Attitude, Skills, and Knowledge in Oncology Biosimilars

ASK 'Empowering patients as part of a successful biosimilar switching strategy' transcript

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Emma Foreman: Hello everybody, and welcome to our webinar "Empowering patients as part of a successful biosimilar switching strategy".

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Emma Foreman: A few notes for you before we get going. This webinar is supported by grant funding from Pfizer, and PCM Scientific is the medical education company acting as scientific secretariat and organiser for this programme. The activities run independently of the financial supporter and all content is created by the faculty. No funder had input into the content of this activity.

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Emma Foreman: We'd like this to be an interactive webinar, so please participate.

Thanks for your question, Michael. The chat box is disabled, but you can ask questions using the Q&A function. I'm going to keep my eye on the Q&A box throughout the webinar and then feed your comments and your questions into the discussion.

There will also be interactive questions displayed on the screen and you can choose your answer by selecting the options when they appear on the screen. If you're watching this webinar as archive footage, you won't be able to take part in the live polls.

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Emma Foreman: OK, so let me introduce your panel for today. My name is Emma Foreman and I'm a consultant pharmacist at the Royal Marsden Hospital in London in the UK.

I can introduce you to María-José Tames, who is Assistant Director at the Onkologikoa Foundation, San Sebastián, Spain.

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Emma Foreman: And here are our disclosures.

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Emma Foreman: And the learning objectives for this webinar.

At the end of the webinar, you should all be able:

- to discuss the main concerns patients may have about safety, efficacy, and extrapolation of indications or biosimilars;
- to apply effective education strategies for ensuring patient understanding and confidence in the approval process for biosimilars and what that means for their treatment;
- to discuss the difference in educational requirements for patients new to biologics and patients who are being switched from an originator biologic to a biosimilar.

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Emma Foreman: Before we kick off then, I'm going to test out our polling function with a pre-learning assessment question.

When you are implementing new biosimilar medicines, how often does your patient communication strategy include the wider multidisciplinary team? So please choose: (A) routinely, (B) often, (C) sometimes, (D) rarely, or (E) never.

Just click on the little circle next to the answer that you choose, and I'll be able to see everybody's replies shortly.

OK, so 50% of you are saying sometimes and 50% rarely, so that might be something that we're trying to encourage you to do a bit more of during the course of this webinar.

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Emma Foreman: We're going to start you off with another question – just to get your mind thinking.

As a pharmacist, are you regularly involved in discussing treatments or therapies with patients? Please choose either:

- (A) Yes, you regularly discuss treatments and therapy directly with patients, or
- (B) yes, you sometimes discuss treatments or therapies with patients, or
- (C) no, you don't actually get the opportunity to discuss treatments directly with patients at all.

So, let's see where you are at the moment in your current practice.

Oh, that's really encouraging! So, 25% of you regularly do this, which is great, and 75% at least get the chance to do this sometimes. That's good news.

I'm handing you over to María now. So, get the slides started. Over to you, María.

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María-José Tamés: Hello, good afternoon. Thank you, Emma, for your introduction to this interesting topic.

I'm going to get straight to the point because our time is limited. I'm going to start with a question I think we should ask ourselves – "why is patient education important?".

It's very simple, education is important because our patients are concerned about their disease, which is under treatment with biosimilars. These concerns were reported by large studies and we acknowledge that the limitations in patient information contributes to negative attitudes towards biosimilar use. This information, and the education we provide, contributes to resolving this concern.

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María-José Tamés: And this information needs to be clear, consistent, coherent, from various sources, and obviously directed to address the patient concerns.

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María-José Tamés: To resolve their concerns, our patients go surfing the web. One of our main aims will be to counter incorrect and negative information they can get and promote a positive message, always in an understandable way.

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María-José Tamés: The level of knowledge on safety and efficacy amongst patients is low. An international survey showed that 70% of the public had never heard about biosimilars. This gap in knowledge between biosimilar and originator also existed among patients who were supposed to be familiar with the biosimilars and originators.

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María-José Tamés: The same study found that another factor influencing the patients' willingness to try biosimilars is based on the identity of the manufacturer.

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María-José Tamés: Here are two areas to cover with patients where more information is needed. First, although knowledge of extrapolation is obviously low, I consider this a difficult area to understand for many, patients. Second, a better understanding of societal benefits, but this can, of course, be a subject of discussion later.

Emma Foreman: Yes, María, I was just going to ask. There are some concepts that are quite complicated to explain to patients – things like extrapolation. Do you think when we're tailoring information to patients, we need to have a really simple form and then perhaps have something a bit more complex for patients who want to know more?

María-José Tamés: Oh well, maybe if it's oral information, I think yes. Having it in a well-written format is more complicated. I would start with a really simple format and, if the patient asks for more information, then I would have more complete information available. What is your opinion?

Emma Foreman: I think we're always worried about patients Googling information and finding out things that perhaps aren't entirely correct or picking up negative information or opinions on biosimilars. I think that you do get some patients that really like to read up on things and if we are pre-armed with some links for good quality information that we can direct patients to, then we can actually channel the internet for positive information. As long as we can direct them to the good quality information, the use of the internet for patient information can be a good thing as well as a bad thing.

María-José Tamés: Maybe directing them to this good information on the internet.

Emma Foreman: Brilliant, so let's move on, then. María tell us about the use of multi-stakeholder approaches in education.

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María-José Tamés: Who will be responsible for this education? Well, we need a multidisciplinary approach. It's going to be a team effort with the involvement of several stakeholders, as you see in the slide, each one playing their role.

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María-José Tamés: First of all, we have the physicians. These are the healthcare professionals that have first contact with the patient, and they are the most trusted source of information for patients.

But on some occasions, the relationship between physicians and patients is not as close as the one that patients can have with the nurses. Nurses are placed in a very good position to provide guidance and explanations to the patients.

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María-José Tamés: And then we have the pharmacist, often with a simplified role, limited to delivery of drugs, but I think they can play a very active role and serve as a healthcare team coordinator, especially when switching to a biosimilar. The pharmacist usually is the first-line contact for any questions involving drugs.

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María-José Tamés: We also cannot forget medical and scientific associations as well as patient organisations. They should join forces to ensure good quality and consistency of the information provided.

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María-José Tamés: Finally, there are national and international regulatory authorities giving very good information. As an example of that, there is the brochure developed by the European Commission and the European Medicines Agency regarding biosimilars.

Emma Foreman: Yes, that's a really good reference to look at.

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Emma Foreman: I've got a little series of interactive questions for you here. We had a little debate at the last webinar because, in the UK we've been using biosimilars for a long time now, and some biosimilars we're just using so routinely that we don't even think to tell patients that we're initiating them on a biosimilar, because that's what we always use, and we refer to the drug by its internationally approved name.

Some people are starting to say, “do we need to tell people that we're switching them to a biosimilar at all in oncology?”. I'm going to ask you these questions, just to gauge what your feelings are about it.

My first question is, do we always need to inform existing patients of a switch from an originator to a biosimilar, or a biosimilar to another biosimilar?

So please choose either

- (A) Yes, patients should be informed of all switching,
- (B) Yes, for an originator–biosimilar switch, but not biosimilar to another biosimilar switch because the patients are already on a biosimilar
- (C) No, the patient doesn't need this information.
- (D) Not sure.

So please make your choice. I'm interested to see what you think.

OK, so 83% of you think patients should be informed of all switching; 17% are unsure.

In our practice we have been informing patients when they switch from the originator to the biosimilar but when we have subsequently done a biosimilar-to-biosimilar switch we haven't informed them that we're switching brands. To be honest, we haven't had any issues with that.

We've had no difference in hypersensitivity rates and almost you kind of wonder by perhaps informing the patients and making an issue out of it, you're almost risking getting a bit of a nocebo effect by telling them to expect that something might be different. So, although there is an argument that it's a different product, so you should be telling them they are on a different product, on the other hand we wouldn't do that for generics.

What do you do in your practise, María? Have you done a biosimilar-to-biosimilar switch yet?

María-José Tamés: Not yet, when we have decided to change to biosimilar, at the moment we are having the same biosimilar we started with. Well, I'm speaking about oncology and mostly solid tumours, those are the diseases I usually treat.

But we don't have a switch. We inform when we switch to a biosimilar just because of the side effects, hypersensitivity, we don’t tell them this is going to happen but it's something that could happen. Of course, this is safe and the possibility of having the side effect is really very low. There are multiple studies that supported the use etc, etc.

Emma Foreman: Yeah, so you have to be careful about the way you tell patients about a switch so that you don't raise concerns.

María-José Tamés: In fact, I would like to add that in the majority of regions in Spain, we have no choice to choose the biosimilar. It's imposed by our regulatory authorities – so this is what they need to accept.

Emma Foreman: We’ve had some comments come in: Just to say that some pharma companies produce practical booklets and resources with their biosimilar products, and some have a paediatric pack targeted at children which included a teddy bear and colourful stickers. That sounds really good. And it's really nice because I think it's important to tailor the information that you give to the patient themselves. So, to know that there are resources out there targeted at children is brilliant.

Yes, about the biosimilar to biosimilar switching – patients may ask what other medicine information is being withheld. If you don't tell them openly about switching from one biosimilar to another, and perhaps they came to learn about it afterwards – it might cause some kind of reduction in trust, I think that is perhaps where you're coming from there.

Certainly, when we're doing this sort of regional switch from an originator to a biosimilar, the worry is that perhaps patient groups and the press are talking about biosimilars, and if a patient found out that they've been switched and not being told or not being given any information, then they certainly might feel that there's been a breakdown in the carer–patient relationship there.

Emma Foreman: So let's move on to the next polling question.

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Emma Foreman: As I mentioned earlier, particularly for things like rituximab and trastuzumab, our standard practice is to use a biosimilar right from the very beginning. We'll tell the patient that we're starting them on a biologic medicine called trastuzumab. We won't specifically tell them that it's a biosimilar. I guess we felt we didn't really need to because it's just our standard form of rituximab that we're using.

This only came up because we were doing a study looking at outcomes for patients on biosimilars and when we were consenting them for the study we were saying, "oh, you've been treated with a biosimilar rituximab. Could we please use your information to show how safe and effective biosimilars are?". The patients are going "what's a biosimilar" and "I didn't know why I was on one", we thought, oh we probably should be telling patients.

So, what do you think? Should we always inform a new patient that they're being prescribed a biosimilar, rather than the originator when we commence a patient, standardly on a biosimilar?

And you are saying the patient doesn't necessarily need this information. 17% of you think they should be informed. I kind of agree with you there. I think once biosimilars have fallen into standard practice and that's the thing that we're using, raising the issue at that point doesn't feel natural somehow.

I say "no". María, what do you do in your practice?

María-José Tamés: Well, we don't inform them when they start with the biosimilar. While they think that this is the drug the physician and pharmacist have decided is the best for the disease and we don't inform them.

Emma Foreman: Yeah, OK.

María-José Tamés: This is our standard practice at the moment.

Emma Foreman: This is our standard practice in the UK, and it was really only because of this clinical trial that we suddenly started to question ourselves. I think for most patients that's perfectly fine.

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Emma Foreman: Right so María, tell us a bit about differing strategies for new versus switch over patients.

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María-José Tamés: Well, when informing patients, we can face two different situations or profiles: (1) new or naïve patients to biologics, and (2) patients already on treatment who are switched from the originator to the biosimilar. Those who are switched already have better basic knowledge, but in

both cases the information provided should always be tailored to individual patient demographics and health literacy levels.

And we should ensure that the information obtained by them from the internet is correct. This is maybe linked with the question you asked me before if “according to the level of knowledge of education of the patient”, if we should change our information or not?

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María-José Tamés: We arrive at my last slide. This is a little summary and shows you useful tips to consider for when you plan your patient education. Most of the areas have been covered through the presentation, which you can now see on the screen. We are not going to go through them one by one because they have been covered already, but I think they will help in your daily practice.

You have steered the patient, which we have already spoken about, positive tailoring of supportive materials, etc, etc, simple written and oral information, etc, etc.

And now, Emma, I think you have some practical examples.

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Emma Foreman: I think I can lead here to go through the practical examples.

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Emma Foreman: What patients want. So, this was a study of interviews with patients with chronic rheumatic disease, switching from infliximab originator to a biosimilar infliximab.

Their interview results showed a low knowledge level of biosimilars: they had concerns around safety and efficacy, and they didn't know the difference between a generic drug and biosimilar – which is not hard to believe because a lot of doctors don't know the difference between generics and biosimilars.

What did they want from their healthcare professionals? They wanted honest information. They wanted to understand the perceptions, experience, and attitudes of the staff carrying out biosimilar switches because they trust us, and you know, if we're comfortable with them and we're honestly telling them that we think they're fine, they're safe, and they're effective, then we can set their minds at rest quite easily by being open and honest. It's important that the staff feel well-educated on this themselves to be able to give that sort of information and reassurance.

Patients want to be given their support and information to come to a decision themselves and they want the opportunity to return to the originator, if desired, which, for example in the NHS in the UK, you don't necessarily get a choice of product. Really, it's the job of the healthcare professionals to convince the patient that the product that we have available to us in the NHS is safe and effective for them.

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Emma Foreman: So, the results of what the patients wanted were shared with the multidisciplinary team who developed the switch modality and came up with specific messaging and vocabulary tools

to make sure that all the staff knew the best way to communicate the information to patients and all the staff felt confident in their own knowledge.

Patients were given oral information, a treatment leaflet, and given the opportunity to ask questions. This was tailored to the patient needs with standardised answers given. I think what is important is that staff are confidently giving clear and well evidenced answers. In the follow up, the patients showed that discontinuation rates in the biosimilar cohorts were very similar to discontinuation rates of historical originator treatments.

Some previous studies have shown higher discontinuation rates as a result of the nocebo effect, where patients' concerns lead them to feel that their treatment isn't working so well, or get artificially inflated numbers of reactions because patients are so concerned.

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Emma Foreman: OK, so the next example is a practical example: patient knowledge before and after leaflet distribution. This is a US study looking at the awareness of biosimilars amongst oncology patients.

They assessed their knowledge by an online survey. Oncology and haematology offices were provided with printed materials that were designed to cover things like safety and efficacy, as well as other well-known concerns. There were 12 questions: two different demographic questions and 10 relating to biosimilars, and the responses were given on a Likert scale of 1 to 10.

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Emma Foreman: The results showed that after the education, 70% were aware of the correct definition of biosimilars, 80% identified correct answers relating to regulation, adverse events and costs, 65% believed biologics were an important part of cancer combination therapy, and >60% reported a willingness to discuss biosimilars with their healthcare professionals.

So, this shows that by giving them that information and that knowledge, it's raised their awareness and raised the acceptability of biosimilars amongst those patients. Over 1/3 of patients preferred printed brochures and flyers, just under 1/3 liked seminars and group discussions; 16% chose online presentations and webinars, and 16% did not have a preferred learning style.

I think printed information is generally easier, but oral is always the best way to offer an opportunity to ask questions.

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Emma Foreman: We've come to the end of today's webinar, apart from a little bit of closing-down housekeeping. So, if you've got any burning questions, quickly type them into the Q&A for us. I think it's been interesting – particularly finding out what your views are on when we need to give information about biosimilars, when we need to really tell patients that we're doing a switch and when perhaps it's less important.

María has given us some really good tips on how we go about giving information and tailoring it to the individual patients, using a mixture of printed materials or material and the good old internet.

María, what's your big take home from the webinar today?

María-José Tamés: I would like to say something regarding one of your remarks around oral and printed information. I think it's important to give both of them because sometimes when you are going to give patients just oral information they get upset. With the addition of the written information, it provides a backup. You can say don't worry, because everything I'm going to tell you is also in the brochure, I'm going to give to you. So, patients become more relaxed and it's just a question of understanding the written content and you will have time to go over it slowly.

Emma Foreman: Yes, patients get quite a lot of information when they come to see us, and sometimes they get a bit overwhelmed with the amount that we tell them. It's really good for them to have something to look at when they get home that reinforces what's being said.

Right, so that's about all we've got time for today.

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Emma Foreman: I'm just going to run through some our post learning assessment question first.

So, just to repeat the question asked at the beginning: since listening to the webinar, will you now routinely include the wider multidisciplinary team in your patient communication strategy? So, will you do it routinely, often, sometimes, rarely, or never.

Let's just see if we've influenced your thoughts.

OK, oh, lovely – 83% are now going to routinely try and involve the multidisciplinary team in their communication strategy. That's brilliant to see. Thank you very much.

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Emma Foreman: Just before I go, I want to make you aware of some free learning resources we have available on the ASK biosimilars website.

We have a biosimilars handbook – which is available in English, but will soon be available in French, German, Italian, Japanese, and Spanish.

We also have an abstract library of references. We'll soon be adding to this with learning chapters, national guideline summary documents, and the archive footage from these webinars.

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Emma Foreman: Just one last 'thank you' – thank you for joining this webinar. Thank you so much, María, for speaking.

María-José Tamés: Thank you, thank you all of you.

Emma Foreman: Lovely, and thanks for your questions and participation, and I wish you all a very good rest of the day – wherever you are.

María-José Tamés: Bye-bye, thank you.