1.28) and outpatient bronchitis: 0.80 (0.57, 1.14). Results remained unchanged with sensitivity analyses.
Conclusions: In this real-world study of patients with RA and COPD, the incidence of pre-specified respiratory SAEs was not significantly increased in patients using abatacept compared with those using other bDMARDs or tofa. The safety signal based on the subgroup of 54 patients from the ASSURE trial could not be confirmed in this large and long-term cohort study of over 5000 patients.

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FRI0140 INDIVIDUALISED INFLIXIMAB TREATMENT: A TREATMENT STRATEGY BASED ON THERAPEUTIC DRUG MONITORING

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Background: Infliximab (INX) and other targeted therapies have greatly improved the treatment of patients with RA, SpA and PsA, but a significant proportion of patients either do not respond sufficiently to therapy or loose efficacy over time. Recent advances in assay development have revealed an extensive individual variation in serum drug concentrations suggesting both under- and overtreatment of a substantial proportion of patients. Many patients develop anti-drug antibodies (ADAb) during therapy, contributing to reduced drug levels, inefficacy and adverse events. Therapeutic drug monitoring (TDM), i.e. individual dose adjustments according to serum drug levels, can probably increase effectiveness of treatment with INX and other biological drugs.
Objectives: To develop an individualised treatment strategy based on TDM in order to optimise efficacy of INX treatment.
Methods: The treatment strategy has been developed by the steering committee of the NORwegian DRUg Monitoring study (NOR-DRUM), based on a systematic literature review (SLR), unpublished data and expert opinion. A SLR was performed in May 2016 to identify the therapeutic range. In Norway neutralising ADAb are measured with an "in house" assay. For this assay, ADAb levels>50 µg/L are defined as "high" leading to a recommendation to switch therapy. This cut-off is based on own s-INX and ADAb data (Diakonhjemmet Hospital during 2015–2016) and clinical experience. The proposed strategy has been developed through a series of meetings in the project group consisting of national leading experts in this field (both clinicians experienced with TDM and laboratory physicians) and with additional input from international key experts in the scientific advisory board of the NOR-DRUM study.

Serum INX level (µg/ml)	≤2.0 and high ADAb (>50 µg/L)	≤2.0	2.1 – 2.9	3.0 – 8.0	8.1 – 10.0	>10.0
Action	Switch therapy if possible to another TNFi	Increase dose if no ADAb or low level ADAb (<50 µg/L)	Consider increasing dose	No action	Consider decreasing dose	Decrease dose
Guideline for action		Increase the dose by increasing the dose by 2-2,5 mg/kg to a max dose of 10 mg/kg or by decreasing the dose interval by 2 weeks to a min of 4 weeks	Consider increasing the dose based on clinical judgement and the patients factors given below*	Within target range. Continue with the same dose and dosing interval	Consider to decrease the dose based on clinical judgement and the patients factors given below*	Decrease the dose by increasing the dose interval by 2 weeks to a max of 10 weeks or by decreasing the given dose by 2-2,5 mg/kg

*Patient factors to be considered when making the treatment decisions in the yellow zones:
Disease activity and trend in disease activity, the trend of the trough level over time, previous drug interval changes, availability of alternative drug, diagnosis (RA patients are expected to have lower trough levels due to lower recommended dosing)

Results: The treatment strategy from infusion number 4 onwards is depicted in the figure 1. The therapeutic range for serum INX (through levels) is defined as 3–8 µg/ml (figure 1, green zone). During the induction phase (infusion 1–3) the recommendation is to keep the level >20 µg/ml at infusion 2 and >15 µg/ml at infusion 3. A guideline for action according to levels outside the therapeutic range is given in the figure 1. Dose modifications may be performed either as changes in doses or intervals as stated in the figure 1. If the patients develop high levels of ADAb the recommendation is to switch therapy.

Conclusions: An individualised treatment strategy based on TDM has the potential to optimise therapy with infliximab and other biological drugs by; 1) prevention of treatment failure by identification of patients with drug levels below the therapeutic range, 2) reduction of overtreatment, which predispose to side effects and increase costs, and 3) early identification of ADAb development, with the possibility to detect treatment failures prior to a clinical flare and to prevent hypersensitivity reactions. This approach has high face validity, and the effectiveness compared to regular care is being investigated in an ongoing randomised clinical trial, NOR-DRUM (NCT03074656).
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FRI0141 VACCINATION DECISIONS AND INCIDENCE OF NEONATAL INFECTIONS IN MOTHERS EXPOSED TO BIOLOGICALS DURING PREGNANCY

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Background: Rheumatologic diseases commonly affect women of childbearing age(.[1,2] There is currently limited data available regarding the safety of vaccinations in infants after in utero exposure to biologics.
Objectives: To determine the vaccination decisions of mothers with rheumatologic diseases exposed to biologics during pregnancy and the incidence of serious neonatal infections after third trimester exposure.
Methods: All Australian women with inflammatory arthritis, exposed to biologics during the preconception, antenatal and/or postpartum periods, were invited to participate in the Pregnancy Exposed to Biological (PEB) study from May 2009 – . Jan 2018 Recruitment was via direct invitation from patients treating rheumatologists, community groups, and via social media. Following self-referral to the study, retrospective data was collected, including biological exposure, vaccination history and the incidence of serious neonatal infections, defined as infection requiring hospitalisation.
Results: Preliminary data is available regarding 35 offspring from 28 mothers. 34 of 35 offspring were vaccinated. 29 received vaccinations in accordance with the Australian National Immunisation Program Schedule. 1 mother declined to immunise her infant due to personal preference.
13 infants were exposed to a tumour necrosis factor inhibitor (TNFi) during the third trimester. Of these, 4 had Rotavirus vaccine delayed from 2 to 4 months and 1 infant until 6 months. 1 infant did not receive the Rotavirus vaccine at 2 months due to exposure to a TNFi while breastfeeding. There were no incidences of serious neonatal infections.
Conclusions: Current guidelines recommend deferring live vaccines, such as rotavirus, until after 6 months if exposed to a biologic in the third trimesterr.([2–5] Compliance with these recommendations was only observed in one infant in our study. One infant received delayed Rotavirus vaccination due to concern about TNFi exposure during breastfeeding; this is not in keeping with current guidelines. Of the 12 infants exposed to a biologic during the third trimester who did not delay live vaccination until after 6 months, there were no incidents of serious neonatal infections, in keeping with the findings of current published case series.

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