

Burden of in-clinic and at-home administration of injectable biologics for severe asthma and chronic rhinosinusitis with nasal polyps: Interim results from a time and motion study

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This poster is being presented by Elise Kuylen (an employee of GSK) on behalf of the authors

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*At the time of the analysis



Both in-clinic and at-home injectable biologic administration demonstrated a considerable burden on HCPs and patients. Higher dosing frequency was associated with a greater burden for in-clinic administration



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Background

- Biologics targeting type 2 inflammation, administered every 2–8 weeks depending on the product, are approved as add-on maintenance therapy for patients with inadequately controlled severe asthma and/or CRSwNP¹
- Previous findings suggest that a lower frequency of biologic administration is associated with greater treatment adherence among patients³ and is preferred by physicians and patients⁴
- However, a paucity of data exists regarding the burden and time associated with biologic administration
- Time and motion methodology deconstructs often complex workflows associated with specific healthcare practice into individual tasks.⁵ By measuring the time needed for each task through multiple observations, time and motion studies can help identify time burdens associated with dynamic workflows^{5,6}

Aim

- To quantify HCP and patient time associated with in-clinic and at-home injectable biologic administration for severe asthma and/or CRSwNP

Methods

Observational, non-interventional, multi-country, time and motion study (GSK ID: 214575)



Data subjects

HCPs performing pre-specified management and/or administration tasks related to injectable biologics of adult patients with severe asthma and/or CRSwNP

15 sites across 8 countries
China (2), France (1), Germany (1), Italy (3), Japan (2), Spain (2), UK (2), and US (2)

Outcomes

Active HCP time	Patient time
Measured via stopwatch (sequential tasks) and time-of-day self-observation/estimates via interview (non-sequential tasks)	Collected as time-of-day (in-clinic) and via patient surveys (in-clinic and at-home)
Analysis and modelling (descriptive, non-hypothesis testing study)	
<ul style="list-style-type: none"> Target samples per site: ≤20 in-clinic observations (Workflow 1); excluding France); ≤10 self-observations per task (Workflow 2) Time model included biologic administration frequency for: dupilumab (Q2W; 26/year), mepolizumab (Q4W; 13/year), omalizumab (Q4W; 12/year), tezepelumab (Q4W; 13/year), benralizumab (Q8W; 4/year) Observed time (via CRF) or reported time (via interview) for each task related to injectable biologics management was multiplied by its expected annual frequency and time for all tasks was summed to yield total time per patient per year 	

Interim analysis was conducted across 4 countries (7 sites)

China (2) France (1) Japan (2) UK (2)

Pooled country results were calculated assuming an equal weight for each site for the first year of treatment (weighted means approach)

At each site, a semi-structured interview was conducted to support the development of two site-specific CRFs

HCP perspective

Workflow 1 (in-clinic)

Sequential tasks per visit (CRF)

- Check patient schedule (i.e. injectable biologics type and dose)*
- Collect injectable biologics and consumables
- Pre-administration vital signs check*
- Administer injectable biologics
- Waste disposal
- Record-keeping related to injectable biologics[†]
- Post-administration monitoring[§]
- Post-administration vital signs check[¶]

Other relevant non-sequential tasks (CRF and interview)

- Patient registration (injection visit day)
- Pick up drug from pharmacy (injection visit day)
- Scheduled doctor consultation visit
- Scheduled nurse biologic review clinic**
- Prescription of biologics^{††}
- Dispensing of injectable biologics to individual patient (at hospital pharmacy)
- Schedule appointment for next visit(s)
- Clinical tests (prior to administration visit)**

*Except China site 2; [†]except China (both sites) and UK site 1; [‡]except China (both sites); [§]except China (both sites) and Japan site 1; [¶]except China (both sites) and Japan (both sites); ^{**}UK only; ^{††}communication with doctor, generation, approval (UK only), hand to patient; ^{†††}time and frequency of other relevant non-sequential tasks that were not included in Workflow 2 CRF were elicited via interview; ^{§§}Japan site 2 and UK; ^{¶¶}Japan site 1 only; ^{**}China site 2 only; ^{††††}France only; ^{†††††}except China and UK

Workflow 2 (at home)^{‡‡}

Relevant non-sequential tasks (CRF and interview) in addition to Workflow 1 CRF sequential steps 1–8

- Extra training time during initial in-clinic visit(s)
- During scheduled doctor consultation visit, extra time for education/counselling regarding self-administration at home^{§§}
- Consultation eVisit**
- Patient obtains dispensing information and queue ticket^{¶¶}
- Routine check on home administration (via phone/email^{***})
- Patient/community pharmacy contacts clinic related to injectable biologics and subsequent outreach to doctor^{†††}
- Discuss patient call^{††††}
- Clinic staff contacts patients related to injectable biologics^{†††††}

Patient perspective

- Travel time (to and from community pharmacy to pick up biologic) [Workflow 2 only]^{‡‡}
- Travel time (to and from healthcare facility)
- Chair time
- Facility time (injection visit and doctor visit)
- Facility time (injection visit only)
- Facility time (doctor visit only)

Conclusions

In-clinic and at-home injectable biologic administration demonstrated a substantial overall burden on HCPs and patients

Among the biologics assessed, dupilumab was associated with the highest in-clinic time burden, while benralizumab had the lowest

Heterogeneity was observed between countries, likely driven by healthcare system differences, especially in how the biologics are dispensed to the patient

Abbreviations

CRF, case report form; CRSwNP, chronic rhinosinusitis with nasal polyps; HCP, healthcare professional; Q2/4/8W, every 2/4/8 weeks; UK, United Kingdom; US, United States

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