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GaBI Scientific Meetings

ROUNDTABLE ON REGISTRIES
Practical Considerations for Registries – making them work

26 January 2017, Pullman London St Pancras, London, UK

Patient perspective on biosimilars safety data and other concerns

Clare Jacklin, NRAS, London, UK

26 January 2017

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GENERICS AND BIOSIMILARS INITIATIVE
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for people with RA and JIA

Clare Jacklin
Director of Exernal Affairs

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Biosimilars …….. The Patient Perspective

- What really matters to patients about biosimilars?
- What are NRAS's top concerns about the present and future of biosimilars for patients?

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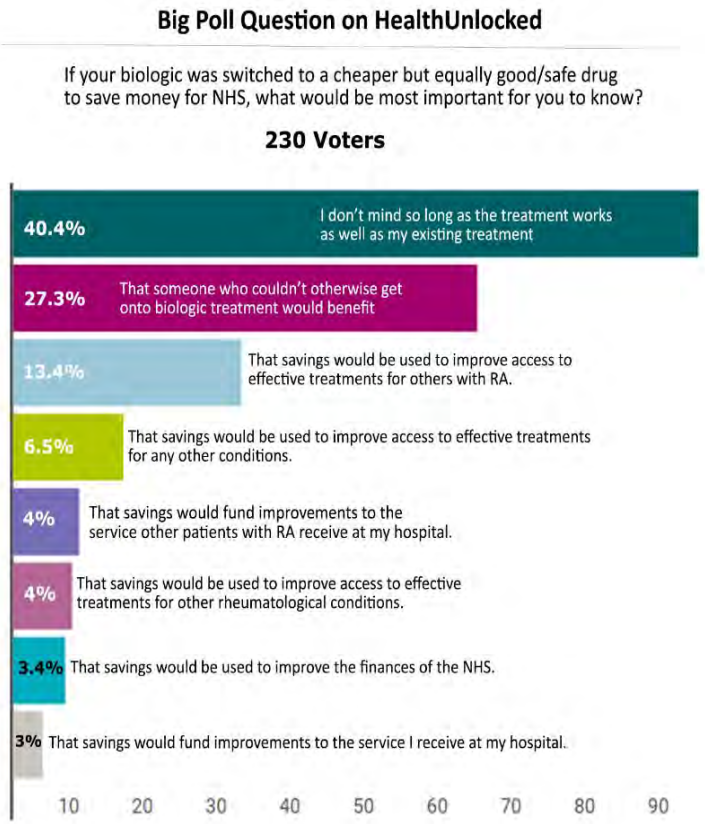
What really matters to patients about switching?

Well, unsurprisingly safety and efficacy

Patients, consulted in the right way seem to be actually very altruistic

But switched inappropriately or the threat of being switched inappropriately, without consultation ……..



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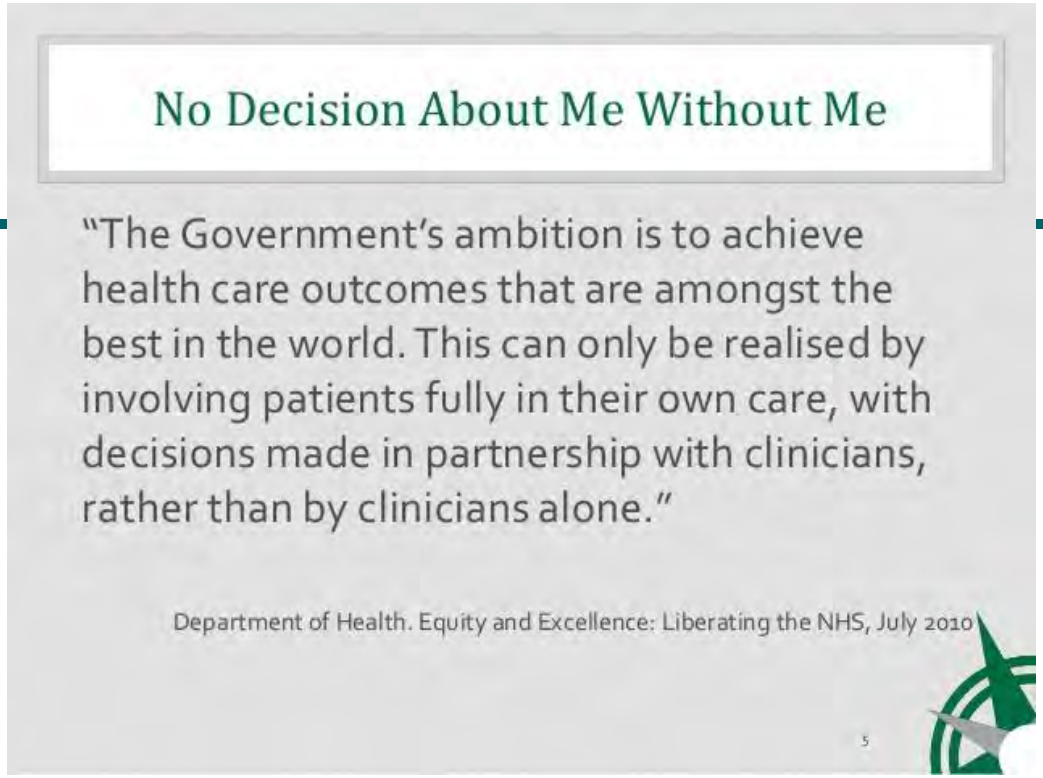

The aim of the Right Care Shared Decision Making Programme is to embed Shared Decision Making in NHS care. This is part of the wider ambition to promote patient centred care, to increase patient choice, autonomy and involvement in clinical decision making and make "no decision about me, without me" a reality.

Quality Improvement Productivity and Prevention (QIPP) Right Care programme, 2012

To achieve this, (SDM) we are encouraging the development of new relationships between patients, carers and clinicians, where they work together, in equal partnership, to make decisions ……

……Without these changes, we cannot achieve the required transformational culture change to support Shared Decision Making.

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Comments & concerns from patients

If only all savings would be put back into research for treatment of RA but I don't trust the management of the NHS to do it

I would be suspicious about the efficacy of the cheaper drug. Why is it cheaper? Would the delivery service be compromised? But as long as I experienced at least the same effect, I would be happy if the money was ploughed back into research, helping others to get onto Biologics or have whatever treatment is best for them. This sounds rather selfish, but if my RA is kept under control, this saves hospital time and, as we know, time means money.

Would this biosimilar be monitored by the BSR Biologics Register or a register set up for biosimilars? This change is obviously cost saving exercise for my Trust, however, if problems arise with the use of this biosimilar would the funds be there for patients to return to the original biologic?

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We had to be assessed for the need for the biologic in the first place.(a long process when you're desperate!) If something cheaper had the same effect of course I'd be happy to have that and for savings to be used on others. The whole point is to control the disease and limit damage which then costs the NHS a fortune in treatments, operations, disability aids, appointments etc

Can we be **absolutely sure they are as safe**? My understanding is that they only have to do short, small studies to show this, unlike the original medications

I know when I see my Rhuemy next Wednesday and ***I tell him I don't want to try this medication he will get very cross with me so I'm dreading the appointment***

What is the safety and effectiveness record of this drug [biosimilar]? Where can I read about this data?

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What particularly concerns us?

Bearing in mind that each product from the different manufacturers .....will drive cost down, will we, the patients, be at risk of being flipped from one brand to another depending on which is cheapest that month?

- NHS staff taking huge decisions without proper stakeholder input
- Switching from drug to drug – flip flopping
- Time taken to negotiate gain-share
- Fact we are once again in a less flexible situation than much of the rest of Europe

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Would be very pleased if the biosimilar drug had the same efficacy and lack of unpleasant side effects as current biologic/anti-Tnf. I would be particularly supportive if the drug company's price for biologic drugs was reduced to make it affordable for NICE to change their guidelines and open the door for many more to be given a another chance and/or choice in the fight to control this RD and reduce disability.

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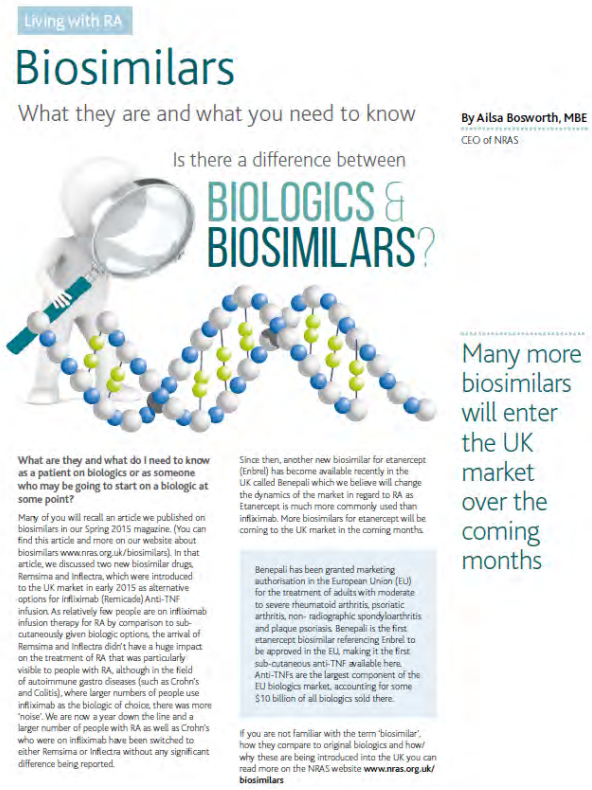
What is NRAS doing to support patients and rheumatology teams?


Living with RA

Biosimilars

What they are and what you need to know

By Ailsa Bosworth, MBE
CEO of NRAS

Is there a difference between
BIOLOGICS & BIOSIMILARS?

Many more biosimilars will enter the UK market over the coming months

What are they and what do I need to know as a patient on biologics or as someone who may be going to start on a biologic at some point?

Many of you will recall an article we published on biosimilars in our Spring 2015 magazine. (You can find this article and more on our website about biosimilars www.nras.org.uk/biosimilars). In that article, we discussed two new biosimilar drugs, Remsima and Inflectra, which were introduced to the UK market in early 2015 as alternative options for infliximab (Remicade) Anti-TNF infusion. As relatively few people are on infliximab infusion therapy for RA by comparison to sub-cutaneously given biologic options, the arrival of Remsima and Inflectra didn't have a huge impact on the treatment of RA that was particularly visible to people with RA, although in the field of autoimmune gastro diseases (such as Crohn's and Colitis), where larger numbers of people use infliximab as the biologic of choice, there was more 'noise'. We are now a year down the line and a larger number of people with RA as well as Crohn's who were on infliximab have been switched to either Remsima or Inflectra without any significant difference being reported.

Since then, another new biosimilar for etanercept (Enbrel) has become available recently in the UK called Benepali which we believe will change the dynamics of the market in regard to RA as Etanercept is much more commonly used than infliximab. More biosimilars for etanercept will be coming to the UK market in the coming months.

Benepali has been granted marketing authorisation in the European Union (EU) for the treatment of adults with moderate to severe rheumatoid arthritis, psoriatic arthritis, non- radiographic spondyloarthritis and plaque psoriasis. Benepali is the first etanercept biosimilar referencing Enbrel to be approved in the EU, making it the first sub-cutaneous anti-TNF available here. Anti-TNFs are the largest component of the EU biologics market, accounting for some $10 billion of all biologics sold there.

If you are not familiar with the term 'biosimilar', how they compare to original biologics and how/ why these are being introduced into the UK you can read more on the NRAS website **www.nras.org.uk/ biosimilars**

We're developing a new booklet on all medicines in RA

The NRAS position paper on biosimilars is available online at www.nras.org.uk

We're collaborating with the BSRBR on production of patient information to encourage patients to sign up to the Register

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NRAS position on Biosimilars

We have updated our position paper twice since 2014 to reflect current data on safety and efficacy and pragmatism about what's really happening on the ground

There are 4 key areas we want to see being properly addressed at a national level:

✓Patients must be properly informed through robust shared decision making mechanisms about being switched – a round robin letter from Trust with inadequate information is not satisfactory
✓The manufacturers must agree to long term safety data collection through the BSR Biologics Registers
✓Gain share from the savings must benefit rheumatology and patients in an equitable way (i.e. it doesn't all go to the CCG or Trust for use in other therapeutic areas or for plugging deficits)
✓Both we and the BSR would like to see NICE review the health economic model as we believe that calculated today, given the drop in pricing the ICERS would be well within the £30,000 limit so more could benefit from treatment with biosimilars.

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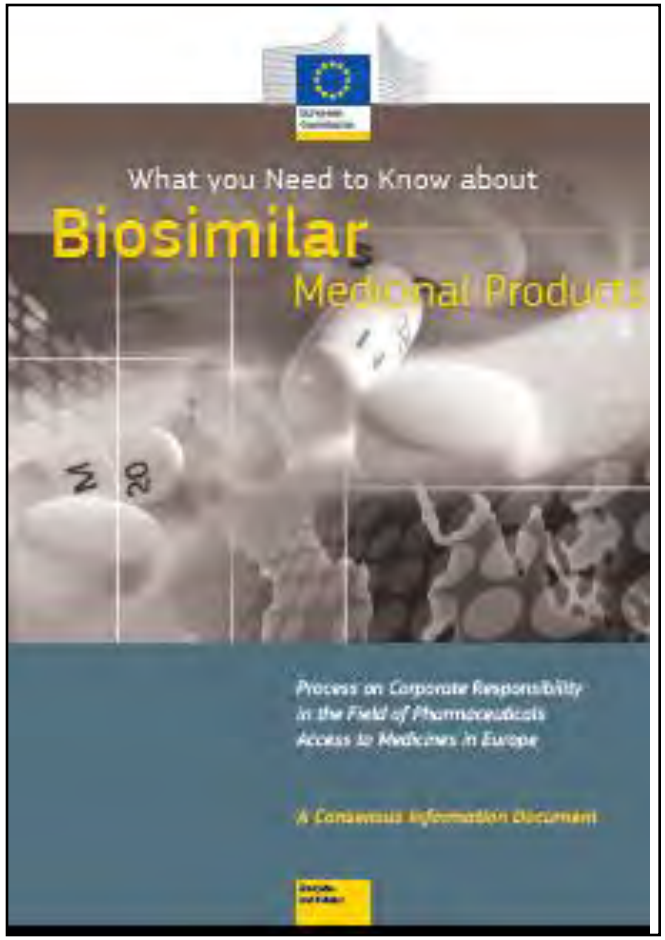
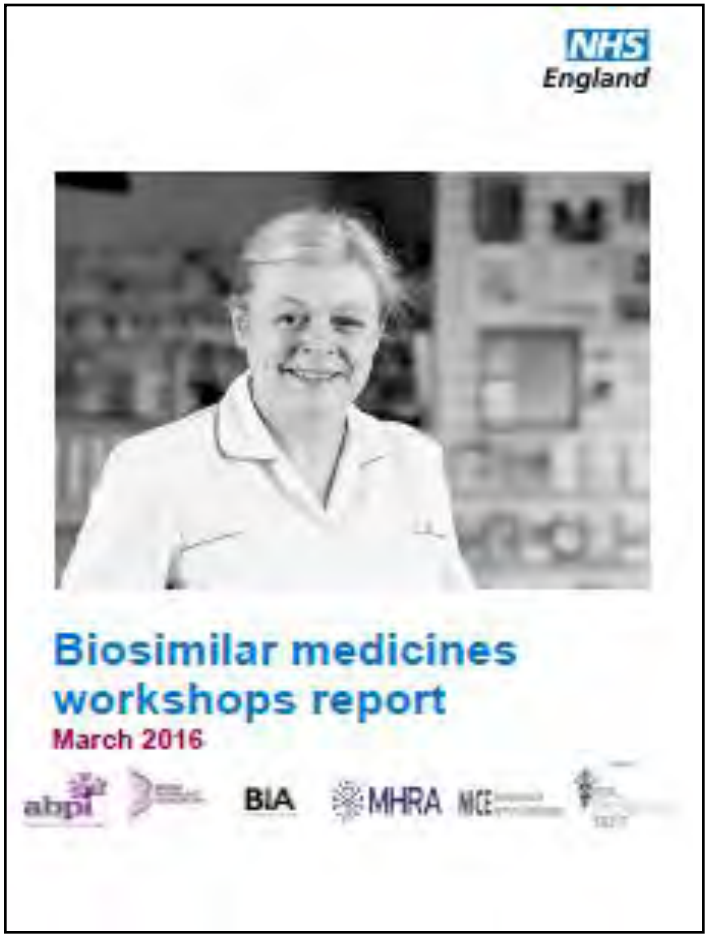
Other resources





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Thank you
Questions?

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