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Treatment preferences of patients with Crohn's disease: Development of the IMPLICA questionnaire

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ABSTRACT

Introduction and objective: Patient preferences with respect to available therapies must be taken into account if the quality of care of patients with Crohn's disease is to be improved. The objective was to develop the IMPLICA preferences questionnaire for Crohn's disease patients treated with biological therapies.

Methods: As per standard methodology, the questionnaire was developed in Spanish language, in five stages: 1. Literature review to identify attributes related to biological therapies in Crohn's disease; 2. Expert meeting to identify attributes most relevant for patients; 3. Scoring of the most relevant attributes and generation of scenarios; 4. Patient comprehension test for selection and validation of scenarios; and 5. Final list of scenarios and qualitative evaluation of those most accepted by patients.

Results: Three attributes related to various characteristics of biological treatments were selected: route of administration, place/duration of administration and person administering the treatment; a combination of them produced seven possible scenarios. The comprehension test gave rise to significant modifications in the instructions, text of the scenarios and response categories.

Conclusion: IMPLICA is the first questionnaire to evaluate treatment preferences of Crohn's disease patients receiving biological therapies. This questionnaire facilitates patient's selection of the most appropriate real world treatment option and, therefore, it can be considered a useful tool when deciding the most appropriate and feasible treatment in normal clinical practice.

Key words: Crohn's disease. Preferences. Biological therapy.

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INTRODUCTION

Crohn's disease (CD) is a chronic gastrointestinal (GI) inflammatory disease that may affect any part of the digestive tract. The prevalence of CD in Spain is estimated to be 87.5 patients per 100,000 of the general population (1).

The introduction of anti-TNF biological therapies for the treatment of CD has significantly reduced the number of relapses, invasive tests and hospitalizations (2,3). CD causes an important deterioration in quality of life of patients (4) which may improve, even to a normal perceived health status, in the majority of patients treated with biological therapies (5). Short and long term beneficial effects of biological therapies, for CD patients suggest that their use will increase over time.

Aspects such as price and access to biological treatments do not currently impact CD patients in Spain. For this reason, and because of the similar efficacy and safety profiles of available biological treatments (7) it seems logical to seek patient's involvement in the choice of treatment. Various studies have shown that patients with CD wish to be actively involved in the decision making process (8,9), which is also related to better therapeutic adherence (10,11) and leads to more effective treatment and a consequent better control of the disease and improvement in quality of life.

Previous studies have assessed patient preferences with respect to the risk-benefit balance of treatments that can be determinant when making a treatment choice (12). The majority of those performed on patients with CD are based on the risk-benefit of treatments (13-15), while few are based on patient preferences related to the method or route of administration of a biological treatment (16).

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Evaluation of preferences is performed by means of questionnaires that usually compare different types of treatment. "Conjoint analysis" is one of the techniques used to develop questionnaires and evaluate preferences in areas such as market investigations (17) or in healthcare (18,19), conjoint analysis is based on the preferences expressed by patients based on a defined set of options or therapeutic scenarios.

Since the use of biological therapies in the treatment of CD is becoming more common and more frequently patients are involved in deciding which biological treatment they are going to be treated with, it seems necessary to have a tool or questionnaire for the standardized evaluation of patient preferences with respect to biological therapies that will at the same time improve the quality of care of CD patients.

The aim of this qualitative research is to describe the development of the IMPLICA patient preferences questionnaire for CD patients treated with biological drugs.

METHODS - DEVELOPMENT OF THE QUESTIONNAIRE

The IMPLICA (patient involvement in decision making in Crohn's disease) questionnaire for the evaluation of preferences for treatments of patients with CD. We would like to highlight that patients' participation in different phases was essential in IMPLICA questionnaire development. This questionnaire has been developed in Spanish language, and the development process included the five following phases:

1. Literature review and identification of attributes

A literature search and review was first performed to identify treatment characteristics that would be most relevant from the point of view of a CD patient. Based on this information, a list of attributes (characteristics) related to patient preferences, with respect to CD treatment, was prepared.

2. Expert meeting

A group of four CD experts with previous experience in patients preference studies reviewed the list and selected those attributes that, in their opinion, patients would find feasible and important. Each one of the experts rated the attributes from greatest to least importance. Also, the group assigned different levels/options to each of the selected attributes. Furthermore, it was agreed that the IMPLICA questionnaire should be based on real treatment options. An assumption of equivalence of efficacy and safety of biological treatments was made, based on the European evidence-based Consensus on the prevention, diagnosis and management of opportunistic infections in inflammatory bowel disease of the European Crohn's and Colitis Organization (ECCO) guidelines (6).

3. Scoring of attributes and generation of scenarios

Based on the work of the experts, the various attributes and levels were combined to prepare an initial group of scenarios. Scenarios that did not reflect a real situation were eliminated, as consensually recommended by the experts.

Using the resultant group of scenarios, the attributes related to biological treatments that would be most useful or important to patients when making decisions on the choice of treatment for CD were selected. This was achieved by using the scores assigned to each attribute/characteristic in the expert meeting. The resultant scenarios were used to prepare the first version of the IMPLICA questionnaire.

4. Selection and validation of scenarios

Using the selected scenarios, linguistic comprehension of the questionnaire was assessed by administering it to a group of five CD patients treated with biological therapies, without particular disease severity.

For each scenario, patients had to answer questions related to wording of the questionnaire's instructions, to the scenarios, and to the response options. As a result, the second version of the IMPLICA questionnaire was produced.

5. Final wording of the questionnaire

Because the redaction of the scenarios and response categories had changed in a significant manner, it was decided that a modified IMPLICA questionnaire (version 2) should be administered to a group of 20 patients to test its comprehension and a final version of the questionnaire was prepared. In addition, a quantitative evaluation of the scenarios that were most accepted by patients was performed.

RESULTS

A MEDLINE search (limited to publications from the previous 10 years) was performed with the following descriptors: Patient* AND preferences AND (IBD OR "inflammatory bowel" OR CROH* OR "ulcerative colitis"). The search resulted in 51 articles, of which 31 were eliminated (not evaluating patient's treatment preferences or not related to any type of inflammatory bowel

disease. The attributes identified by the search were: Mode of administration, time free of symptoms/disease control, symptoms/disease control, non-serious adverse events, serious adverse events and long term serious adverse events.

The expert meeting resulted in six attributes: Route of administration, administration site and total administration time, person administering treatment, treatment adverse events (local), product source (human, animal) and time the drug has been on the market. The levels and categories shown in table I were agreed for every attribute in the same meeting.

Combining these factors produced a total of 144 scenarios, two attributes with three levels and four attributes with two levels. The total number of scenarios can be calculated as follows: $3^2x2^4 = 144$. Scenarios or situations that could not occur in real treatment were excluded, leaving 22 possible scenarios.

Of these 22 scenarios, it was observed that the attributes "adverse events", "product source", and "time on market" were directly related to the route of administration (for example, intravenous administration is associated with infusion reactions, while subcutaneous administration is associated with local reactions). Therefore, there was no reason to maintain these three attributes; the selection of one scenario or the other within a route of administration will always be associated with one of these three constant attributes. Thus, 18 possible scenarios were identified, with three variable attributes; route of administration, administration site and person who administers the treatment.

Of these 18 scenarios, those that were logically impossible or that could not occur in a real-life situation were eliminated, producing the final seven scenarios that are presented in table II. Because these seven scenarios were considered feasible, it was not necessary to undertake a fractional factorial procedure (SPSS orthoplan) (20); a technique used when the number of scenarios is much greater.

The first version of the IMPLICA questionnaire (Fig. 1) was prepared using the seven scenarios; it was then administered to a group of five CD patients for a comprehension test.

Changes were made to the instructions, scenarios and response options based on the results of the comprehension test. Changes were considered relevant when at least two patients suggested changes to the text. In summary, the instructions section was abbreviated, the text of the scenarios was reduced to make it more direct (for example, "Treatment administered by intravenous route" was changed to "Type of injection: INTRAVENOUS") and, the response options were changed from a 0 to 9 to a 0 to 4 scale (never to always) because two of the patients found it easier to score on a reduced scale. The format of the response categories was also changed. These changes were included in version 2 of the IMPLICA questionnaire (Fig. 2).

The administration of version 2 of the IMPLICA questionnaire to 20 CD patients did not result in additional changes, neither in the content nor in the format of the questionnaire. The 90 % of the CD patients answered all scenarios included in the IMPLICA questionnaire.

Scenario "F" (subcutaneous treatment, self-administration and in patient's home in less than 30 minutes) (Fig. 3) was selected "always" or "almost always" by 80.0 % of the 20 patients. The next best rated scenarios were "G" and "E" (50.0 % and 40.0 %, respectively rated them "always" or "almost always"). These three scenarios included subcutaneous treatment, and administration in the patient's

Table I. Summary of the attributes and categories selected by the expert group

Attribute	*Categories*	*Definition*	*Score*
1. Route of administration of the treatment	– Intravenous 2 h/8 weeks – Subcutaneous 5 min/2 weeks	Route of administration, duration of administration and guideline	8
2. Place of administration and total duration of administration of the treatment	– Hospital (2 h-4 h) – Home (10 min-30 min) – Outpatient (30 m-2 h)	Total time from preparation of the medication until it has been administered	7
3. Person who administers the treatment	– Healthcare personnel – Autoadministered (personnel requiring treatment) – Carer (non-healthcare personnel requiring training)	Person who can administer the drug and whether or not prior training is required	6
4. Adverse effects of the treatment	– Infusion reaction – Local reaction	Adverse reactions associated with the form of administration	1
5. Drug source	– Completely human – Partially human	Product components	3
6. Time drug has been on the market	– 12 years – 4 years	Years since commercialization of the drug	4

Table II. Scenarios selected by conjoint analysis

Route	*Site*	*Who*	*CARD_*	*Scenario eliminated*
Intravenous	Hospital (2-4 h)	Healthcare personnel	1	
Subcutaneous	Hospital (2-4 h)	Healthcare personnel	2	
Subcutaneous	Home (10-30 min)	Healthcare personnel	3	
Intravenous	Outpatient (30 m-2 h)	Healthcare personnel	4	
Subcutaneous	Outpatient (30 m-2 h)	Healthcare personnel	5	
Subcutaneous	Hospital (2-4 h)	Self administration	6	X
Subcutaneous	Home (10-30 min)	Self administration	7	
Subcutaneous	Outpatient (30 m-2 h)	Self administration	8	X
Subcutaneous	Hospital (2-4 h)	Carer	9	X
Subcutaneous	Home (10-30 min)	Carer	10	
Subcutaneous	Outpatient (30 m-2 h)	Carer	11	X
Intravenous	Home (10-30 min)	Personal sanitario	12	X
Intravenous	Hospital (2-4 h)	Self administration	13	X
Intravenous	Home (10-30 min)	Self administration	14	X
Intravenous	Outpatient (30 m-2 h)	Self administration	15	X
Intravenous	Hospital (2-4 h)	Carer	16	X
Intravenous	Home (10-30 min)	Carer	17	X
Intravenous	Outpatient (30 m-2 h)	Carer	18	X

home. The least selected scenario was "C", with 77.8 % of patients rating it "never" or "almost never", followed by options "A" and "D", with 66.6 % and 65 %, respectively. None of the least rated scenarios included home-administration.

None scenario obtained minimum overall scores (all patients answered "never") or maximum (all patients answered "always"), in other words, there are not any scenarios of IMPLICA questionnaire that have floor effect or ceiling effect.

In terms of value or scoring of the importance of attributes, it was observed that the factor "person administering treatment" had greatest influence over the selection of scenarios (importance 49.6 %), followed by "administration site of the treatment" and "route of administration", with 36.3 % and 14.1 %, respectively.

The attribute "site of administration of treatment" was selected as being most important or second most important by 84.2 % of patients when selecting scenarios in the section in which they had to place in order the three attributes of the IMPLICA questionnaire in order of importance.

Once the development phase of the IMPLICA questionnaire had been completed, the final questionnaire contained seven scenarios. Each of the scenarios had three attributes; route of administration, person administering treatment and administration site. The attribute administration site also included administration time but patients stated that it would be preferable to separate administration site from duration, as patients said there was quite information in one sentence. The English version was translated literally into Spanish and not validated in English population.

DISCUSSION

The IMPLICA is the first questionnaire for the evaluation of CD patient's preferences on biological treatments under real options of treatment.

There are many benefits, both for the patient and the healthcare professional, associated with involvement of the patient in treatment related decisions. Such an improvement in communication increases patient's satisfaction with quality of care and treatment adherence (21). It has been observed in oncology patients that the relation between communication and therapeutic adherence helps patients to better psychologically adapt to their illness (22).

It is important that CD patients are informed of the characteristics of each possible therapeutic option and understand the associated risks and benefits (23). For this reason, it is necessary that all messages and information are clear, so that each patient can make the best possible informed decision.

Option A:
Carefully read the characteristics that Option A would have:
– Treatment administered by intravenous route.
– Treatment administered by healthcare personnel.
– To have to come to hospital and be there for between 2 and 4 hours each time that you need to receive treatment for your Crohn's disease.

Now, mark with and X the score that you would give to this treatment option if you had to tell your doctor up to what point you would like/prefer this treatment.

Least preferred option Most preferred option

0 1 2 3 4 5 6 7 8 9

Option B:
Carefully read the characteristics that Option B would have:
– Treatment administered by subcutaneous injection.
– Treatment administered by healthcare personnel.
– To have to come to hospital and be there for between 2 and 4 hours each time that you need to receive treatment for your Crohn's disease.

Option C:
Carefully read the characteristics that Option C would have:
– Treatment administered by subcutaneous injection.
– Treatment administered by healthcare personnel.
– To be able to be administrated in your home and to take between 10 and -30 minutes each time that you need to receive treatment for your Crohn´s disease.

Option D:
Carefully read the characteristics that Option D would have:
– Treatment administered by intravenous route.
– Treatment administered by healthcare personnel.
– To be able to be administrated in your doctor´s practice and be there for between 30 minutes and 2 hours each time that you need to receive treatment for your Crohn´s disease.

Option E:
Carefully read the characteristics that Option E would have:
– Treatment administered by subcutaneous injection.
– Treatment administered by healthcare personnel.
– To be able to be administrated in your doctor´s practice and be there for between 30 minutes and 2 hours each time that you need to receive treatment for your Crohn´s disease.

Option F:
Carefully read the characteristics that Option F would have:
– Treatment administered by subcutaneous injection.
– Treatment that you can administer yourself.
– To be able to be administrated in your home and to take between 10 and 30 minutes each time that you need to receive treatment for your Crohn´s disease.

Option G:
Carefully read the characteristics that Option G would have:
– Treatment administered by subcutaneous route.
– Treatment that can be administered by a family member or carer.
– To be able to be administrated in your home and to take between 10 and -30 minutes each time that you need to receive treatment for your Crohn´s disease.

Remember that once you have read all of the options, you must select a score from 0 (least preferred option) to 9 (most preferred option) for each one.

Continue thinking that your doctor has proposed that you start a treatment and that you can choose the characteristics that are most important to you in the moment of deciding your treatment. Select a score of 1 (least important), 2 (of neither great or little importance) and 3 (most important), for each of the following treatment characteristics that, in your opinion, would be most important for you if you were to decide your treatment.

☐ The route of administration of the treatment (if intravenous, or subcutaneous injection)
☐ Who administers the treatment (if it is a treatment that can be administered by oneself, or that must be administered by a healthcare professional or another person)
☐ The site of administration of the drug (if it can be administered in the patient´s own home, or if it is necessary to come to hospital or an out-patient clinic)

Fig. 1. IMPLICA Questionnaire - Version 1. This is a literal translation to English language. The English version has not been validated yet in English population.

Treatment Option A:
– Type of injection: INTRAVENOUS
– Person who administers it: HEALTHCARE PERSONNEL
– Administration site: HOSPITAL
– Time needed: FROM 2 TO 4 HOURS (including waiting and treatment time)

When would you choose this treatment?

NEVER	ALMOST NEVER	SOMETIMES	ALMOST ALWAYS	ALWAYS
☐	☐	☐	☐	☐

Treatment Option B:
– Type of injection: INTRAVENOUS
– Person who administers it: HEALTHCARE PERSONNEL
– Administration site: OUTPATIENT CLINIC
– Time needed: FROM 30 MINUTES TO 2 HOURS (including waiting and treatment time)

Treatment Option C:
– Type of injection: SUBCUTANEOUS
– Person who administers it: HEALTHCARE PERSONNEL
– Administration site: HOSPITAL
– Time needed: FROM 2 TO 4 HOURS (including waiting and treatment time)

Treatment Option D:
– Type of injection: SUBCUTANEOUS
– Person who administers it: HEALTHCARE PERSONNEL
– Administration site: OUTPATIENT CLINIC
– Time needed: FROM 30 MINUTES TO 2 HOURS (including waiting and treatment time)

Treatment Option E:
– Type of injection: SUBCUTANEOUS
– Person who administers it: HEALTHCARE PERSONNEL
– Administration site: OWN HOME
– Time needed: LESS THAN 30 MINUTES (total treatment time)

Treatment Option F:
– Type of injection: SUBCUTANEOUS
– Person who administers it: YOURSELF
– Administration site: OWN HOME
– Time needed: LESS THAN 30 MINUTES (total treatment time)

Treatment Option G:
– Type of injection: SUBCUTANOUS
– Person who administers it: FAMILY MEMBER OR CARER
– Administration site: OWN HOME
– Time needed: LESS THAN 30 MINUTES (total treatment time)

If you think about treatment that would be IDEAL for you, please, choose which of the following characteristics is most important for you and order the others according to you preferences.

1st	2nd	3rd	
☐	☐	☐	The way in which I receive the treatment (intravenous or subcutaneous injection)
☐	☐	☐	The place in which I receive the treatment (in my home, without having to travel, in my doctor's surgery, in hospital)
☐	☐	☐	The person who gives me the injection (myself, a family member, healthcare personnel)

Fig. 2. IMPLICA Questionnaire – Version 2 (English version and Spanish version). This is a literal translation to English language. The English version has not been validated yet in English population.

Opción A de tratamiento:
– Tipo de inyección: INTRAVENOSA
– Persona que lo administra: PERSONAL SANITARIO
– Lugar de administración: HOSPITAL
– Tiempo necesario: DE 2 A 4 HORAS (considerando el tiempo de espera y tratamiento)

¿Cuándo elegiría este tratamiento?

NUNCA	CASI NUNCA	A VECES	CASI SIEMPRE	SIEMPRE
☐	☐	☐	☐	☐

Opción B de tratamiento:
– Tipo de inyección: INTRAVENOSA
– Persona que lo administra: PERSONAL SANITARIO
– Lugar de administración: CONSULTA EXTERNA
– Tiempo necesario: DE 30 MINUTOS A 2 HORAS (considerando el tiempo de espera y tratamiento)

Opción C de tratamiento:
– Tipo de inyección: SUBCUTÁNEA
– Persona que lo administra: PERSONAL SANITARIO
– Lugar de administración: HOSPITAL
– Tiempo necesario: DE 2 A 4 HORAS (considerando el tiempo de espera y tratamiento)

Opción D de tratamiento:
– Tipo de inyección: SUBCUTÁNEA
– Persona que lo administra: PERSONAL SANITARIO
– Lugar de administración: CONSULTA EXTERNA
– Tiempo necesario: ENTRE 30 MINUTOS Y 2 HORAS (considerando el tiempo de espera y tratamiento)

Opción E de tratamiento:
– Tipo de inyección: SUBCUTÁNEA
– Persona que lo administra: PERSONAL SANITARIO
– Lugar de administración: DOMICILIO PROPIO
– Tiempo necesario: MENOS DE 30 MINUTOS (tiempo total de administración)

Opción F de tratamiento:
– Tipo de inyección: SUBCUTÁNEA
– Persona que lo administra: USTED MISMO
– Lugar de administración: DOMICILIO PROPIO
– Tiempo necesario: MENOS DE 30 MINUTOS (tiempo total de administración)

Opción G de tratamiento:
– Tipo de inyección: SUBCUTÁNEA
– Persona que lo administra: FAMILIAR O CUIDADOR
– Lugar de administración: DOMICILIO PROPIO
– Tiempo necesario: MENOS DE 30 MINUTOS (tiempo total de administración)

Si piensa en el tratamiento que para usted sería IDEAL, por favor, escoja cuál de las siguientes características es más importante para usted y ordene el resto según sus preferencias:

1.ª	2.ª	3.ª	
☐	☐	☐	La forma en que recibo el tratamiento (inyección intravenosa o subcutánea)
☐	☐	☐	El lugar en el que recibo el tratamiento (en mi casa, sin desplazarme, en consulta, en el hospital)
☐	☐	☐	La persona que me pone la inyección (yo mismo, un familiar, personal sanitario)

Fig. 2. IMPLICA Questionnaire - Version 2. Spanish version.

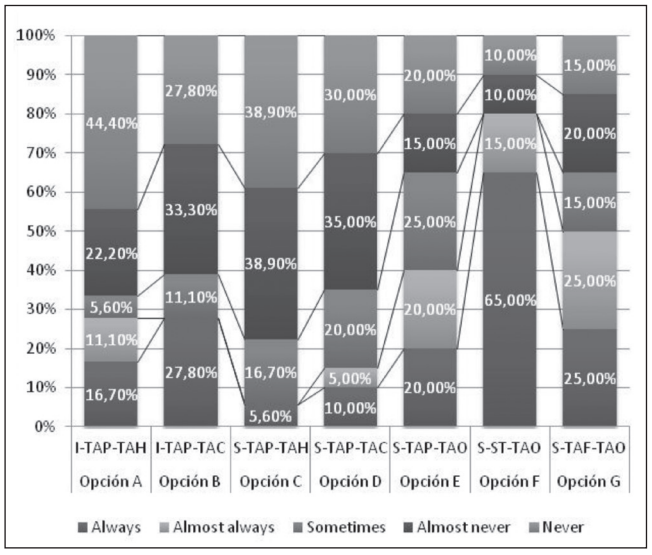

Fig. 3. Scoring of preferences given to scenarios (I: Intravenous administration; TAP: Treatment administered by healthcare professional; ST: Self-treatment; TAF: Treatment administered by a family member of care; TAH: Treatment administered in hospital; TAC: Treatment administered in outpatient consultancy; TAO: Treatment administered in own home).

The IMPLICA questionnaire may improve the quality of treatment of CD patients, allowing them to choose the treatment that best matches their needs, based on the information provided in a standardized way. This questionnaire could be of great help to healthcare professionals allowing them to involve patients in a standard clinical setting in the decision making process in a simple, rapid and easy to use fashion.

The difference between the IMPLICA questionnaire and others assessing preferences of CD patients is that in the majority of studies, treatment risk-benefit is evaluated; with the patient being informed of medium and long term serious adverse reactions, up to and including death (24). To this end, the IMPLICA questionnaire is different despite using a similar methodology for its development. It includes attributes that impact directly, from the first use of the drug, on the day to day life of the patient on aspects as important as work or family life.

Preliminary results of the IMPLICA questionnaire indicate that the scenario most preferred by patients was "F", subcutaneous, home-based, auto-administration. However, since these are purely descriptive data obtained from a small sample of patients, it cannot be concluded that this would be the scenario preferred by the majority of CD patients starting on biological treatment.

The IMPLICA questionnaire development study has the following limitations; firstly, unlike other studies, no question was included to evaluate reasons for selecting scenarios. Nonetheless, the final question asks which of the three attributes has the greatest influence on the decision, thus providing the clinician with sufficient information on the patient's preferences and the treatment characteristics on which the decision was based. The second limitation was that no patients were included in the expert meeting group, thus missing the inclusion of potential additional attributes to the questionnaire; however, this limitation was minimized by the participation of patients in the comprehension test phase. Another limitation is that previous patient experience with biological treatments was not taken into account, nor was the severity of the disease or the number of years from diagnosis in the comprehension validation test. A large sample allow stratification of the sample, by biological treatment type and other clinical variables would have yielded more information and allowed knowing up to what point choice of scenarios was related to previous treatments or CD severity.

These aspects will be analyzed in further work, with a larger sample of CD patients naïve to treatment with biologics, which will allow us to establish the preferences and utilities of patients by means of a "conjoint analysis". In this first phase, it was possible to build a questionnaire that meets the requirement that the number of attributes is not greater than seven (25). Further research is needed to assess the relation between the different sociodemographic and clinical patient characteristics and selection of scenarios in the IMPLICA questionnaire, and the relationship between information received by the patient and preferences found when the IMPLICA questionnaire is administered.

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