Perspective on
NOR-SWITCH

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Background

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The Value of Biosimilars

Biosimilars can increase:

- The options patients have
- The number of patients who can receive life-changing medicines
- Cost savings

As more biosimilars become available, one question lingers:

How does switching to a biosimilar affect patients who are stable on the original biologic?

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Biosimilar Switching

European countries, most hospitals:

- Start new patients on the biosimilar BUT
- Do not require stable patients to switch

However…

Many governments would like to use biosimilars to further reduce costs

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The Need for Data

Little data on switching exists

Limitations of most studies

- Retrospective
- Small sample size
- Not randomized

- Are not powered to have definitive conclusions

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What is it?

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Data on Switching

- Scarcity of data on switching

- As policymakers look for data to inform their decisions, a new study is generating interest:

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What is NORSWITCH?

Funded by the

Norwegian government

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What is NORSWITCH?

- A randomized, double blind study
- 481 patients
- Six inflammatory diseases
- Single switch between Remicade® and Remsima®

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What is NORSWITCH?

A total of 481 enrolled patients at 40 sites across Norway (19 in gastroenterology, 16 in rheumatology and 5 in dermatology) between October 2014 and June 2015

- **247 patients with inflammatory bowel disease** (155 with Crohn's disease, 93 with ulcerative colitis)
- **199 patients with inflammatory joint disease** (78 with rheumatoid arthritis, 91 with spondyloarthritis, and 30 with psoriatic arthritis)
- **35 patients with plaque psoriasis**

Patients who were stable on the original biologic either remained on the original biologic or were switched once to the biosimilar (randomized 1:1).

Patients were followed for 1 year, after which they could roll over into a 6-month open extension study, where everyone received the biosimilar. This meant that everyone in the study switched medicines once, either at the study start, or at the start of the extension phase.

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What is NORSWITCH?

- Professor Tore Kvien – Principal Investigator
  - Department of Rheumatology
  - Diakonhjemmet Hospital, Oslo, Norway
- Multidisciplinary and multiregional project group

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NOR-SWITCH:

What Can it Show?

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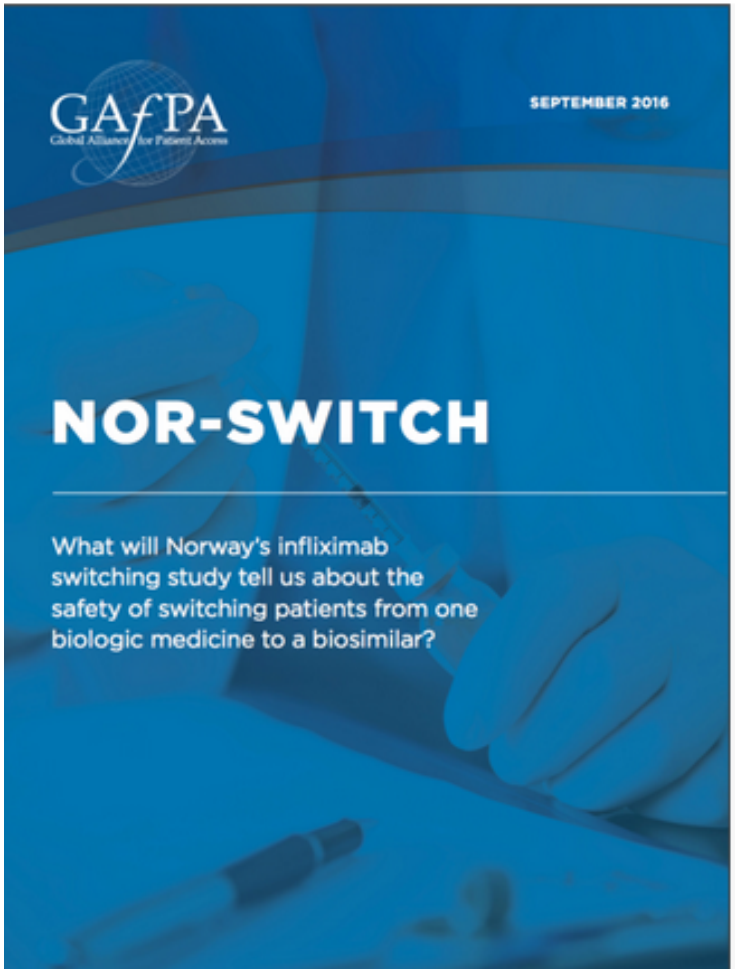

- International group of physicians and scientists
- NOR-SWITCH investigators
- Reviewed
  - The trial design
  - Its potential impact

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NOR-SWITCH **WILL SHOW**

- ✓ Whether or not patients can be switched once from the original biologic to the biosimilar without:
  - Increased occurrence of disease worsening, or
  - Increased incidence of the most frequently occurring adverse events.
- ✓ Results from a pooled population of patients with Crohn's disease, ulcerative colitis, rheumatoid arthritis, spondyloarthritis, psoriatic arthritis, and psoriasis.
- ✓ Whether or not patients can be switched once from the original biologic to the biosimilar without stimulating a patient's immune system.
- ✓ Whether or not the immune system is neutralizing the effects of the medicine.

NOR-SWITCH **WILL NOT SHOW**

- ✗ The effects of a single switch from the original biologic to other biosimilars not evaluated in this study.
- ✗ Definitive data on the effects of a single switch in the individual diseases studied.
- ✗ The effects of multiple switches. For example, from the original biologic to a biosimilar, then to a different biosimilar, etc.
- ✗ The effects of switching in different diseases treated with other biologics and biosimilars not studied in NOR-SWITCH.
- ✗ The effects manifesting beyond the study treatment period.

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What Were the Results?

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Results

United European Gastroenterology Week 2016

- Disease worsening
  - **26.2%** original biologic Remicade®
  - **29.6%** biosimilar Remsima®

- Met pre-defined non-inferiority
  - 95% confidence interval of the adjusted treatment difference
    - (-4.4%) 12.7 – 3.9

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https://cslide.ctimeetingtech.com/ueg2016/confcal/J%C3%B8rgensen

Results

"New data…show that a switch to biosimilar infliximab (CT-P13) from originator infliximab is not inferior to continued treatment with the originator and that patients can be safely switched."

–Celltrion Healthcare Release

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Results

"The data shows that safety and efficacy are maintained post-switch and should give confidence to physicians looking to move their patients onto biosimilar infliximab for non-medical reasons such as cost."

- Jørgen Jahnsen, NOR-SWITCH Co-author & Professor of Gastroenterology at the University of Oslo, Norway

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NOR-SWITCH:

What are the Policy Implications?

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Policy Impact

Will data from this study be used inappropriately?

- Switching of any biosimilar within a class?
- Multiple switches over the course of a treatment?
- Switching in any disease where biosimilars are available?

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The Role of Physicians & Patients

- To maintain quality health care and to respect the physician-patient relationship:
  - Physicians should have a say in whether or when their patients are switched
  - Patients should give their informed consent

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The Importance of Pharmacovigilance

- Biologics have the potential to cause immune reactions
- Slight changes in manufacturing processes can cause differences in two biologic treatments, causing an increase in risk for an immune response
- As switching becomes more common, we must maintain ability to track and trace, keeping patients safe

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Thoughts?

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