

# Ethnographic Observational Study of the Biologic Initiation Conversation Between Rheumatologists and Biologic-Naive Rheumatoid Arthritis Patients

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**Objective.** This ethnographic market research study investigated the biologic initiation conversation between rheumatologists and biologic-naive patients with rheumatoid arthritis to assess how therapy options, particularly mode of administration, were discussed.

**Methods.** Consenting rheumatologists (n = 16) and patients (n = 48) were videotaped during medical visits and interviewed by a trained ethnographer. The content, structure, and timing of conversations regarding biologic initiation were analyzed.

**Results.** The mean duration of physician-patient visits was approximately 15 minutes; biologic therapies were discussed for a mean of 5.6 minutes. Subcutaneous (SC) and intravenous (IV) therapy options were mentioned in 45 and 35 visits, respectively, out of a total of 48 visits. All patients had some familiarity with SC administration, but nearly half of patients (22 of 48) were unfamiliar with IV therapy going into the visit. IV administration was not defined or described by rheumatologists in 77% of visits (27 of 35) mentioning IV therapy. Thus, 19 of 22 patients who were initially unfamiliar with IV therapy remained unfamiliar after the visit. Disparities in physician-patient perceptions were revealed, as all rheumatologists (16 of 16) believed IV therapy would be less convenient than SC therapy for patients, while 46% of patients (22 of 48) felt this way. In post-visit interviews, some patients seemed confused and overwhelmed, particularly when presented with many treatment choices in a visit. Some patients stated they would benefit from visual aids or summary sheets of key points.

**Conclusion.** This study revealed significant educational opportunities to improve the biologic initiation conversation and indicated a disparity between patients' and rheumatologists' perception of IV therapy.

## INTRODUCTION

Biologic agents have demonstrated efficacy in treating moderate to severe rheumatoid arthritis (RA) (1–3). Mode of administration is a key factor in choosing a biologic therapy (4,5), and a growing number of biologic agents, with different routes of administration, has increased the complexity of clinical decision-making.

Biologic therapy for RA is among the American College of Rheumatology's Top 5 topics for promoting physician-patient discussions (6); however, time constraints in

practice may limit discussions on this topic. Shared decision-making (SDM) is a useful and growing approach to educate and involve patients in treatment decisions (7–9). During this process, clinicians offer options and describe risks and benefits, and patients express their preferences and values, facilitating decisions based on balanced consideration of clinical factors and patient preferences. Recent systematic reviews revealed that SDM favorably affects patient outcomes related to satisfaction, reduced decisional conflict, and treatment adherence (7,8).

Ethnographic research can help identify how rheumatologists communicate with RA patients about the need for

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### Significance & Innovations

- This study uncovered opportunities for rheumatologists and office staff to better educate and involve rheumatoid arthritis patients as they consider initiating biologic therapy.
- Patients may be more comfortable and willing to accept or initiate biologic therapies if they are provided with more complete information and in a way that they can easily understand.

biologics, available options, and risks and benefits. Ethnography is a specialized qualitative method, originating in cultural anthropology, that involves observing and interviewing subjects in a real-world setting (10). This approach provides methodologic advantages over traditional qualitative approaches (e.g., research facilities), including the ability to directly observe and record interactions, dialogue, and behavior, rather than relying on subjects' reports. Qualitative research can identify patterns in subjects' experiences, behaviors, and thinking, and has applicability for identifying differences in perceptions between physicians and patients (11).

This ethnographic market research study investigated the structure and content of the biologic initiation conversation between rheumatologists and patients, with a substantial focus on how rheumatologists presented modes of biologic administration to patients with RA. The findings reveal opportunities to enhance SDM between providers and patients when considering and choosing biologic therapy.

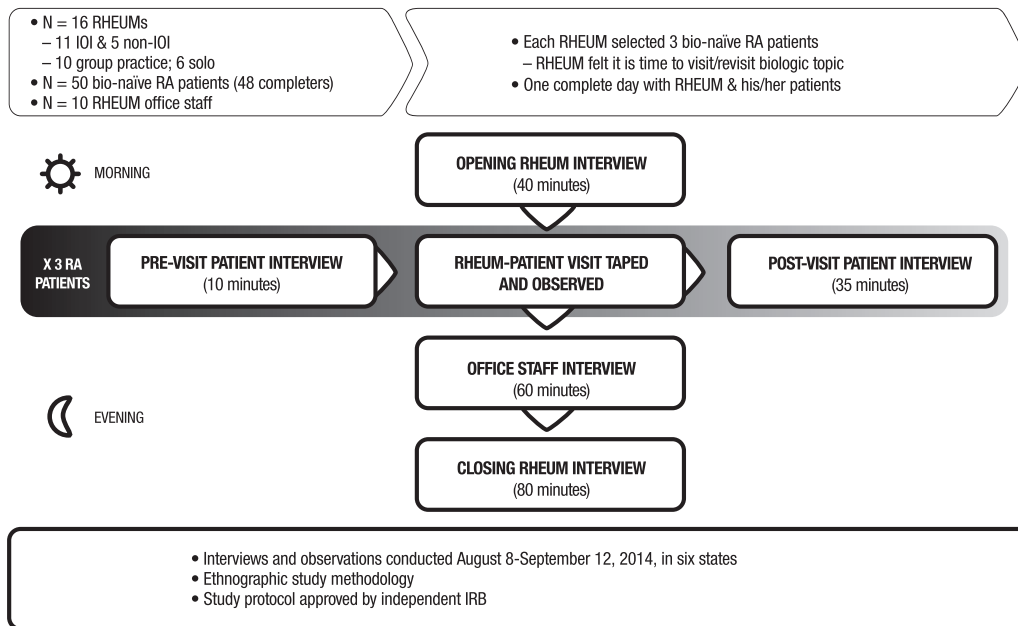
### PATIENTS AND METHODS

The study protocol was approved by an independent institutional review board (Salus IRB), and all study participants

(patients, rheumatologists, and office staff) provided informed consent prior to participation. Participants were compensated financially, and participants and the study sponsor were blinded to each other's identities. Letters outlining study goals/procedures were mailed to approximately 60 rheumatologists, who were eligible to participate if they had 2–32 years in practice, treated ≥100 patients with RA per month, and >30% of their patients with RA used biologic therapy. Eligible rheumatologists invited RA patients to participate on a regular day during standard patient hours. Enrolled patients met the following criteria: diagnosis of RA, no prior biologic therapy, current treatment with methotrexate or a disease-modifying antirheumatic drug (DMARD), symptoms currently inadequately or partially controlled, and appropriate for an initial or followup conversation about potentially initiating biologic treatment.

All participants provided informed consent authorizing videotaping of their visit and pre- and post-visit interviews by a trained ethnographer and releasing medical information for purposes of the study. Rheumatologists participated in a 40-minute opening and 80-minute closing interview (before and after patient hours, respectively, on the same day), while patients participated in a 10-minute pre-visit and a 30- to 40-minute post-visit interview (Figure 1). Semistructured discussion guides facilitated the ethnographer's interviews with both parties. Pre-visit interviews were brief so as not to alter the natural course of rheumatologist-patient visits. General background information was collected, but the ethnographer emphasized establishing participant comfort during the pre-visit interview.

The ethnographer and informed consent documents broadly explained the study goal to observe and better understand interactions and communications between rheumatologists and RA patients, particularly as it relates to treatment. During the pre-visit interview, the ethnographer reviewed the informed consent document and explained how the study



**Figure 1.** Study design and flow. RHEUM = rheumatologist; IOI = in-office infusion; RA = rheumatoid arthritis; IRB = institutional review board.

data would be analyzed. A single ethnographer (NK) conducted all interviews, and participants were advised to ignore the videotaping.

Over the 48 patient visits, the ethnographer observed and videotaped silently and unobtrusively in the room during 9 visits (early on in the study) and videotaped and listened in real time from an adjacent room during the remaining 39 visits. Office staff involved in treatment, including medical assistants, office managers, nurse practitioners, and infusion nurses, were also interviewed per rheumatologists' and patients' suggestions about the most relevant and insightful staff members.

After interviews and visits were completed, all videotaped physician-patient interactions were reviewed twice by the ethnographer, during which a set of codes was developed and refined to categorize topics of the visit, and discussions about biologic therapy based on the study sponsor's interest in how administration options were described and discussed. The ethnographer coded and detailed these aspects of conversations from each visit and documented the time allocated to each coded topic during 2 subsequent viewings. The ethnographer was not blinded to the identity of the study sponsor.

**RESULTS**

Sixteen experienced rheumatologists and 48 patients participated (Table 1). Fifty total patient visits occurred; 2 were excluded because biologics were not mentioned. Of the 48

**Table 1. Participant characteristics\***

	Patients (n = 48)	Rheumatologists (n = 16)
Location, no.		
New Jersey	12	4
Texas	12	4
Arizona	4	1
California	4	2
Illinois	9	3
Maryland	7	2
Group practice, no. (%)	–	10 (62.5)
Individual practice, no. (%)	–	6 (37.5)
In-office infusion provided, no. (%)	–	11 (68.8)
Male, no. (%)	12 (25.0)	12 (75.0)
Female, no. (%)	36 (75.0)	4 (25.0)
Age, mean ± SD years	60.3 ± 15.4	–
Duration since RA diagnosis, mean ± SD years	4.5 ± 4.9	–
Diagnosed within the last year, no. (%)	16 (33.3)	–
Medicare, no. (%)	26 (54.2)	–
Commercial insurance, no. (%)	22 (45.8)	–
Unfamiliar with “IV”/ “infusion” therapy before visit, no. (%)	22 (45.8)	–

\* RA = rheumatoid arthritis; IV = intravenous.

**Table 2. Topics/events of the rheumatologist-patient visit**

Topic/event	Approximate average duration (n = 48 patient visits)
Social talk	30 seconds
Review of last visit, medications, laboratory results	2 minutes, 20 seconds
Symptom assessment and physical examination	4 minutes, 10 seconds
Disease status summary and treatment goals	50 seconds
Biologics	5 minutes, 36 seconds
Procedures	20 seconds
Treatment plan and logistics	1 minute, 20 seconds
Total	15 minutes, 6 seconds

analyzed visits, 34 were with in-office infusion (IOI) rheumatologists. Thirty-nine patients had previous discussions about biologic therapy with their rheumatologist; of these, 24, 12, and 3 patients thought they had discussed biologics 1, 2, and 3 times, respectively, in the past. For 9 patients, this was the first discussion of biologics.

**Conversation characteristics.** Most visits were similar in structure and duration and lasted ≥10 minutes. The general flow and topics covered are summarized in Table 2. Visits typically began with greetings and symptom assessment, followed by social talk; review of prior visit, medications, and laboratory results; symptom assessment and physical examination; disease status and treatment goals; discussion about biologic therapies; treatment procedures (e.g., cortisone injections); then treatment plan and logistics. Biologics were discussed for approximately 5.6 minutes on average and are detailed in Table 3. Approximately 1.6 minutes were spent discussing biologic therapy options. The 5.6 minutes spent discussing biologics in this study did not necessarily comprise total physician-patient discussions on the topic, as additional conversations may have occurred before or after the observed visit. However, 35 of 48 visits were viewed as the most “comprehensive” conversation on biologics to date.

**Table 3. Topics of the biologic discussion**

Topic	Approximate average duration (n = 48 patient visits)
What they are, why they are used, and when they are used	50 seconds
Biologic options (mode of administration and product brands)	1 minute, 36 seconds
Safety and side effects	1 minute, 50 seconds
Cost and insurance	30 seconds
Administration logistics	15 seconds
Biologic benefits	25 seconds
Thoughts/decision	10 seconds
Total	5 minutes, 36 seconds

**Mode of administration discussion results.** Of the 48 conversations involving mode of administration, 45 addressed subcutaneous (SC) administration and 35 addressed intravenous (IV) administration. The oral option tofacitinib citrate was discussed during one-third of visits and, although such molecules are of similar import to the biologic discussion, their oral delivery is a distinct physician-patient discussion and not addressed in this study. Of the 35 patient visits during which IV therapy was discussed, 28 and 7 were conversations with IOI and non-IOI rheumatologists, respectively. Mode of administration was discussed for 34 and 19 seconds on average during visits with IOI and non-IOI rheumatologists, respectively. During 26 visits with Medicare patients, IV and SC therapies were mentioned during 22 and 23 visits, respectively. This is noteworthy as Medicare with

supplemental insurance may preferably cover IV over SC therapy, since IV therapy qualifies as a medical benefit (Part B) and SC therapy falls under pharmacy benefits (Part D).

Nearly half of patients appeared unfamiliar with “IV” or “infusion” therapy entering the visit (Table 1). In contrast, patients uniformly understood when rheumatologists mentioned taking a biologic as a “shot,” “injection,” or as an “injectable.” When IV/infusion therapy was discussed, specific terms included “infusion,” “IV,” and “intravenous” (Table 4). Patients seemed more likely to recognize “intravenous” and least likely to recognize “infusion.” Overall, nearly half of patients still appeared unfamiliar with “IV” or “infusion” therapy after their visit.

Details about topics/concepts covered during conversations are summarized in Table 4. When IV administration was discussed, rheumatologists provided little detail about

**Table 4. Mode of administration conversation characteristics\***

	Value
Relative proportions of terms used by rheumatologists to describe IV administration	
“Infusion”	49/110 (44.5)
“IV”	46/110 (41.8)
“Intravenous”	15/110 (13.6)
Office visit observations	
Conversations in which SC and IV are both discussed	33/48 (68.8)
Conversations in which SC, but not IV, was discussed	12/48 (25.0)
Conversations in which IV, but not SC, was discussed	2/48 (4.2)
Conversations where IV was mentioned	
Rheumatologist told patients where IV therapy is performed (office or hospital)	16/35 (45.7)
Infusion and how administered was defined/explained	8/35 (22.9)
Benefits of health care provider monitoring during infusion discussed	3/35 (8.6)
Infusion setting was physically shown to patient	1/35 (2.9)
Conversations about IV with rheumatologists who offer in-office infusions	
Mentions of IV therapy	28/34 (82.4)
Specified that infusions are done in their offices	12/28 (42.9)
Conversations where both SC and IV therapy options were discussed	
SC was mentioned before IV	28/33 (84.8)
Patient asked which modality he/she would prefer (IV vs. SC)	9/33 (27.3)
Patient would likely prefer IV over SC therapy	7/9 (77.8)
Patient would likely prefer SC over IV therapy	2/9 (22.2)
Patient advised that SC therapy may be more convenient than IV	9/33 (27.2)
IV therapy suggested as option if patient felt he/she could not self-inject	8/33 (24.2)
IV was mentioned before SC	5/33 (15.2)
Patient perceptions about self-injection	
No significant fear of self-injection	24/48 (50.0)
Significant fear of self-injection/probably could self-inject	14/48 (29.2)
Reluctant to admit fear of self-injection	10/48 (20.8)
Significant fear of self-injection/probably could not self-inject	6/48 (12.5)
IV dosing frequency discussed	17/35 (48.6)
IV dosing frequency mentioned <i>only after</i> patient expressed interest in IV	12/17 (70.6)
IV dosing frequency mentioned <i>before</i> patient expressed interest in IV	5/17 (29.4)
Post-visit interviews	
Patient feelings/knowledge after visits	
When IV and SC both discussed, patient could not recall/identify dosing schedules of mentioned products	30/33 (90.9)
Could recall $\geq 1$ product name	33/48 (68.8)
When IV and SC both discussed, patient could not recall how products differed regarding mode of administration	16/33 (48.5)
Patients appeared unfamiliar with “IV” or “infusion” therapy	19/48 (39.6)
Patients could not recall any product names	15/48 (31.3)
Patients confused/overwhelmed with the variety of products mentioned	13/48 (27.1)

\* Values are the number/total number (percentage). IV = intravenous; SC = subcutaneous.



what an infusion/IV is, how it is administered, or the infusion setting. During the majority of visits with IOI rheumatologists, the practitioner did not specify (or forgot to mention) that IV therapy is administered in their own offices.

Frequency of administration was mentioned in approximately half of visits in which IV therapy was discussed, often occurring after the patient expressed aversion to SC or interest in IV therapy. During most of these visits, dosing frequency was mentioned only after the patient expressed interest in IV therapy; although, in fewer than half of visits, the rheumatologist did not provide a clear or correct description of IV dosing schedules. Potential benefits of IV therapy (social support, adherence/certainty of administration, and weight-based dosing) were not discussed with patients.

**IV versus SC mode of administration.** Both IV and SC options were mentioned during 33 visits, and SC therapy was more often mentioned first. One IOI rheumatologist explained, “They are either administered subcutaneously, which means a shot under the skin that you administer yourself or intravenously where you come into the office for an infusion.” During 8 visits, rheumatologists described IV therapy mainly as an option if patients felt they could not self-inject. When asked if they could inject themselves, some patients hesitated, seeming reluctant to admit their fear of self-injecting. In a post-visit interview, one biologic-naïve patient stated, “I could probably give myself those shots...but I’m a big baby when it comes to those things.” Half of patients did not have a significant fear of self-injection, and the other half expressed significant fear of self-injecting and were mixed about whether they could ultimately self-inject.

Throughout visits where both IV and SC were discussed, rheumatologists sometimes suggested SC therapy may be more convenient by emphasizing administration at home and on the patient’s schedule, versus IV, which may conflict with personal schedules. One rheumatologist stated, “The injections give you more independence because you are home.” Yet, during one visit, a rheumatologist discussed logistical challenges of SC therapy, including the need for refrigeration and travel inconvenience. During some visits, rheumatologists asked in a more open-ended manner which mode of administration the patient would “prefer” or “find easier.” IV therapy was preferred more frequently than SC therapy during these visits.

**Differences in physician versus patient perceptions.** Post-visit interviews revealed differences between physician and patient perceptions of relevant benefits and drawbacks of IV and SC therapy (Table 5). For example, all 16 rheumatologists believed IV therapy was less convenient than SC and that “IV as inconvenient” was the primary barrier to IV therapy among patients. By contrast, under half of patients (22 of 48) reported inconvenience as the primary barrier to IV therapy. Twenty-three patients thought SC therapy would be easier, 17 thought IV therapy would be easier, 4 thought they would be the same, and 4 were unsure. Among patients who favored IV therapy, some reasons included the relative infrequency of IV dosing fitting well into their schedule, providing a more “out-of-sight/out-of-mind” and discreet experience, and

injections possibly being stressful or a hassle. One patient remarked: “I’m a diabetic, so I take injections now and I know how to deal with injections. I just don’t want to have to remember to constantly take them, so I was just wanting to know which one am I going to have to take the least often and it sounded like maybe infusion.”

**Discussion of multiple product options.** During 25 visits in which biologics were discussed, rheumatologists mentioned product brand names first rather than mode of administration. One IOI rheumatologist stated “[Advertisements] pop up all over the place. That’s why I say [to the patient], ‘you might have seen these commercials on TV.’” At least 3 product brands were mentioned during 26 visits and <3 during the remaining visits (see Supplementary Figure 1, available on the *Arthritis Care & Research* web site at <http://onlinelibrary.wiley.com/doi/10.1002/acr.23527/abstract>). The most frequently mentioned brands were Enbrel, Humira, and Remicade (see Supplementary Figure 2, available at <http://onlinelibrary.wiley.com/doi/10.1002/acr.23527/abstract>). Mode of administration was mentioned before brand during approximately half of conversations with IOI and non-IOI rheumatologists. The average times spent discussing product brands were 72 and 106 seconds with IOI and non-IOI rheumatologists, respectively. Some patients appeared or reported feeling confused or overwhelmed with the variety of products mentioned. While rheumatologists who presented multiple products invited patients to share in the therapy decision, those patients often did not appear confident that they properly understood the criteria of choice to make the best decision. The following conversation is an example: *Rheumatologist*: “There are medicines like Enbrel, Humira, Remicade, Orenzia, Simponi, Actemra, so there are quite a few available. I would suggest that you try one of these.” *Patient*: “Alright.” *Rheumatologist*: “So do you have any choice, which one you would like to try?” *Patient*: “No, I don’t know much about them, so...” *Rheumatologist*: “So, do you think that you would be able to inject yourself?” *Patient*: (extended pause as patient sighs). *Rheumatologist*: “...Or would you rather come in here and get the medication here in our office?” *Patient*: “How often would I have to get it?”

One frequent conceptual gap between rheumatologists and patients concerned the perceived equivalence of biologic therapies. While rheumatologists assumed the data suggested that biologics maintained roughly equivalent efficacy and safety results, patients did not typically share this assumption. Additionally, rheumatologists felt some trial-and-error is necessary to determine optimal treatment, as there is no way to predict which biologic is the best match for a patient. In contrast, many patients seemed to believe there must be a biologic that would be most effective for their particular disease variation. One patient stated “I was trying to get [the physician] to tell me which one, but he really wouldn’t tell me...”

**Additional insights from patient interviews.** Pre- and post-visit interviews revealed other important findings. First, patients were more receptive to IV therapy if they were aware it is administered in the rheumatologist’s office, understood the dosing schedule, had a personal history with or knew someone treated with an IV biologic, or knew the

**Table 5. Perceptions about IV therapy by rheumatologists and patients based on post-visit interviews\***

Topic, no. (% reporting)/considerations
As perceived by rheumatologists (n = 16)†
Inconvenient, 16 (100)
Takes too much time
Conflicts with patients' schedules
Assume vast majority of patients agree
Financial risk, 6 (38)
May not be fully covered by insurance
Burned by past events, despite verification
Patient may get stuck with steep bill
Slower to start, 6 (38)
Highly symptomatic patients are eager to start
IV insurance approval and rebate programs take longer than SC
Some physicians start patients on SC samples before insurance approval for IV
As perceived by patients (n = 48)‡
Less convenient, 22 (46)
Prefer not to schedule life around IV visits
Do not like hospitals or medical settings
Live substantial distance from rheumatologist's office
Fewer patients have this perception than rheumatologists assume
Unfamiliar, 11 (23)
Although patients are familiar with the idea of a "shot," many are unfamiliar with the terms "IV" and "infusion"
Unsure how and where needle is inserted; whether painful, limiting, or noticeable during infusion
Fear of IV needle, 2 (4)
Fear of needle being inserted into vein
Dread seeing/feeling needle in arm for long period
Fewer patients fear IV needle than SC injection needle
Perception of severe disease, 1 (2)
Assume IV is more potent, last-resort therapy, only for those who fail SC
Associate IV with chemotherapy and sickness
No barrier, 12 (25)
Patients did not articulate any barriers to IV therapy
* IV = intravenous; SC = subcutaneous.
† Rheumatologists could cite >1 barrier, and all rheumatologists cited "IV therapy as inconvenient" as the primary barrier to IV adoption.
‡ Patients were asked to cite the primary barrier to IV therapy.

hours of the IV infusion room. Second, after the initial visit to discuss biologics, patients reported different emotional reactions: two-thirds expressed uncertainty/ambivalence about whether to start a biologic, and one-third expressed reassurance/hope about several available options and the possibility of "getting their life back." Third, patient recall of biologic options discussed during the visit was poor, even immediately following the visit. As mentioned, some patients were confused/overwhelmed with the variety of products; nearly one-third could not remember any product names after the conversation. Patients were more likely to recall products they saw on television advertisements. Moreover, among visits in which both IV and SC therapy were discussed, nearly half of patients could not recall which products were SC versus IV, and the majority could not recall or identify the dosing schedules of the mentioned products. Written material or visual aids were provided by 2 rheumatologists during 4 patient visits. The majority of patients received  $\geq 1$  brand-specific brochure after the observed visit or after a prior visit. Five patients indepen-

dently expressed the need for visual aids or summary sheets of key points.

**Patients' decision to initiate biologic therapy.** Eighteen patients agreed to initiate biologic therapy. Among the remaining patients, approximately half stated their primary unwillingness was fear/concern about side effects. These fears/concerns included a general fear of biologics as very potent medications with unknown long-term side effects, such as lymphoma, cancer, or infection risk. Other barriers included cost and not perceiving a need for biologic therapy. One patient was mostly impeded by needle phobia (IV or SC).

As mentioned above, there was some discussion about the barriers to biologic initiation. Safety of biologics was discussed during most visits, including all 18 in which patients agreed to start a biologic; the mean duration of the discussion about safety was 1 minute and 50 seconds. Specific discussion about benefits of biologics occurred in approximately two-thirds of visits, including two-thirds of visits in which patients agreed to start biologic therapy, the mean duration of

which was 25 seconds. During one-third of visits, rheumatologists did not outline the benefits of biologic therapy; instead, they tended to discuss biologics as the “next step” in therapy when patients’ symptoms are no longer controlled on DMARD therapy. It was also uncommon for rheumatologists to emphasize the risks and potential complications of patients’ disease remaining uncontrolled.

## DISCUSSION

Biologic therapies provide an unparalleled benefit in treating RA symptoms, enhancing patient quality of life, and preventing or delaying disease progression. Thus, the decision to begin biologics represents a vital turning point for a patient with RA. Making this decision merits comprehensive discussions between the rheumatologist and patient, in which patients have sufficient opportunity to educate themselves about the therapeutic class and the best fit for their lifestyles and preferences.

This ethnography study revealed limited discussion about specific biologic treatment options among patients who were candidates to initiate such therapy. During rheumatologist-patient interactions, discussion about biologics averaged <6 minutes (approximately one-third of total discussion time) and was spontaneously fit into a routine flow of the visit. These time constraints may have reduced the amount of information provided to patients about available biologic therapy options, therefore minimizing the opportunity for SDM.

The goal of SDM is to integrate the rheumatologists’ understanding of medical evidence with a consideration of patients’ goals and preferences for care (12–14) and has 3 steps: 1) introducing choice, 2) describing options and their risk-benefit profile, and 3) helping patients explore preferences and make decisions. Distributing these steps across multiple visits may benefit patients by providing adequate time to consider options and develop questions to inform their final decision. Involving the patient in treatment selection may also improve adherence and the chance of success with therapy (15). Rheumatologists are instrumental in SDM (16) by influencing patient decisions through their advice or recommendations for initiating biologic therapy for RA.

These results suggest that rheumatology office staff were not prominent in educating patients on biologic therapy. Medical assistants were sometimes involved in securing prior authorizations and insurance benefits for biologic therapy or in explaining how to self-inject SC therapy. In IOI settings, infusion nurses often helped educate patients about biologic therapy, mainly after the patient already started IV biologic therapy. Two rheumatologists were in offices with one nurse practitioner, who, in both cases, were relatively new to the practice and did not have a defined role in explaining biologic therapy to patients. However, we believe that rheumatology offices with experienced nurse practitioners, physician assistants, and even experienced medical assistants could participate in the biologic initiation conversations.

Patients in this study knew substantially less about biologics than rheumatologists may have assumed about basic concepts about IV/infusion therapy. Discussions on biologics appeared to favor SC therapy and provide few details about how IV therapy is administered. These findings may have

stemmed from differences between rheumatologist and patient perceptions about the ease of IV therapy. For example, all rheumatologists believed IV therapy would be less convenient for patients, while over one-third of patients indicated that IV therapy would be easier than SC. In post-visit interviews, patients also struggled to recall and understand key elements of the discussion, including different treatment options. Based on these findings, opportunities exist for rheumatologists and patients with RA to partner more extensively on biologic therapy decisions.

Our results suggest patients may be overwhelmed during a single visit, as almost half remained unfamiliar with “IV” or “infusion” therapy after their visit. Thus, providing information in an incremental and iterative manner could entail introducing biologic options at one visit, followed by discussion of side effects and the magnitude of risks at subsequent visits. Literature for patients to review after these discussions, including unbranded educational materials that outline the treatment landscape, may facilitate greater retention of key elements of the physician-patient conversation, reinforce understanding of biologic treatments, and allow time to better evaluate options and formulate questions. Other educational assets, such as wall posters to explain the pathophysiology of RA, risks of uncontrolled disease, and mechanism of action of biologics, may help patients appreciate how treatments work and empower them to accept and want to comply with these therapies. Educators from professional organizations and patient advocacy groups may also provide value.

This ethnographic market research study was robust for the direct observation and real-time interviews immediately preceding and following observed visits. First-hand information was obtained, as opposed to requiring participants to recall their discussions, providing practical insight into conversations about biologic treatment choices. The insights gained will be beneficial to RA practices by providing details not thoroughly investigated until now. However, this study was also subject to certain limitations. First, this qualitative approach precludes statistical generalization or projections. Second, by quantitative research standards, this is a small sample size, and the limited number of rheumatologists and patients may subject results to sampling bias. Although more IOI ( $n = 11$ ) than non-IOI ( $n = 5$ ) rheumatologists participated, the explanation of the IV option by IOI rheumatologists was not substantially more thorough than by non-IOI rheumatologists. Third, this study evaluated only one of several possible discussions on the topic of initiating biologic therapy, and previously/subsequently discussed details were not assessed. Finally, no data were collected on patients’ previous experiences with SC treatments (e.g., methotrexate or insulin). Further studies may benefit from considering this point.

Taken together, these results suggest that discussion of biologic therapy options is often limited in a single office visit, and opportunities exist to improve patient-provider communications regarding biologic therapy for RA.

Based on our results, we offer several recommendations to improve patient education and increase involvement in a shared decision to start biologic therapy: 1) Rheumatology practices should consider preparing patients for the biologic decision earlier in the disease process by educating them at

the time of diagnosis about basic pathophysiology of RA and its potential harm to joints and systemically, and then on the overall treatment landscape, including different biologic therapy options. 2) Clinicians should provide educational tools to inform patients about pros and cons of treatment options and routes of administration (e.g., handouts listing biologics and focusing on dosing and mode of administration). Decision aids can help reinforce the information patients heard during the visit with their physician, and they can guide patients through SDM by providing evidence-based information highlighting potential benefits and harms, as well as help clarify preferences and values (12). When provided in a clear, unbiased fashion, such information helps patients feel more knowledgeable and active in SDM (17). 3) SDM can be complex and time-consuming; therefore, structured, more frequent, and longer interactions between patients and physicians and/or support staff may be required (13). Rheumatologists often initiate the conversation with the patient about choosing an appropriate biologic. Nurse practitioners and physician assistants can be trained to participate in facilitating followup SDM with patients across multiple visits. 4) Clinicians should foster a collaborative relationship with patients, creating a partnership where patients' views are valued, and take less of an authoritative or paternalistic role. Studies suggest that outcomes are improved when patients experience an alliance with their physician during SDM (9,14). 5) We advise rheumatologists to invite their patients to participate in the choice of which biologic medication to start. To avoid the confusion noted by some patients, it may help to explain that most biologic therapies offer the potential for very positive outcomes and have relative equivalence in terms of safety. 6) Finally, randomized trial data on how clinical outcomes are affected by SDM and communications between patients and physicians are lacking. Further investigations are needed (7).

#### AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. Dr. Kottak had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Study conception and design.** Kottak, Rosenberg, DeHoratius.

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