

# Patients' and professionals' barriers and facilitators of tailored expectant management in subfertile couples with a good prognosis of a natural conception

N.M. van den Boogaard<sup>1,2,\*</sup>, E. van den Boogaard<sup>1</sup>, A. Bokslag<sup>1</sup>, M.C.B. van Zwieten<sup>3</sup>, P.G.A. Hompes<sup>2</sup>, S. Bhattacharya<sup>4</sup>, W. Nelen<sup>5</sup>, F. van der Veen<sup>1</sup>, and B.W.J. Mol<sup>1</sup>

<sup>1</sup>Centre for Reproductive Medicine, Academic Medical Centre, Amsterdam, the Netherlands <sup>2</sup>Department of Obstetrics and Gynaecology, Vrije Universiteit Medical Centre, Amsterdam, the Netherlands <sup>3</sup>Division Clinical Methods and Public Health, Department of General Practice, Academic Medical Centre, Amsterdam, the Netherlands <sup>4</sup>Department of Obstetrics and Gynaecology, University of Aberdeen, Aberdeen, UK <sup>5</sup>Department of Obstetrics and Gynaecology, Radboud University Nijmegen Medical Centre, Nijmegen, the Netherlands

\*Correspondence address. E-mail: n.m.vandenboogaard@amc.uva.nl

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**BACKGROUND:** European guidelines on fertility care emphasize that subfertile couples should receive information about their chances of a natural conception and should not be exposed to unnecessary treatments and risks. Prognostic models can help to estimate their chances and select couples with a good prognosis for tailored expectant management (TEM). Nevertheless, TEM is not always practiced. The aim of this study was to identify any barriers or facilitators for TEM among professionals and subfertile couples.

**METHODS:** A qualitative study was performed with semi-structured in-depth interviews of 21 subfertile patients who were counselled for TEM and three focus-group interviews of 21 professionals in the field of reproductive medicine. Two theoretical models were used to guide the interviews and the analyses. The primary outcome was the set of identified barriers and facilitators which influence implementation of TEM.

**RESULTS:** Among the subfertile couples, main barriers were a lack of confidence in natural conception, a perception that expectant management is a waste of time, inappropriate expectations prior to the first consultation, misunderstanding the reason for expectant management and overestimation of the success rates of treatment. Both couples and professionals saw the lack of patient information materials as a barrier. Among professionals, limited knowledge about prognostic models leading to a decision in favour of treatment was recognized as a main barrier. A main facilitator mentioned by the professionals was better management of patients' expectations.

**CONCLUSIONS:** We identified several barriers and facilitators which can be addressed to improve the implementation of TEM. These should be taken into account when designing future implementation strategies.

**Key words:** infertility / prognostic models / implementation / barriers / expectant management

## Introduction

Approximately 9% of all couples of reproductive age fail to conceive after 12 months of unprotected intercourse (Gnoth *et al.*, 2003; Boivin *et al.*, 2007). When they subsequently undergo a fertility work-up, no major cause can be found in half of these couples (Aboulghar *et al.*, 2009). Previous studies have shown that many of these couples can still conceive without treatment (Evers *et al.*, 1998;

Collins, 2004; Steures *et al.*, 2006; Pinborg *et al.*, 2009; Brandes *et al.*, 2010). It is therefore crucial to be aware of the prognosis in these couples in order to discriminate between those who would benefit from active treatment and those who are likely to conceive naturally (Brandes *et al.*, 2011).

The chances of a spontaneous pregnancy can be calculated with the help of validated prediction models (Hunault *et al.*, 2004; van der Steeg *et al.*, 2007). When the calculated prognosis to conceive

within 12 months is  $\geq 30\%$ , tailored expectant management (TEM) is as effective as treatment, which makes TEM a cost effective strategy that prevents overtreatment, complications and costs (Steures *et al.*, 2006). Therefore, in the Dutch fertility guidelines, expectant management is recommended for couples with a  $\geq 30\%$  chance of conceiving within 12 months (NVOG, 2004). In agreement with this, both the European Society of Human Reproduction and Embryology (ESHRE) guidelines and the guidelines of the National Institute of Clinical Excellence (NICE) emphasize that couples should not be exposed to unnecessary risks or ineffective treatments and encourage that each couple should receive information about their chances of natural conception (ESHRE, 2001; NICE, 2004).

Despite this, the number of Assisted Reproductive Therapy (ART) cycles performed in Europe has more than doubled in the period 1996–2006 (Andersen *et al.*, 2009). This development is disconcerting for several reasons. First, this increase is likely to lead to a high number of multiple pregnancies. Even though multiple pregnancy rates per ART cycle are decreasing, the risks are still substantially higher than those in spontaneous conceptions. Multiple pregnancies are associated with a higher morbidity and mortality in both mothers and neonates (Helmerhorst *et al.*, 2004). Second, ART carries a significant physical and a psychological burden (Verhaak *et al.*, 2002, 2007; Verberg *et al.*, 2008). Third, ART is expensive and puts considerable financial strain on societies where ART is reimbursed or on the couples in societies where ART is not or only partially reimbursed.

For all these reasons, it is important to treat only couples who genuinely need ART and are likely to benefit from it. Prognostic models, such as the prognostic model of Hunault, can help to select those couples. Nevertheless, these models and subsequent TEM are not fully applied in clinical practice (Mourad *et al.*, 2008; van den Boogaard *et al.*, 2011). A clear understanding of why the prognostic models and subsequent TEM are not used in practice is lacking. Therefore, the aim of this study was to identify patients' and professionals' barriers and facilitators for the implementation of TEM.

## Materials and Methods

A qualitative study was performed with subfertile couples and professionals working within the field of reproductive medicine. We performed semi-structured in-depth interviews among subfertile couples and professionals in an individual and group setting, respectively. We opted for semi-structured interviews to let the participants (i.e. patients and professionals) talk freely with structured guidance from the interviewer, using a topic list. The topic list (Supplementary Information 1) was based on the literature and on the knowledge and experiences of all of the co-authors, working in the fields of reproductive medicine, qualitative research or implementation research. The topic list was adapted when new barriers or facilitators were identified. Prior to the start of the interviews, confidentiality was assured and the process of the interview was explained. We continued interviewing until data saturation was achieved, i.e. no additional information was gathered during subsequent interviews. The interviews were audio taped and fully transcribed and quotes were all made anonymous. The primary outcome was the set of identified barriers and facilitators which might influence the implementation of TEM.

The subfertile couples whom we interviewed were diagnosed with unexplained subfertility and had a chance of conceiving within 12 months of  $\geq 30\%$ . For that reason they had been counselled for TEM. We interviewed couples who had been advised TEM between April 2008 and April 2009.

The couples were recruited from two hospitals in Amsterdam: one academic hospital and one non-academic teaching hospital. We chose an individual setting as we expected that in this setting patients would feel more free to speak. Couples with different ethnic backgrounds and education levels were sampled on purpose because we hypothesized these characteristics could influence their experience of the expectant management. The couple could choose the location of the interview which was conducted either at their hospital or at their own home. We preferred to interview the man and the woman separately, unless the couple preferred to be interviewed together. We performed 15 interviews with 21 patients: 6 women and 3 men were interviewed individually and 6 couples were interviewed together. The interviews were performed by two researchers (N.B. and A.B.) and took 30–50 min.

We also interviewed 21 professionals in 3 focus-group interviews. Gynaecologists specialized in Reproductive Medicine and registered as such at the Dutch Society of Obstetrics and Gynaecology (NVOG) and gynaecologists with interest in the field of reproductive endocrinology and infertility and fertility doctors, from 17 different hospitals from 4 different regions were all invited per mail. In total, we invited 53 professionals: 3 gynaecologists, 7 fertility doctors from an academic hospital, 27 gynaecologists and 16 fertility doctors from non-academic hospitals. Gynaecologists and fertility doctors of 10 different academic and non-academic hospitals from 4 different provinces in the Netherlands participated voluntarily. In the Netherlands, fertility doctors are basic doctors working in fertility care, while most gynaecologists also work in the field of obstetrics and general gynaecology. Prior to the interviews, it was unclear to what extent the professionals used the prognostic models and subsequent TEM. The group setting was chosen because we expected that the group interaction might lead to the identification of more relevant barriers. The focus-group interviews were guided by a chairman (E.B.) and another researcher (N.B.) attended as a back up. The focus-group interviews took 60–90 min.

## Setting

In the Netherlands, intrauterine insemination (IUI) is performed in 91 of the country's 101 hospitals and IVF is performed in 13 licensed hospitals. All 101 hospitals can perform a fertility work-up and give advice on TEM. The costs of IUI (for an undefined number of cycles) and the first three fresh IVF or ICSI cycles are currently reimbursed by medical insurance companies. In the Netherlands, it is compulsory to have medical insurance. Professionals have access to prognostic models via two websites ([www.amc.nl/prognosticmodel](http://www.amc.nl/prognosticmodel) and [www.freya.nl](http://www.freya.nl)), with the help of electronic patient files or with the use of paper versions of the models.

## Analysis

All interview transcripts were independently analysed by two researchers: the interviews with the subfertile couples were analysed by A.B. and N.B. and the focus-group interviews with the professionals were analysed by E.B. and N.B. MAXqda10, an analysis programme for qualitative data-analysis, was used for the analysis which was based on the strategy described by Boeije *et al.* (2010). The aim of the analysis was to conceptualize the content of the interviews in structured categories. First, the interviews were analysed by means of line by line coding, using a constant comparison method: newly gathered data are continually compared with previously collected data and their coding in order to refine the development of theoretical categories. After this open coding, the codes were rearranged by axial coding and finally categorized by means of selective coding. Axial coding is relating codes to each other and selective coding is the process of choosing one category to be the core category, and relating all other categories to that category. Finally, all transcripts were reread and recoded, using the improved coding structure to ensure no codes were missing. To ensure consistency, codes were compared and any

discrepancies were resolved by discussion between the two researchers. Differences of opinions were discussed with a third researcher (M.Z. for the patient interviews and W.N. for the focus-group interviews).

We used two theoretical models to group our findings within four domains: characteristics of the intervention itself (TEM), of the professional, of the patient and of the context (Cabana et al., 1999; Peters et al., 2003).

## Results

Patient characteristics, summarized in Table I, showing a degree of variety in terms of educational and cultural backgrounds. Characteristics of the professionals are listed in Table II, which shows the variation in experience and use of the prognostic model between gynaecologists (50%) and fertility doctors (100%).

Factors (barriers and facilitators) mentioned by at least two participants are listed in Table III (subfertile couples) and Table IV (professionals). Factors mentioned by more than 50% of the participants are described in the text and marked in the tables with an asterisk (\*). In both the tables and the text, the barriers and facilitators are ranked by how much they were mentioned. Quotes illustrating some of the barriers and facilitators are provided in Supplementary data, Table S1.

**Table I Patient characteristics.**

Characteristics	Value, n (%)
Gender	
Female	12 (57%)
Male	9 (43%)
Age (median)	
Female (range)	32 (21–37)
Male (range)	35 (27–43)
Diagnosis	
Unexplained primary subfertility	9 (43%)
Unexplained secondary subfertility	12 (57%)
Prognosis (median, range)	36% (33–57%)
Duration of subfertility (months) (median, range)	22 (18–48)
Education level	
Low <sup>a</sup>	4 (19%)
Medium <sup>b</sup>	6 (29%)
High <sup>c</sup>	11 (52%)
Ethnic background	
Dutch	12 (57%)
Non-Dutch <sup>d</sup>	9 (43%)
Turkish	2
Moroccan	3
Afghan	1
Colombian	2
Unknown	1

<sup>a</sup>Primary school or less.

<sup>b</sup>High school.

<sup>c</sup>University/postgraduate.

<sup>d</sup>The place of birth of the patient or both parents is outside the Netherlands, excluding its dominions.

## Barriers and facilitators related to the implementation of TEM according to subfertile couples

There were 16 barriers and facilitators identified among the 15 subfertile couples, i.e. 21 patients (Table III). Three men did not participate because they had no time or did not remember the details and referred us to their partners, who were more involved. Overall women were more committed and informed about the whole procedure than men. At the time of the interview, two couples were pregnant and three couples had started treatment of intrauterine insemination with controlled ovarian hyperstimulation. The other nine interviewed couples were still in the period of expectant management.

### Domain 1: Characteristics of the intervention

A lack of confidence in natural conception and a perception that expectant management is a waste of time were barriers in this domain. These two factors had a common underlying cause in that they were based on the perception of the couples that they had already been trying to conceive for a long period.

The subfertile couples could not remember the information that had been given concerning their prognosis and the reason for expectant management. Therefore, information provision by means of a brochure or a website about the prognostic model and subsequent expectant management was mentioned as a facilitator.

### Domain 2: Characteristics of the professional

Not informing the couple about the option of TEM during the first consultation was mentioned as a barrier in this domain. Couples expected treatment after the fertility work-up unless they were already told beforehand that TEM was an option.

### Domain 3: Characteristics of the patient

Barriers mentioned in domain 3 were: inappropriate expectations prior to the first consultation, misunderstanding the reason for TEM, overestimation of success rates of treatment, inability to comprehend and retain the information given during the consultation and irrational interpretations of pregnancy chances. The last, i.e. 'irrational interpretations of chances' refers to the finding that despite awareness of their prognosis and understanding why it was better to wait, couples still wanted treatment. Couples saw treatment as a forgone conclusion after the fertility work-up, did not

**Table II Characteristics of professionals.**

	Gynaecologists, n = 9	Fertility doctors, n = 13
Male, n (%)	3 (33%)	3 (23%)
Female, n (%)	6 (67%)	10 (77%)
Median age, (range)	48 (41–64)	34 (27–45)
Median years of expertise (range)	17 (8–35)	6 (1–13)
Academic hospital, n (%)	1 (11%)	5 (38%)
Regular use of the prognostic model, n (%)	4 (50%)	13 (100%)

**Table III Barriers (b) and facilitators (f) of TEM according the subfertile couples.**

Domain 1: Characteristics of the intervention	Domain 2: Characteristics of the professional	Domain 3: Characteristics of the patient	Domain 4: Characteristics of the context
Lack of confidence in natural conception (b)*	Not informing the couple about the option of TEM during the first consultation (b)*	Inappropriate expectations prior to the first consultation (b)*	The length of time taken for the whole process (b)*
Patient information material about prognosis and TEM (f)*	Unclear way of counselling and communicating chances (b)	Misunderstanding the reason for TEM (b)*	Practice in other clinics (b)
A perception that TEM is considered as a waste of time (b)*	Not explicitly mentioning TEM, but concealing TEM in waiting period for treatment (f)	Overestimation of the success rates of treatment (b)*	
Complexity of the prognostic model (b)		Inability to comprehend and retain information given during the consultation (b)*	
		Irrational interpretation of pregnancy chances (b)*	
		Progressing female age (b)	
		Twin pregnancy is a welcome complication (b)	

\*Factors mentioned by more than 50% of the participants.

**Table IV Barriers (b) and facilitators (f) of TEM according professionals.**

Domain 1: Characteristics of the intervention	Domain 2: Characteristics of the professional	Domain 3: Characteristics of the patient	Domain 4: Characteristics of the context
Existing prognostic models do not include all the relevant predictors (b)*	Limited knowledge about the prognostic models and subsequent TEM (b)*	High expectations of success with treatment (b)*	Regular Fertility meeting (f)*
Lack of appropriate patient information materials (b)*	Difficulties convincing couples who have their minds made up (b)*	Urgency for action in the couple (b)*	Local protocol (f)*
Not convinced about the usefulness of the prognostic models and TEM (b)	Difficulties in counselling and communicating chances (b)*	Expectations of immediate treatment after the fertility work-up (b)*	Local consensus (f)*
Explaining TEM takes time (b)	Comparison of treatment chances versus spontaneous pregnancy chances (f)*	Couples' misinterpretation of pregnancy chances (b)*	Centralization of fertility care (f)*
	Close relationship with couple (b)	Progressing female age (b)	Regional organization (f)
		Miscarriage population (b)	

\*Factors mentioned by more than 50% of the participants.

understand why expectant management was advised and had unrealistic high expectations of treatment outcomes.

#### Domain 4: Characteristics of the context

The length of time taken for the whole process was mentioned as a barrier: the period prior to the couples' hospital visit plus the subsequent time needed for the fertility work-up already took 'too long' such that TEM was seen as another delaying factor.

### Barriers and facilitators related to the implementation of TEM according to professionals

Among the 21 professionals, 20 barriers and facilitators influencing the implementation of TEM were identified (Table IV). There was a wide

range of knowledge and attitudes concerning prognostic models and subsequent TEM. For some professionals, it made sense to use a prognostic model to plan TEM, but others had less faith in the TEM strategy and did not use it in their clinic on a regular basis.

#### Domain 1: Characteristics of the intervention

Two barriers were identified in this domain: existing prognostic models do not include all the relevant predictors and there is a lack of appropriate patient information materials. The missing predictors within prognostic models mentioned by professionals were mainly lifestyle factors such as body mass index and frequency of coitus. To overcome the barrier 'lack of adequate patient information materials', the professionals suggested the development of a brochure and/or the introduction of a website.

### Domain 2: Characteristics of the professional

Limited knowledge about the prognostic models and subsequent TEM, difficulties in convincing couples who have their minds made-up and difficulties in counselling and communicating pregnancy chances, were barriers in the second domain. There was consensus that good counselling skills were very important for communication to the patient that TEM was their best treatment option at that moment.

A facilitator in this domain was the comparison between the spontaneous chances of pregnancy with the realistic pregnancy chances after treatment. Professionals mentioned that many couples have unrealistically high expectations of treatment, which make it difficult for the professional to convince them that TEM is the best option. In this way, the comparison helped in counselling the couples for TEM.

### Domain 3: Characteristics of the patient

The couples' high expectations of treatment, urgency for action, expectation of immediate treatment after the fertility work-up and misinterpretation of pregnancy chances were barriers in the third domain. According to professionals, couples expectations of treatment were too high and the couples' urgency for action made it difficult to counsel them for TEM. Managing couples' expectations regarding treatment success and the moment of treatment were mentioned as major facilitators.

### Domain 4: Characteristics of the context

A regular fertility meeting involving other professionals, a clinical protocol based on local consensus, and centralization of fertility care were facilitators mentioned in the fourth domain. A fertility meeting is a weekly or monthly meeting, during which all fertility patients who have finished their basic fertility workup are discussed.

## Discussion

We identified a wide variety of barriers and facilitators influencing the implementation of TEM for unexplained subfertility. Among the subfertile couples the main barriers were: (i) a lack of confidence in natural conception, (ii) inappropriate expectations at the first consultation, (iii) misunderstanding the reason for the expectant management and (iv) overestimation of the chances of success with treatment. Both couples and professionals experienced the lack of patient information materials as a barrier. Among the professionals, limited knowledge about prognostic models and subsequent TEM and inappropriate expectations of couples were recognized as main barriers. Better management of couples' expectations was suggested as a main facilitator.

Many barriers involved patients, which is in line with results of existing studies on barriers for implementation within the scope of fertility health care (Haagen et al., 2005; van Peperstraten et al., 2008). The professionals' barriers concerning the difficulties counselling, convincing and communicating with the couple can be summarized as a lack of self-efficacy, which is a common barrier in guideline adherence (Cabana et al., 1999; Haagen et al., 2005; Lugtenberg et al., 2009). The barriers concerning misunderstanding the prognosis, inappropriate expectations and lack of patient information materials all have to do with communication and information provision. Previous research among 1499 Dutch subfertile couples who fulfilled a questionnaire concerning their experiences with fertility care also found that

information provision is poor and in need for improvement (Mourad et al., 2009, 2010). Also in other countries, couples often express a need for more written information about fertility treatment (Schmidt, 1998; Souter et al., 1998). The subfertile couples' preference for treatment compared with expectant management is consistent with the findings of several other studies, including a three arm randomized controlled trial in which the women treated actively with intrauterine insemination or clomifene citrate, found the process of treatment more acceptable than those randomized to expectant management (Bhattacharya et al., 2008). In a questionnaire study where coping strategies of couples presenting for IVF were evaluated, taking direct action was the coping strategy most frequently used (Edelmann et al., 1994). In a preference study evaluating patients' preferences between intrauterine insemination with or without controlled ovarian hyperstimulation and expectant management, couples preferred treatment when the treatment independent pregnancy chances in the next 12 months were lower than 50 or 40%, respectively (Steures et al., 2005).

Only half of the gynaecologists, but all of the fertility doctors interviewed in this study reported using a prognostic model to recommend subsequent TEM on a regular basis. This corresponds with a previous study about risk factors for overtreatment, in which the non-adherence to TEM was >35% and the presence of a fertility doctor was associated with an increase of this adherence (van den Boogaard et al., 2011). This variation in adherence to TEM in the interviewed professionals, as well as the heterogeneity of the cultural background and educational level of the interviewed patients, lead to the identification of a wide variety of barriers and facilitators and is therefore a strength of our study.

In our study, both the subfertile couples and the professionals mentioned difficulties in interpreting and communicating chances of success. From previous research, we know that the perception of chances is influenced by the way chances are framed. In this respect, a comparison with a baseline-risk and the use of visual tools can help to communicate chances in a more user friendly manner (Wertz et al., 1986; Shiloh S and Saxe L, 1989; Edwards and Prior, 1997; Grimes and Snively, 1999). Regarding the chances of natural conception in our study, no defined 'baseline prognosis' is available yet and the professionals in this study did not use visual tools to facilitate the communication of the prognosis. Therefore this can be opportunity for improvement.

Among the subfertile couples, women were generally more committed and informed than were men. This gender difference is in concordance with other studies where couples were asked about their expectations and motivation for seeking fertility treatment. In most cases the woman sought treatment for herself and her partner and the man sought treatment more for his partner than for himself (Schmidt et al., 2003).

We realize there are some limitations in this study that should be considered. First, all interviewed couples were recruited from only two hospitals both in the region of Amsterdam. The barriers and facilitators could be biased by the way fertility care was provided in those two hospitals. However, the two hospitals are large training hospitals, one academic and one non-academic hospital, working according the guidelines and we do not expect the provided fertility care differs much from that at other hospitals. Couples living in rural areas might have a different view on TEM compared with patients from

an urban area. Nevertheless we think that the patients' origin has limited influence on the experienced barriers and facilitators because in such a densely inhabited country as the Netherlands differences between urbanized and non-urbanized areas are small and with the current use of internet and social media, patients from the 'non-urbanized' areas are able to be as informed and up to date as patients from the 'urbanized areas'. Moreover, further quantification of the barriers and facilitators is needed among patients from more hospitals. Second, a limitation of this study might be the Dutch setting. Dutch patients and professionals may have different opinions about the use of prognostic models and subsequent TEM than patients and professionals in other countries. However, the barriers and facilitators we found were not specifically related to the Dutch setting. We therefore consider the identified barriers and facilitators applicable for an international setting, if the reimbursement system is comparable. Third, the participation rate of the professionals (21 out of 54) was low, possibly because the participation was voluntarily. Because we continued interviewing until data saturation was achieved, we do not think this response rate influenced the set of identified barriers and facilitators. Fourth, a potential limitation of qualitative research is the introduction of bias by different interpretations of the transcripts. Therefore, two individual researchers examined all transcripts and differences of opinions were discussed with a third researcher. Discrepancies were discussed until agreement was reached. Finally, although we aimed to interview men and women separately, we interviewed half of the couples together at their request. Nevertheless, we did not find different results in couples interviewed together compared with couples interviewed separately. We also did not get the impression during the interviews that one of the interviewees was unable to speak freely because of the presence of the other partner.

As stated above, to measure the impact of the barriers and facilitators found in this study, a further quantification of these results is needed. After quantification of these barriers and facilitators, an implementation strategy can be developed. On the basis of the results of this study, this strategy needs to focus on better management of couples' expectations, education of the professionals about prognostic models and subsequent TEM, training professionals for communication about TEM and adequate patient information materials.

In summary, this study gives insight into the barriers and facilitators of the use of prognostic models and subsequent TEM. Knowledge of these factors may help to improve implementation of TEM in clinical practice and reduce potentially harmful and costly overtreatment.

## Ethical approval

Subjects did not undergo additional investigations nor treatment. As assessed by the Institutional Review Board (IRB) of the Academic Medical Centre Amsterdam, the study was not subject to the Dutch 'Medical Research Involving Human Subjects Act', meaning that no formal IRB approval was needed.

## Supplementary data

Supplementary data are available at <http://humrep.oxfordjournals.org/>.

## Authors' roles

B.W.J.M., F.V. and P.G.A.H. initiated and designed and contributed in the interpretation of the data. N.B, E.B. and A.B. performed the interviews and did the analysis under the supervision of M.Z. and W.N. S.B. contributed in the interpretation of the data. N.B. wrote the manuscript and all authors helped to prepare the final manuscript.

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