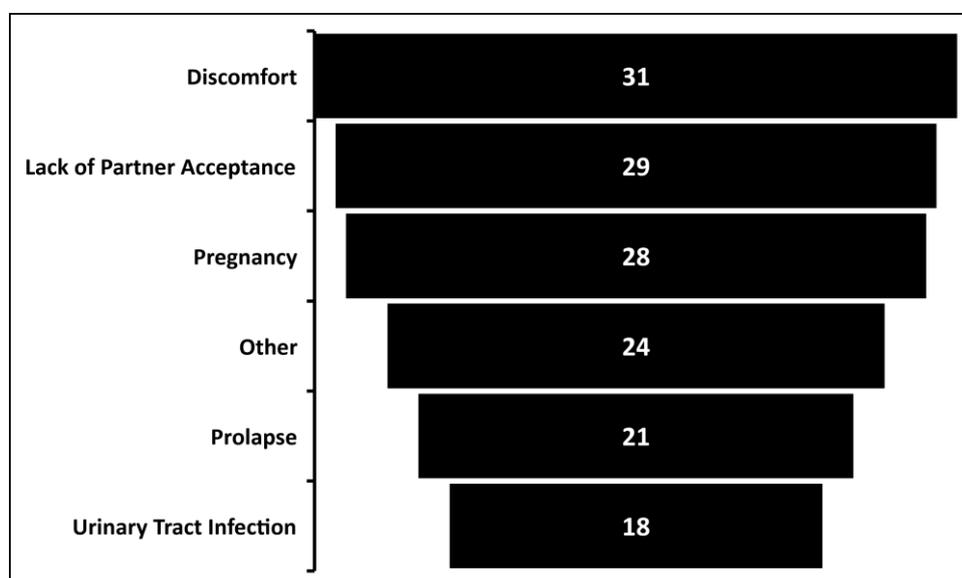


Caya Provider Survey

Providers were asked the key reasons why they thought clients choose and continue using Caya diaphragm. Overwhelmingly, providers responded “hormone free”. The next two most frequently cited reasons were “reusable/cost-effective”; and “user determined” (or user controlled). Almost 98% of providers reported their clients prefer Caya because it is hormone free, reusable (66%), user determined (61%), convenient (28%) and over the counter available (18%).

Note: This was a multiple-choice question, and providers could check as many responses as they felt applied.

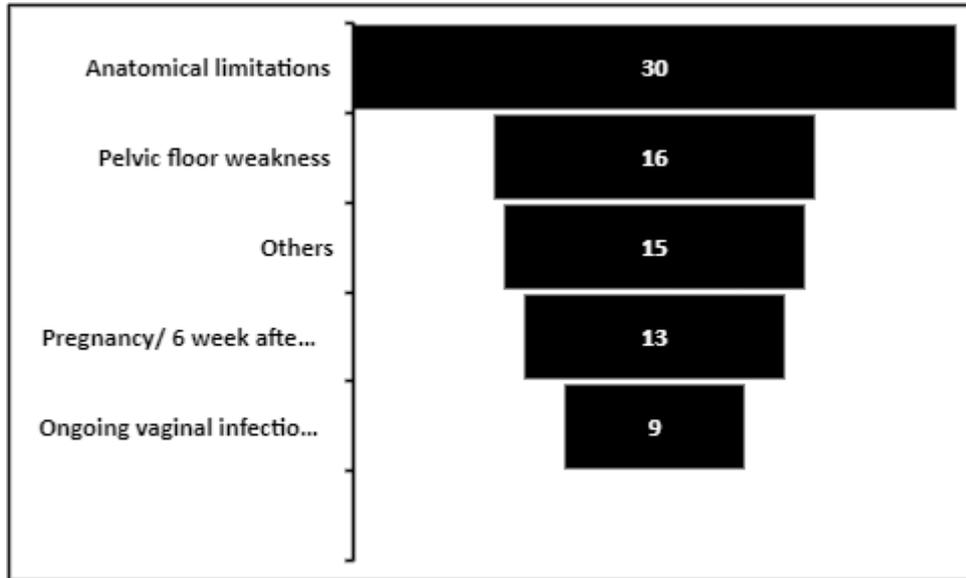
Q. Of your patients who discontinue using Caya, what do you think are the primary reasons they discontinue?



We also asked providers if clients stopped using Caya, what did they think were the main reasons for stopping use. This graph shows the percentage of provider responses across the categories listed in this multiple-choice question. Nearly 48% (31/65) providers felt the primary reason women discontinue is due to “discomfort” and 45% (29/65) mentioned “lack of partner acceptance”. 43% (28/65) of the providers stated that their clients stopped diaphragm use due to planned pregnancy, followed by 32% (21/65) citing prolapse and 28% (18/65) mentioned UTI. Other reasons were referred by 37% (24/65) of the professionals. In the context of this survey, we were not able to follow-up to clarify what discomfort means or to probe understanding lack of partner acceptance. We were also not able to find out what these other reasons were which led to the discontinuation of this barrier contraception. Also, we do not have data about the discontinuation rates of clients, so it is not clear how many clients this represents.

Note: This was a multiple-choice question, and providers could check as many responses as they felt applied. The percentages reflect the number of responses.

Q. Did you have patients who are not able to use Caya diaphragm for these reasons?

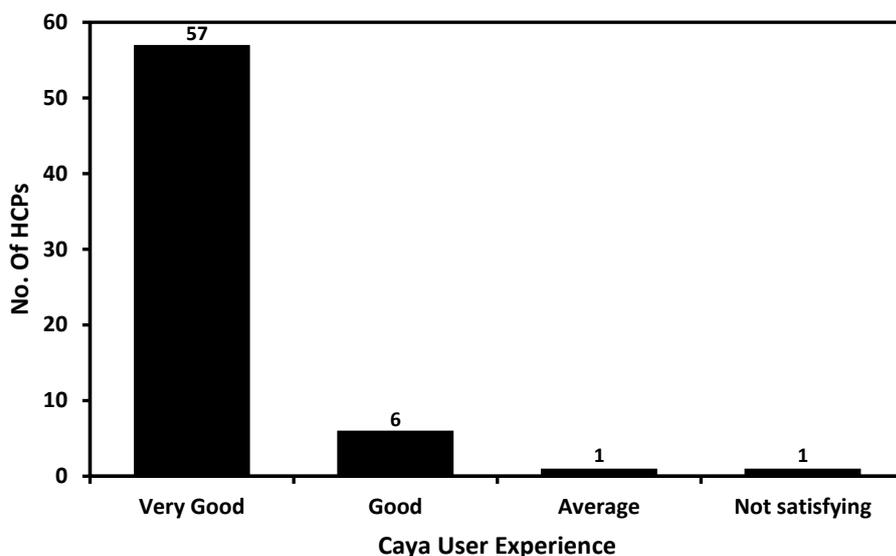


We asked providers if they had clients who could not use Caya, and if so for what reasons. This graph ranks the primary reasons why Caya diaphragm is not suitable for some clients. Anatomical limitations received the highest number of responses of about 46% (30/65), followed by “pelvic floor weakness” (25%; 16/65) and “other reasons” (23%; 15/65). Almost 20% (13/65) of providers also mentioned that women couldn’t use Caya due to ongoing pregnancy or 6 weeks after giving birth or 14% (9/65) due to undergoing treatment for vaginal infections. In context to this survey, we did not probe what is meant by “other reasons”. Also, we do not have data about the estimated number or percent of clients who providers determine are not able to use Caya, so we do not know how frequently providers encounter these women.

These reasons why a woman might not be able to use Caya already are listed in the Caya instructions for use, and provider guidance. In future discussion with providers, it might be interesting to explore what types of “anatomical limitations” are encountered, if this is separate from “pelvic floor weakness”, and some examples of “other reasons”.

Note: This was a multiple-choice question, and providers could check as many responses as they felt applied. The percentages reflect the number of responses.

Q. What is the overall experience of your patients with Caya diaphragm?



Providers responding to this survey reported that almost all their clients have positive experience using Caya diaphragms, with 98% of respondents indicating client experience was either “Very good” or “good” and only 2% of respondents indicating their perception of women’s experience with Caya was “average” or “not satisfying”.

Discussion:

This survey sheds light on the experience and perceptions of health care providers in Germany whose clients use Caya diaphragm and their perceptions of women’s experience using Caya.

Recruiting participants from the database of qualified Caya providers was a successful strategy. While response rates to online surveys vary widely depending on the subject matter, how recruited and how the survey is administered, the 49% response rate is considered in the market research field to be a good/very good response rate for online survey.

The respondents represented both experienced providers (i.e., having provided Caya for more than 4 years) and a less experienced providers (i.e., those who provided Caya for 1-2 years). The providers cumulatively estimated about 3000 clients used Caya diaphragm. Providers estimated that a majority of clients (2087/2895) had used Caya diaphragm for 18 months or longer, but some providers had clients who were relatively new Caya users. So overall, these respondents were able to reflect on experience of a range of women using Caya in Germany.

Providers reported that most clients previously used some form of hormonal contraception. This is not surprising as hormonal contraceptives—particularly oral contraceptive pills—are the most widely used contraceptive method in Germany.

Interestingly, more than 70% of providers reported clients use Caya along with another contraceptive method. The survey did not ask follow-up questions to understand if this means dual method use (i.e., using two methods at the same time) or alternating methods (using different methods at different times). We know from the consumer surveys that have been implemented that about 50% of women

Caya Provider Survey

report using Caya along with another method. The methods most frequently listed by women are condoms, natural family planning and fertility awareness methods.

Providers confirmed the key reasons they believe women choose and continue using Caya, i.e., because Caya is nonhormonal, user-initiated, and reusable. These reasons are important to women, especially those who cannot or do not want to use other methods. These characteristics are part of what makes Caya unique among other contraceptive options.

Most providers (48/65; 65%) indicated that their clients did not have difficulty using Caya diaphragm. Of the 23 providers (35%) who indicated some clients had difficulty, providers reported most difficulties with insertion of the diaphragm and fewer difficulties with removal. Again, results from the consumer surveys provides additional insights. In those surveys, across the years where this question has been asked, about 17% of women responded they had some difficulty using Caya, and difficulty confirming correct placement of the diaphragm over the cervix was the most common challenge.

Most providers (61%) indicated clients did not experience displacement of the diaphragm during sex. It is troubling that 39% of providers responded that some clients experienced displacement of Caya during sex. The survey did not include follow-up questions to probe these responses and better understand how many clients experienced displacement, what is meant by displacement, i.e., did the provider/client believe displacement put her at risk of unintended pregnancy—the cervix uncovered) or did the diaphragm rotate during sex, and any actions the woman took after she noted displacement. Without having more detail about the number of cases where providers believed clients experienced Caya being displaced during sex, it is hard to interpret this finding. From the consumer survey, women who use Caya have not reported displacement as a problem associated with Caya use. This might be due to first time use, incorrect use, discontinuous use, or other factors. Further, the displacement of Caya diaphragm during intercourse led to discontinuous use of this method in these women is unknown. It is also possible that these women could address and solve this issue on their own or after consultation with their HCPS.

Providers in this survey confirm that Caya diaphragm is safe, and few women report side effects from the diaphragm or using Caya Gel (or Contragel). In this survey, 97% of providers said clients did not experience side effects with Caya diaphragm and 89% of providers reported no side effects with use of Caya Gel (Contragel).

For clients who discontinue using Caya diaphragm, providers reported their perception of the most frequent reasons were “discomfort” or “lack of partner acceptance”. This survey did not include probes to better understand these provider responses and we don’t have data about discontinuation rates, so it is not possible to know how many clients these perceptions refer to. We know that no one method will meet all users’ needs and there will be women who decide Caya is not the right for them for various reasons.

However, most providers responded that their client’s experience with the Caya diaphragm was either very good (87%) or good (11%), with only 2% reporting client experience as average or negative, so it seems that the number of clients who discontinue due to discomfort or lack of partner acceptance may be small relative to the overall client experience the providers are reflecting.

Limitations:

This survey was conducted among health care professionals in Germany exploring provider perception about Caya diaphragm and providers' perception about client experience with the diaphragm. These results reflect experiences and perceptions of health care providers who were recruited from a database of qualified Caya providers. These results may not reflect all Caya providers in Germany or the experience of all Caya users, and so are not generalizable to other countries and communities. Providers were asked to estimate the number of clients in their practice who use Caya diaphragm, characterize the approximate length of time clients have used Caya, and respond to questions about provider perception of client experiences overall. We recognize that summarizing client experience leads to generalizations that can lose detail of specific user experiences, but this initial survey helped us explore provider perception of clients' experiences and of the Caya diaphragm. The survey did not provide follow-up probes which could have given participants the opportunity to further explain their responses. We realized that some questions were worded in a way that could be confusing. The Medintim team has refined the survey questions to improve clarity.

Implications of this study:

This is the first study among healthcare providers exploring provider experience and perception about client experience with the Caya diaphragm. Implementation of this survey led to some questions being refined to improve clarity and reduce confusion. Medintim is encouraging Caya distribution partners in other countries to implement similar surveys in their markets to build understanding about Caya diaphragm experience and improve service delivery and training.

Attachment 1

Questions in the Survey

1. About how long have you been providing Caya diaphragms in your practice?
2. About how many of your patients currently use Caya diaphragms (estimated number)?
3. Among your patients who choose Caya diaphragm as their contraceptive, about how long do you think they have been using this method?
4. What contraceptive method did your patients use before switching to Caya diaphragms?
5. Do your patients use the Caya diaphragm in combination (alternate/combined) with other contraceptive methods?
6. Did your patients report any difficulty in insertion or removal of Caya diaphragm?
7. Did your patients report any side effects of using Caya diaphragm?
8. Did your patients report any side effects using Caya Gel / Contragel with the Caya diaphragm?
9. About how many of your patients report displacement of Caya diaphragm during intercourse?
10. Of your patients who continue using Caya, what do you think are the primary reasons they like this method?
11. Of your patients who discontinue using Caya, what do you think are the primary reasons they discontinue?
12. Did you have patients who can't use Caya diaphragms due to the following reasons? (Provide a column for estimated numbers?)
13. What is the overall experience of your patients with Caya diaphragm?