

Clinical Senate Council Meeting



Wednesday 6th December 2017

South West Clinical Senate Council: Biosimilars Recommendations

Question

To what extent and how should the transition to use of biosimilar medicines be prioritised to enable the provision of best value care in the NHS?

Does the Clinical Senate support the uptake of biosimilar medicines at pace and how can their best practice use be maximised?

Overview

Biological monoclonal antibodies are widely used across the NHS to treat patients with very effective results. As originator biological medicines come off patent, biosimilars are being produced and marketed to the NHS at significantly less cost. Whilst chemically produced medicines that come off patent can be exactly replicated as generics by a generics manufacturer, biological molecules are 'grown' and therefore will be very similar but not 100% the same as the original molecule in the patented medicine. The minor changes in licensed biosimilars however are not regarded as having clinically meaningful differences and even originator biologicals may vary between batches over time. NICE guidance applies to biosimilars as it does to originator biological drugs.

Common biosimilars already in use in the NHS include Infliximab (2015), Rituximab (2016) and Etanercept (2017). Adalimumab which is due to come off patent in October 2018 is the world's number one selling medicine (by revenue) and there are therefore significant savings opportunities for the NHS through switching patients onto biosimilar drugs. The NHS England Medicines Value Programme has identified biosimilar medicines as a key priority, and the national commissioning framework for biological medicines (including biosimilar medicines) (ref 2) states 'There is the potential to realise savings of at least £200-300m per year by 2020/21 if the NHS embraces the use of best value biological medicines in a proactive, systematic, and safe way'. In England, £17.4bn is spent per year on drugs in the NHS at present (ie £1 in every 7), with the total bill increasing. Time is regarded as critical in switching to biologicals in order to maximise savings. To date the switch to infliximab and etanercept has saved the NHS an estimated £160m. At January 2017, 50% less was being spent on infliximab than would have been spent if biosimilars were not available, despite usage having increased by 30% since biosimilar launch, and this has therefore potentially resulted in improved access. While the biosimilar price for adalimumab is not yet confirmed it has been calculated that £4.6m - £9.2m potential savings could be missed in month one alone if patients are not switched any quicker than for previous biosimilar products.

The present NHS England Specialised Commissioning approach outlined in the national CQUIN is for 'Adoption of best value biologic products in 90% of new patients within one quarter of guidance being made available; and adoption of best value biologic products in 80% of applicable existing patients within one year of being made available (except if standard treatment course is < 6 months)'.

Evidence

All the available evidence and research regarding biosimilars is considered reassuring regarding their use but it is felt that ongoing monitoring is needed. There are also some practical issues to consider in managing the transition to new biosimilars and whether repeated switching as new biosimilars become available would become less cost effective and potentially harmful through greater immunogenicity. The contracting and procurement to ensure sustainability of supply also needs to be considered. Incentives or gain share arrangements can also be considered to encourage switching. The Senate reviewed current uptake data in the South West and noted that in some areas for some drugs uptake is 100% where as in others it can be much lower depending on the specialty, trust approach, capacity to implement change, and individual consultant clinical perspective. For example, in situations where the severity of illness is great and impact of the treatment is significant, there may be a desire not to destabilise control. Biosimilars are delivered either intravenously or via subcutaneous injection and a change from one method to another would impact on the ease of switching. It is also arguably easier to switch a patient on IV drugs delivered in a hospital setting than those patients whose subcutaneous medication is provided in the community via homecare services. Additionally some biologics pharmaceutical companies provide support services to patients, so for the drug adalimumab these may have to be switched also, with costings factored in.

The MHRA (Medicines and Healthcare Products Regulatory Agency) have a robust evaluation process for licensing drugs and are equipped to evaluate differences between biological molecules. Extensive analytical quality assessment of biosimilars, comparing them to originator products, is led by regulatory authorities such as the MHRA, and biosimilars must be highly similar to the originator to obtain a licence. This demonstrates that there are no clinically meaningful differences in terms of quality, safety and efficacy. The same principles are used to evaluate biosimilars as originators for manufacturing, control and inspection, but larger quality dossiers are required for biosimilars, to include comparability with the originator medicine. However they don't need undergo the same level of clinical testing for all indications (as has been undertaken for the originator), and this supports savings in development costs for biosimilars. The licensing process has specification limits and ranges for batch production and too great a difference out of range compared to the originator would prevent licensing of a drug.

It was noted that when infliximab (which is the most widely used biosimilar) first came to the market, there was not as much information about biosimilars as there is now. The "Nor Switch" one year switching trial has recently been completed (ref 1), supporting the increasing evidence that there are no clinical differences between originator and biosimilar drugs. There has been some caution about switching existing patients to biosimilars particularly if their condition had been difficult to bring into remission, but the Nor Switch data does not support this concern. At the Royal Devon and Exeter trust the gastroenterologists have also been reviewing data via their PANTS study. Learning from Devon and elsewhere suggests that a provider switch team is key to good uptake rates, and that an incentivisation arrangement with commissioners in the first year will support the provider to facilitate the switch. At the RD&E the financial benefits from switching allowed the team to expand and supported a biologics service for ongoing review of patients. Full support from the clinical team is also thought to minimise the potential 'nocebo' effect (ie the potential negative placebo effect of change), giving patients confidence in the switch.

Patient feedback has also suggested that patients would not object to switching as part of a cost reduction programme recognising that more people can receive the drug and would have faith in their clinician's decision that it was suitable for them. Clear communications with patients about a switch of medication from a cohesive clinical team fully behind switching is essential and the role of nurse specialists is regarded

as key. The impact on drugs companies in terms of moving to biosimilars was considered to be low as they can invest in other originators and have had market exclusivity of originators up to the point of them coming off patent. Furthermore the savings to the NHS drug spend will potentially allow for increased spend on other drugs.

Recommendations

The South West Clinical Senate Council supports the prioritisation of moving to an uptake of biosimilars at pace as part of the provision of best value care in the NHS. The South West Clinical Senate Council supported the switch of patients to licensed biosimilars and believes that there is a clinical duty to manage the medicines spend responsibly to maximise overall patient care and healthcare funding for the health service. The current parameters for switching where 90% of new patients are commenced on the best value biological product within 3 months of its release, and 80% of existing patients are switched to a biosimilar within 12 months are strongly supported. With timely planning in advance of the release of a new biosimilar these timelines should seek to be improved upon. 100% uptake would not be expected as a target in order to allow for individual clinical decision making, however mandating a switch within the described parameters is supported. Clinical preferences in prescribing that are not evidence based are not affordable and are not supported by the large national body of evidence supporting the use of biosimilars.

To deliver best practice and support transition the following is recommended;

- The same principles for switching to biosimilars must be adopted across England with uniform timescales, processes and information. National commercial plans and pricing need to translate into local plans across the country.
- Commissioning decisions and medicines procurement should be done at scale to encourage consistency, best value and to support sustainability of supply in contracts.
- There must be clear education and clinical engagement ahead of a new biosimilar going to market to prepare for successful whole-scale switching.
- Incentive agreements or shared benefit agreements are essential and should be consistent across the country with a national standard agreement developed.
- Prescribers and providers need to be informed by commissioners and the NHSE pharmacy team about the biosimilars available for their specialty and the licensed indications.
- Prescribing should be done by brand name for traceability of drugs and as required by the MHRA.
- Whole service switches will be more successful with unanimous support within both a trust and a clinical team. Clear evidence and information to support the use of biosimilars must be provided to trusts.
- Identification of a clinical switch champion within a trust or service is encouraged.
- National preparation for the marketing of adalimumab in October 2018 should begin now to maximise the savings from switching with consideration given to the method of delivery of the medicine and additional support provided through homecare delivery.
- A systematic national approach to switching to biosimilars should also support the benchmarking of data to help add to the evidence base around biologics.
- Strong patient involvement is required, best practice would be setting up a provider switch team as demonstrated at Royal Devon & Exeter.
- Where possible patients would be informed of the switch in a consultation where the appropriateness of their prescription was also reviewed, with access to clinical support for follow-up

questions. Virtual or telephone clinics could be used. However, the use of letters only to inform patients of the switch was not supported.

- New patients commencing any biological product should be introduced to the possibility that at a future date a biosimilar product may be selected for their treatment if one becomes available, thereby enabling future treatment transitions through increasing patient awareness.
- The Senate supports the proposals for patients, prescribers, providers and commissioners on page 4 of the commissioning framework for biosimilars.

Next steps

- These recommendations will be signed off by the South West Clinical Senate Council and shared with CCGs, STPs, NHSE and other Senates across England.
- These recommendations will be taken to the South of England Regional Medicines Optimisation Committee for the next meeting on 30th January 2018 and then shared with the three other Regional Medicines Optimisation Committees across the country.
- The recommendations will be fed into the follow up work to the letter sent to all CCGs by NHSE/NHSI and specialised commissioning in November 2017 regarding the direction of travel for commissioning biosimilars.

Pre-reading

1. Biosimilar Guide <https://www.england.nhs.uk/wp-content/uploads/2015/09/biosimilar-guide.pdf>
2. Biologicals Commissioning Framework <https://www.england.nhs.uk/wp-content/uploads/2017/09/biosimilar-medicines-commissioning-framework.pdf>
3. Nice position statement <https://www.nice.org.uk/guidance/ktt15/resources/biosimilar-medicines-58757954414533>
4. Regional Uptake Data (available on request from the Senate team)
5. Biosimilars in the EU available at www.swsenate.nhs.uk

References

1. Nor Switch Trial [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(17\)30068-5/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)30068-5/fulltext)

The Council Agenda, Speaker slides and meeting notes are available at www.swsenate.nhs.uk