PSS68

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BACKGROUND

- Chronic spontaneous (also known as idiopathic) urticaria (CSU/CIU) is the occurrence of wheals (hives), angioedema or both for 6 weeks or longer due to known or unknown causes¹
- CSU/CIU has an impact on healthcare payers and also on society in terms of indirect costs (i.e., productivity losses arising from reduced performance at work or absence from work²)
- There is limited real world research quantifying the impact of CSU/CIU on work and non-work activity in patients who are symptomatic despite treatment

OBJECTIVE

- The ASSURE-CSU study is an observational, non-interventional, multinational study conducted in Canada, France, Germany, Italy, United Kingdom (UK), Spain and the Netherlands to identify and quantify the humanistic and economic burden of illness in inadequately controlled CSU/CIU patients
- Here we summarise the work and activity impairment among patients enrolled in Canada, Germany, UK, and the Netherlands

METHODS

Study design

• This study included a 1-year retrospective medical record abstraction, a cross-sectional patient reported outcomes survey, and a 7-day prospective patient diary

Patient population

- Adult patients with a clinician-confirmed, guideline-defined diagnosis of CSU/CIU
- Patients had received at least one treatment course with an H₁-antihistamine
- Patients had been symptomatic for more than 12 months at least 3 days per week and were currently symptomatic despite treatment

Outcomes

- CSU/CIU-related work days missed and productivity losses were measured using the Work Productivity and Activity Impairment - Specific Health Problem (WPAI-SHP)3.
- Patients completed a 7-day diary for itch severity and number of hives Urticaria Activity Score over 7 days (UAS7) and in the 8th day responded to the WPAI-SH (recall period – previous 7 days coinciding with the UAS assessment period)
- WPAI-SHP measures four metrics pertaining to:
 - Absenteeism (the percentage of work time missed because of one's health problem in the past 7 days)
 - Presenteeism (the percentage of impairment experienced while at work in the past 7 days because of one's health problem)
 - Overall work impairment (an overall impairment estimate calculated by an algorithm of absenteeism and presenteeism)
- Activity impairment (the percentage of impairment in daily activities because of one's health problem in the past 7 days)
- WPAI-SHP scores were multiplied by 100 to be expressed as percentages. Higher scores reflect greater impairment and reduced productivity
- UAS7 scores range from 0 to 42 with higher scores meaning higher severity of urticaria signs and symptoms
- UAS7 scores were used to define categorical disease states (Table 1)⁴

Table 1. CSU/CIU disease health states defined using UAS7 scores **UAS7 Score Urticaria Severity Level** 28-42 SEVERE urticaria MODERATE urticaria 16-27 7-15 MILD urticaria 1-6 WELL-CONTROLLED urticaria UAS7=Weekly Urticaria Activity Score

Data analysis

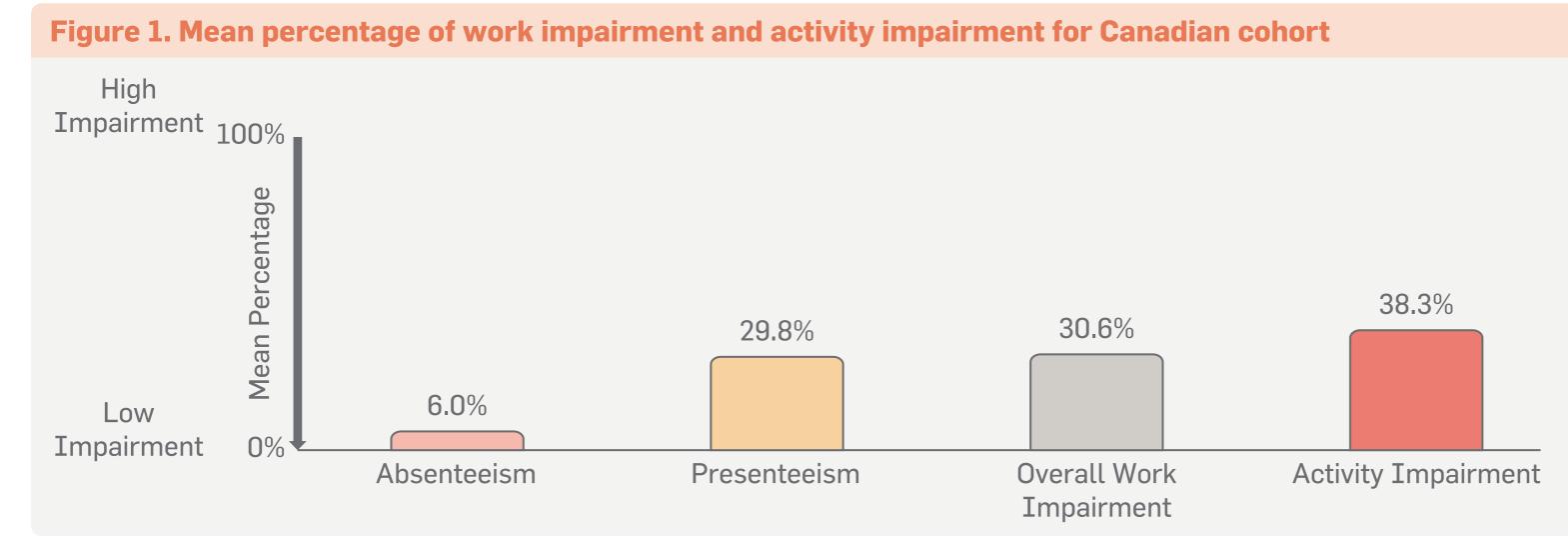
- Data were summarized descriptively using mean values and standard deviations for continuous variables and counts and proportions for categorical variables
- All patients were included for activity impairment analysis; only employed patients were included for absenteeism, presenteeism
- and work impairment analysis WPAI-SHP were reported descriptively by four disease severity levels based on UAS7 scores

RESULTS

• A total of 86, 94, 74 and 93 patients completed the patient diary in Canada, Germany, UK and the Netherlands, respectively. Of these, 54.7%, 72.3%, 51.4% and 52.7% patients were currently employed, respectively.

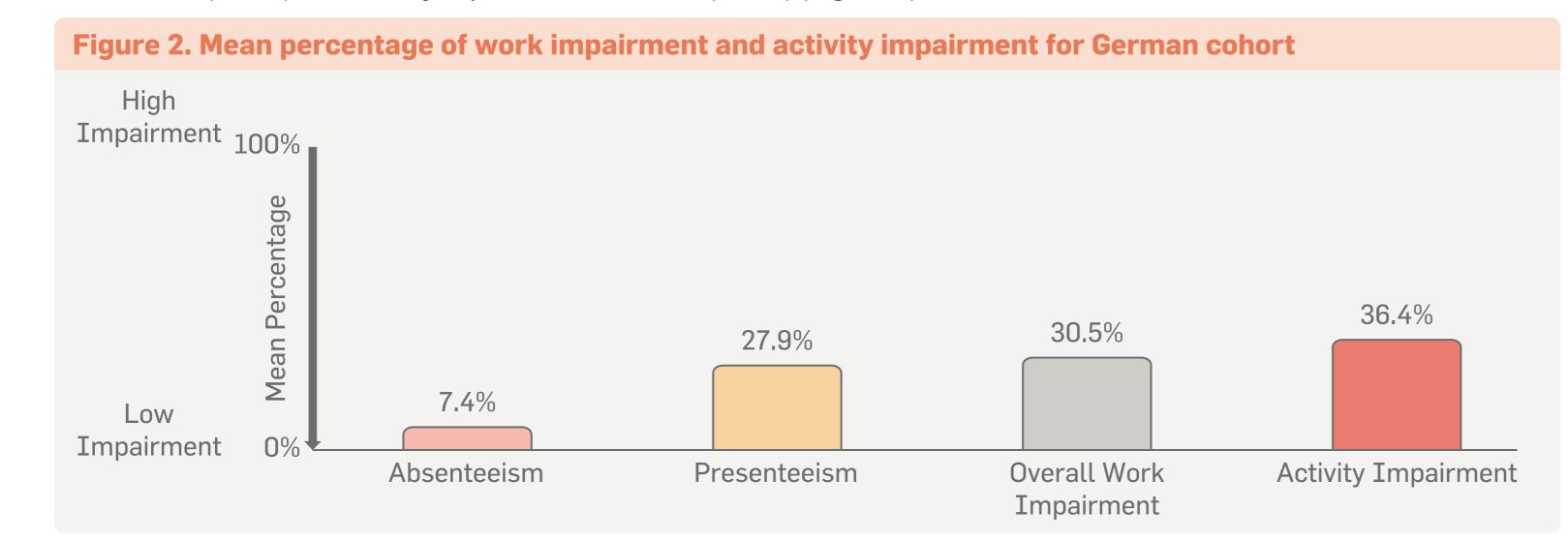
Canada

• Mean (SD) time loss due to absenteeism and presenteeism were 6.0% (12.0%) and 29.8% (26.3%), respectively, with an overall work impairment of 30.6% (27.0%) and activity impairment of 38.3% (31.3%) (Figure 1)



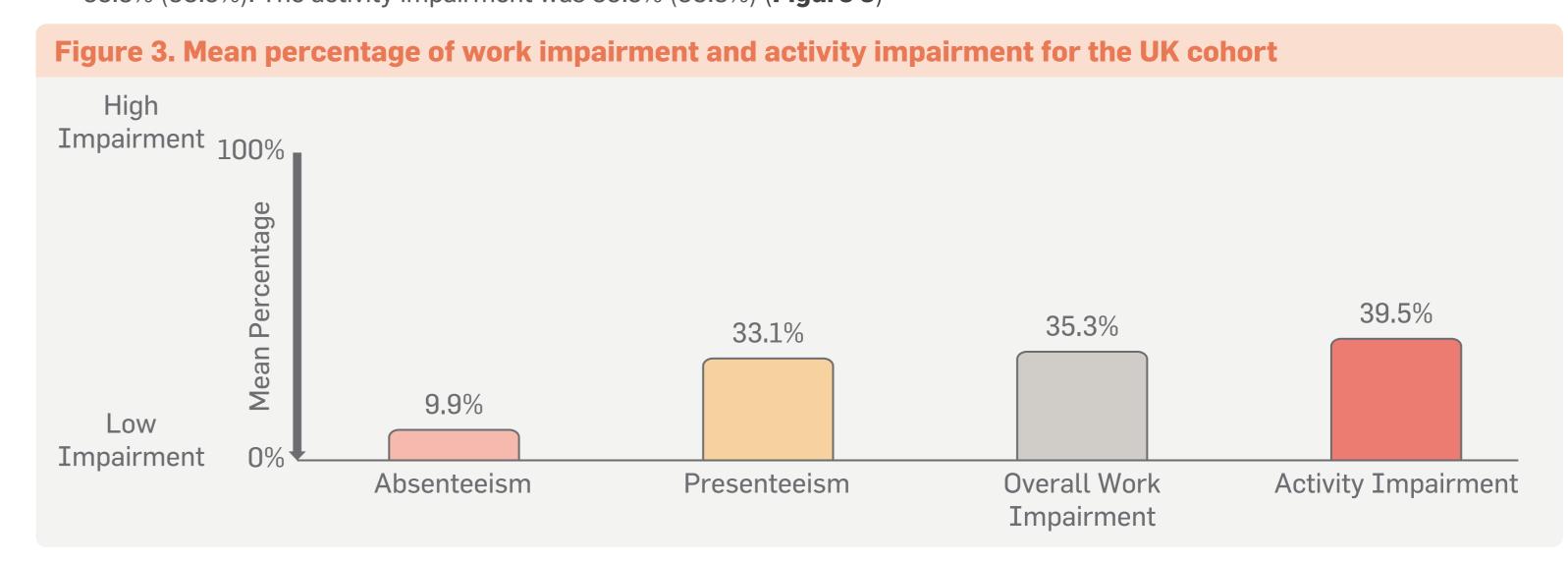
Germany

• Mean (SD) time loss due to absenteeism was 7.4% (20.0%), presenteeism was 27.9% (25.7%), within an overall work impairment of 30.5% (26.6%). The activity impairment was 36.4% (28.5%) (**Figure 2**)



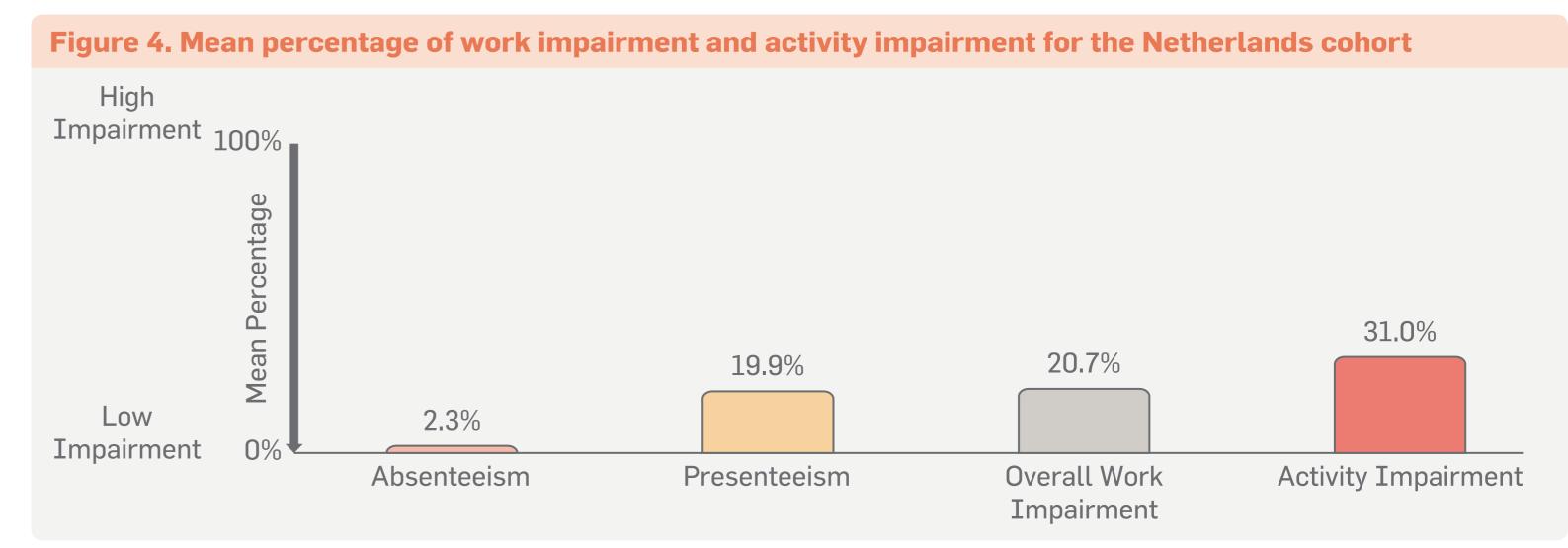
United Kingdom

• Mean (SD) time loss due to absenteeism was 9.9% (23.2%), presenteeism was 33.1% (30.0%), with an overall work impairment of 35.3% (30.9%). The activity impairment was 39.5% (30.3%) (**Figure 3**)



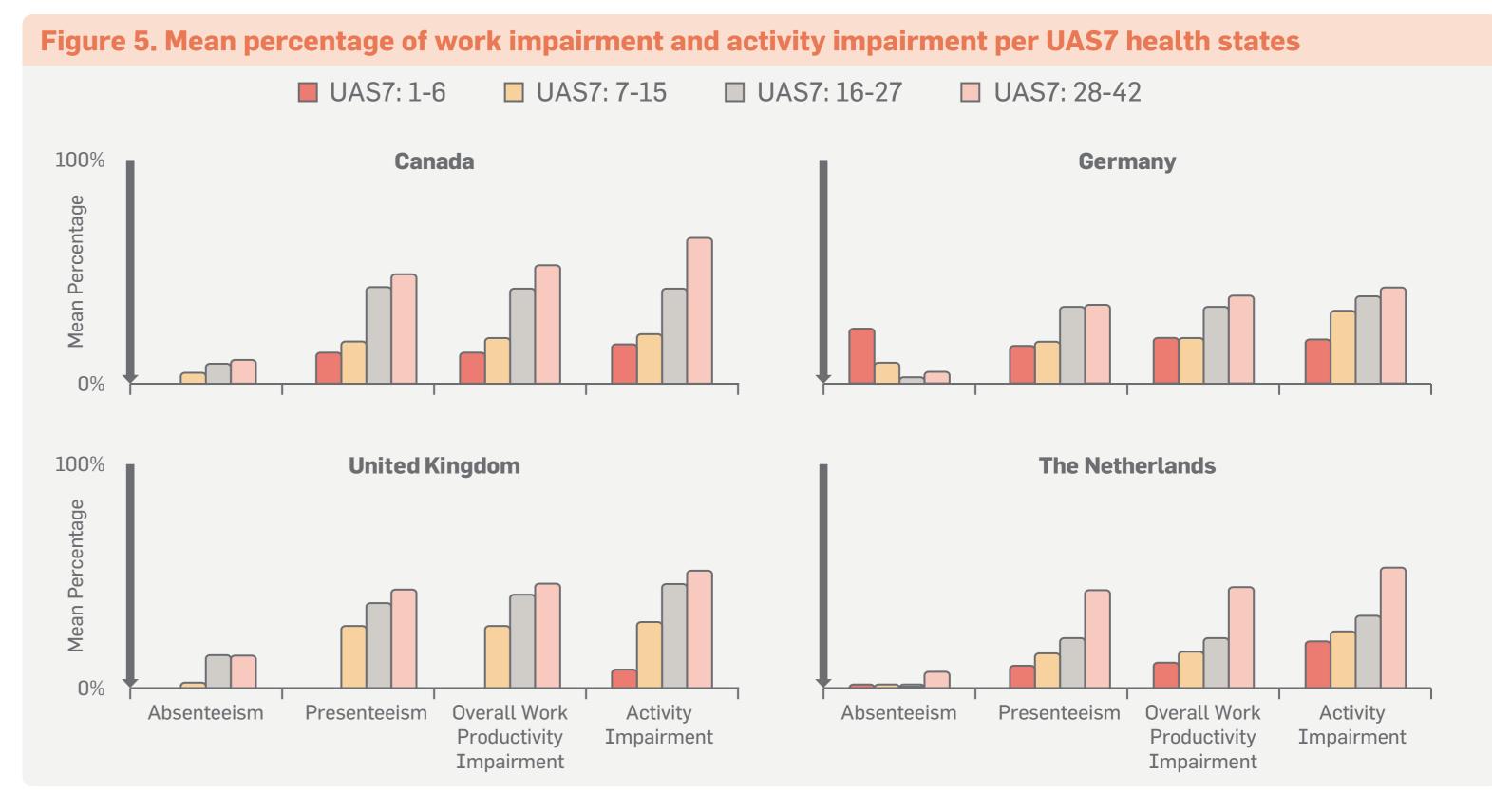
The Netherlands

• Mean (SD) time loss due to absenteeism and presenteeism were 2.3% (8.9%) and 19.9% (25.4%), respectively, with an overall work impairment of 20.7% (26.8%) and activity impairment of 31.0% (27.9%) (**Figure 4**)



Impact on work increases with increased UAS7 severity

• Across the countries, the percentage of work time missed due to CSU/CIU and the other parameters increased with the increase in UAS7 scores. The highest absence and impairment were observed in the UAS7 score 28-42 category (Figure 5)



CONCLUSION

- The results are consistent among the countries and demonstrate that symptomatic patients with CSU/CIU experience a substantial impact on their daily activities. Many employed patients are affected at work by their disease through absenteeism or reduced productivity at work resulting in substantial economic impact for employers and society
- Across the countries, percentage of work time missed due to CSU/CIU and overall work and activity impairment increased with disease severity

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CONFLICT OF INTEREST

AH, HT, JK, MMB, NC-R, OC, SC-R and STA are employed by Novartis. CL has served as a consultant, principal investigator, and speaker for Amgen, AbbVie, Janssen, Novartis, Merck, Eli Lilly, LEO Pharma, and Celgene. GS has acted as a consultant for Novartis and in the past three years, he has conducted studies for Novartis, CSL Behring, Merck, and DBV Technologies. He is also president of the Allergy, Asthma & Immunology Society of Ontario. KW was recently a speaker, investigator and/ or advisor for Novartis, RTI, Uriach, FAES, UCB, MSD, Shire, Viropharma, Biocryst and MOXIE. MM has received grant, research or clinical trial support from Novartis, Genentech, Uriach, Abbott Laboratories, FAES, UCB and Moxie. He has acted as a consultant/participated in advisory board meetings for Novartis, Genentech, Uriach, Abbott Laboratories, FAES, MSD, Almirall, UCB and Sanofi. ACK has received honoraria from Novartis for participation in advisory board Meetings, speakerfees and financial support for scientific studies. AN has received honoraria from Novartis for participation in advisory board Meetings in 2014. CG has participated in an advisory board for Novartis, was a principal investigator for a Novartis supported study and has received honoraria for Novartis supported meetings. MA is a member of the Coeliac Disease Guidelines Development Group with N.I.C.E. JNGOE has served as a speaker for Novartis. CS, CR, DW, DMcB, and KH are employed by RTI Health Solutions, which provides consulting and other research services to pharmaceutical, device, government, and non-government organizations. In this salaried position, they work with a variety of companies and organizations. They receive no payment or honoraria directly from these organizations for services rendered

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