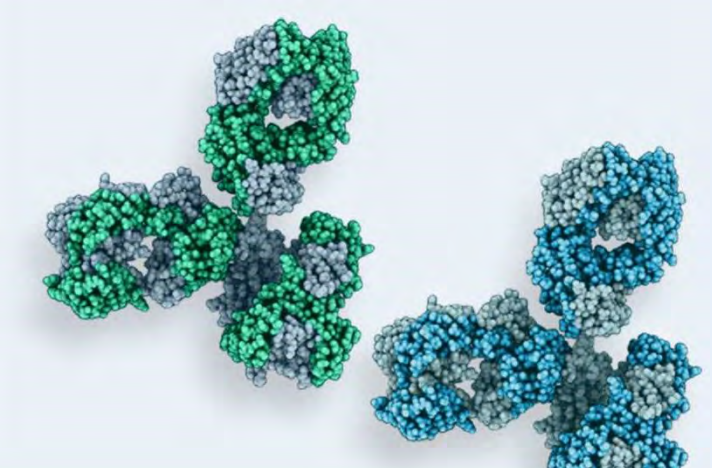
International Society of Nurses in Cancer Care

BIOsim

A train the trainer programme for nurses

Module 3



(Supported by an unrestricted grant from Pfizer)

Administration of biosimilars

Objectives of the session

At the end of this session the nurse will be able to,

- Understanding the administration requirements
- Understand the side effect profiles
- Appreciate the concern regarding interchangeability
- Appreciate the need for local audit

Prior to administration

Nurses should,

- be confident they have enough knowledge of that person's health and are satisfied that the medicines or treatment serve that person's health needs
- make sure that the care or treatment you advise on, prescribe, supply, dispense or administer for each person is compatible with any other care or treatment they are receiving…
- take all steps to keep medicines stored securely
- Confirm consent with patients

- www.nmc.org.uk/standards

A key role of the nurse is administration of medicines

- What are the important considerations for nurses with regard to administration of medicines ?

A word about consent

Defining consent

- For consent to be valid, it must be voluntary and informed, and the person consenting must have the capacity to make the decision.
- These terms are explained below:
- **voluntary** – the decision to either consent or not to consent to treatment must be made by the person themselves, and must not be influenced by pressure from medical staff, friends or family
- **informed** – the person must be given all of the information in terms of what the treatment involves, including the benefits and risks, whether there are reasonable alternative treatments, and what will happen if treatment doesn't go ahead
- **capacity** – the person must be capable of giving consent, which means they understand the information given to them and they can use it to make an informed decision

How is consent given?

Consent can be given:

- **verbally** – for example, by saying they're happy to have an X-ray
- **in writing** – for example, by signing a consent form for surgery

- Someone could also give non-verbal consent, as long as they understand the treatment or examination about to take place – for example, holding out an arm for a blood test.
- If someone is going to have a major medical procedure, such as an chemotherapy, their consent should ideally be secured well in advance, so they have plenty of time to obtain information about the procedure and ask questions.
- If they change their mind at any point before the procedure, the person is entitled to withdraw their previous consent.

Who takes consent at your organisation ?

How do you confirm consent for treatment ?

Is there a need to re consent if you switch to a biosimilar?

Administration by nurses

- None of the drug administration elements of a code of professional practice should be altered by introducing biosimilars. Medicines management still includes;
- Right drug
- Right route
- Right dose
- Right time
- Right rate

Right drug

Brand name must be used to prescribe a biosimilar drug

NB Others may be available

Trastuzumab

- Herzuma
- Ogivri
- Kanjinti
- Ontruzant

Rituximab

- Truxima
- Rituxan
- Rixathon

https://www.google.co.uk/search?biw=1433&bih=672&tbm=isch&sa=1&ei=Sc1_W4K9LOHPgAa11KmoAw&q=100ml+infusion+bag+versus+500ml+infusion+bag&oq=100ml+infusion+bag+versus+500ml+infusion+bag&gs_l=img.3...18917.39205.0.3980.42.40.2.0.0.0.278.2545.34j3j1.38.0....0...1c.1.64.img..2.1.89...0i67k1j0i7i30k1j0i5i30k1.0.0dQ2KbWO3_w#imgrc=DGxIwuGtjB

Right route

- All cancer biosimilars to date are given intravenously

- NB there are no S/C biosimilars

https://www.google.co.uk/search?q=intravenous+chemotherapy&source=lnms&tbm=isch&sa=X&ved=0ahUKEwjm7_nArIXdAhUC-aQKHd2XDaIQ_AUICigB&biw=1433&bih=672#imgrc=pE79gkaz7AnydM:

Right dose

- Dosing will vary by brand
- There may be loading dose and then reduced dose
- Dose may be flat or calculated by body surface area or dose/kg

Right time

- The biosimilar drug should be the same schedule as the originator drug.

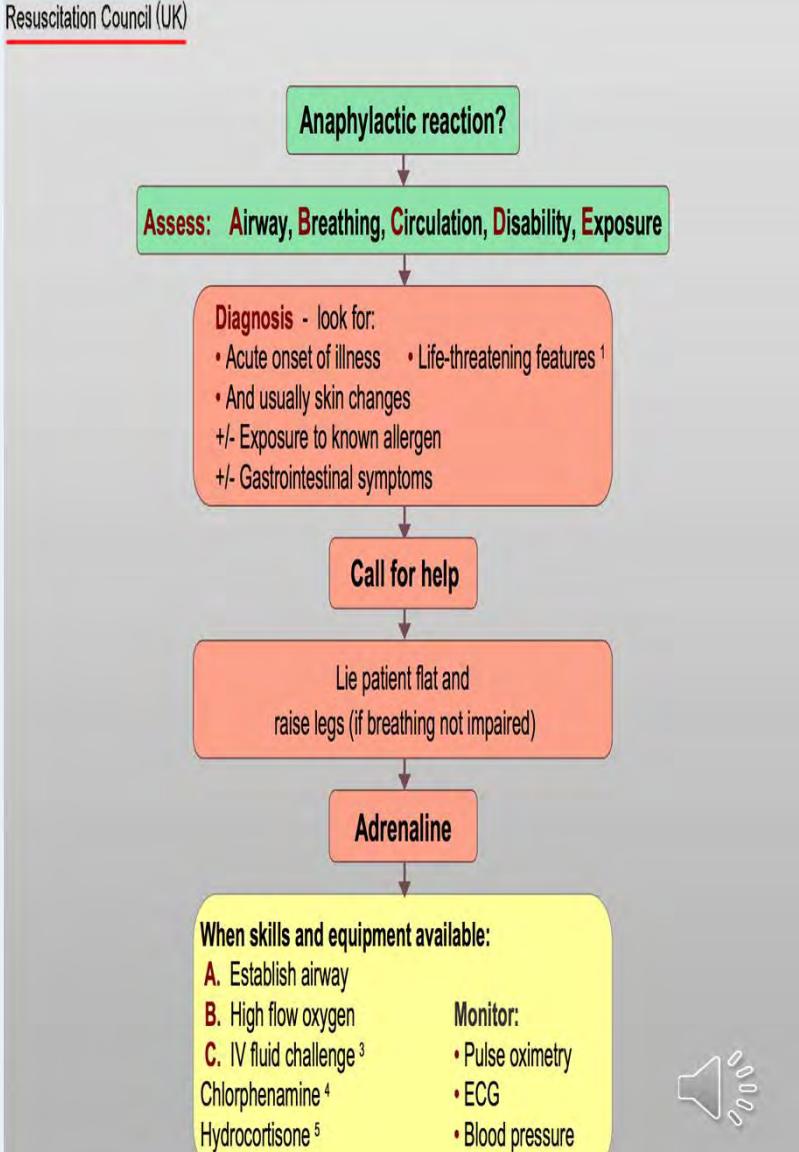
		Sep-18				
Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
		Oct-18				
1	2	3	4	5	6	7

Right rate

- Need to check summary of product characteristics (SPC)
- Local institutions will need to decide on rapid infusions

Side effects

- Any biologic drug has the potential to cause an immune reaction of an infusion related reaction.
- This is no different in biosimilar medicines .
- However the development process described in module one has tested the safety profile of the biosimilar and has been determined to be within the acceptable reference guide from the originator drug



2018 Resusitation council Uk accessed July 18

Generation of real world evidence to support biosimilar adoption

Real-world experience

700 million patient days[1]

"Over the last 10 years, the EU monitoring system for safety concerns has not identified any difference in the nature, severity or frequency of adverse effects between biosimilars and their reference medicines"[2]

Controlled experience

Articles

Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial

Clinical and epidemiological research

CONCISE REPORT

A nationwide non-medical switch from originator infliximab to biosimilar CT-P13 in 802 patients with inflammatory arthritis: 1-year clinical outcomes from the DANBIO registry

Bente Glintborg,[1,2] Inge Juul Sørensen,[3,4] Anne Gitte Loft,[5] Hanne Lindegaard,[6] Asta Linauskas,[7] Oliver Hendricks,[8] Inger Marie Jensen Hansen,[9]

Audit/case study

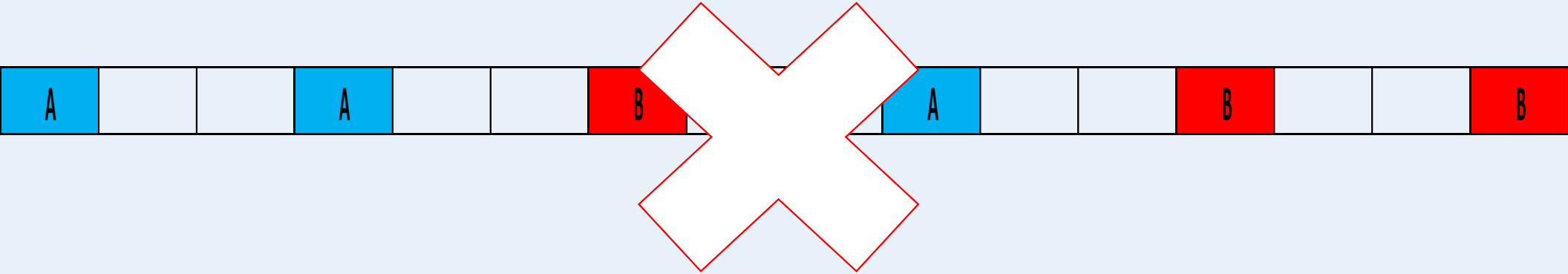
NHS
University Hospital Southampton
NHS Foundation Trust

NHS
University College London Hospitals
NHS Foundation Trust
70 YEARS

[1] Medicines for Europe information based on EMA Post-authorisation safety Update Reports (PSURs)
[2] EMA – European Commission: Biosimilars in the EU – Information guide for healthcare professionals
http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2017/05/WC500226648.pdf accessed June 2018

Interchangeability

- That is the changing between biosimilar brands is not recommended and there is no current safety data



Switch back guidelines

- Inevitably a patient will relapse coinciding with a recent switch

or

- A new side effect will convince a patient of cause

- Be prepared
  - Switch back arrangements
  - Knowledge to support patient
  - Psychological assessment

Summary

- Education is key for nurses and building confidence that drugs are the same as originator drug
- Understanding side effect profile of each drug is important but should be no different to originator
- Brand names are to be used to prescribing and documentation
- Local audit key including error reporting

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Questions?

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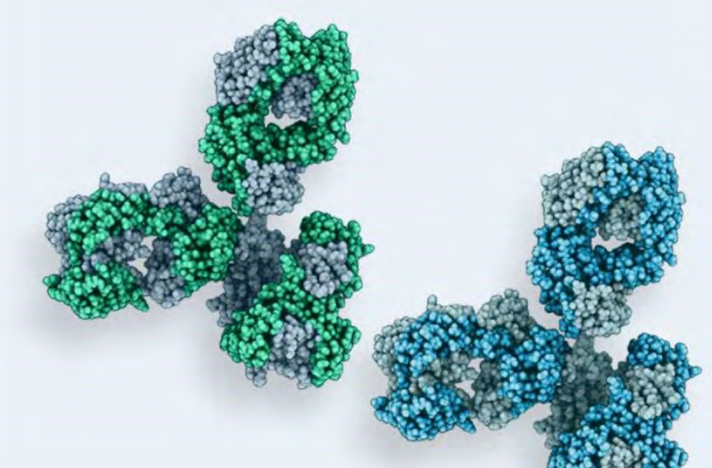

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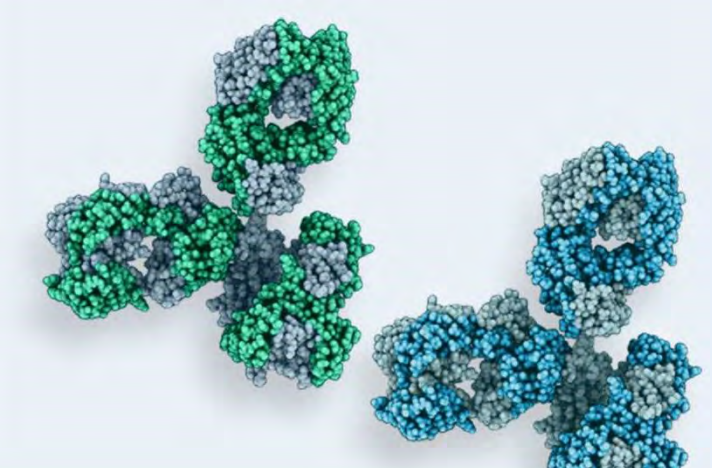

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