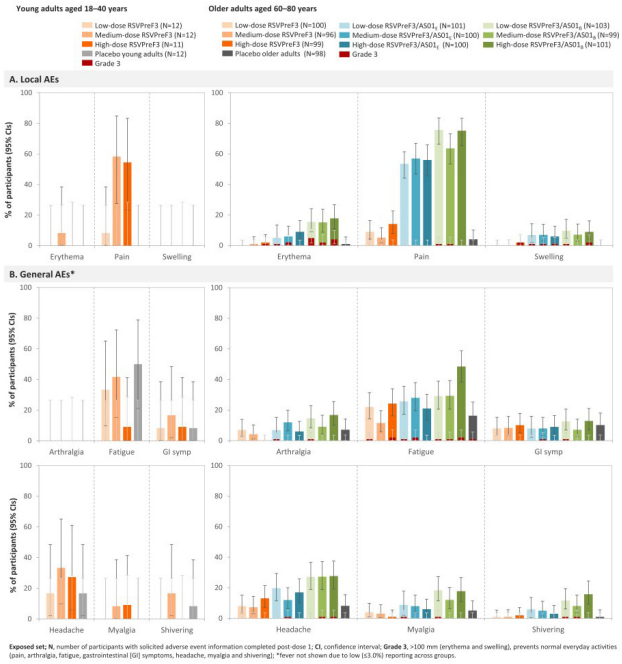
Figure 2. Percentage of participants with at least one type of solicited adverse event (AE) within 7 days post-dose 1



Conclusion: First dose of RSVPreF3 candidate vaccine is well tolerated. AE rates tended to be higher after $AS01_B$-adjuvanted formulations compared to other vaccine formulations. No safety concerns were raised.

Funding: GlaxoSmithKline Biologicals SA

Disclosures: Jelena Tica, PhD, GSK group of companies (Employee, Shareholder) Javier Ruiz Guiñazú, MD MSc, GSK group of companies (Employee, Shareholder) Charles P. Andrews, MD, GSK group of companies (Scientific Research Study Investigator) Charles Fogarty, MD, GSK group of companies (Grant/Research Support) Edward Kerwin, MD, Amphastar (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)AstraZeneca (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Boehringer Ingelheim (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Chiesi (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Cipla (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)GSK group of companies (Employee, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Mylan (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Novartis (Employee, Advisor or Review Panel member, Research Grant or Support, Speaker's Bureau)other around 40 pharmaceutical companies (Other Financial or Material Support, conducted multicenter clinical research trials)Pearl (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Sunovion (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Theravance (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau) Isabel Leroux-Roels, MD PhD, GSK group of companies (Scientific Research Study Investigator) Corinne Vandermeulen, MD PhD, GSK group of companies (Other Financial or Material Support, My university only received Grant/Research Support) Marie-Pierre David, MSc, GSK group of companies (Employee, Shareholder) Nancy Dezutter, PhD, PharmD, RPh, GSK group of companies (Employee, Shareholder) Laurence Fissette, MSc, GSK group of companies (Employee) Juliane Koch, MD, GSK group of companies (Employee, Shareholder) Narcisa Mesaros, MD, MSc, GSK group of companies (Employee)

120. Impact of a Molecular Point-of-care 'test and Treat' Strategy for Influenza in Hospitalised adults: A Multi-centre, Randomised Controlled Trial (FluPOC)

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Session: O-23. Hot Clinical Trials

Background: The diagnosis of Influenza in hospitalised patients is delayed due to long turnaround times of laboratory testing, leading to inappropriate and late antiviral and isolation facility use. Molecular point-of-care test (mPOCT) are highly accurate, easy to use and generate results in under 1 hour but high quality evidence for their clinical impact is lacking.

Methods: In this multicentre, randomised controlled trial we enrolled adults hospitalised with acute respiratory illness during influenza seasons. Patients were randomised (1:1) to receive mPOCT for influenza or routine clinical care. The primary outcome was the proportion of influenza-infected patients who received antivirals. Secondary outcomes included time to antivirals, isolation facility use, and clinical outcome. This study is registered with ISRCTN, number:17197293, and has completed.

Results: Between December 2017 and May 2019, 613 patients were enrolled (307 assigned to mPOCT and 306 to routine care) and all were analysed. 100 (33%) of 307 patients in the mPOCT group and 102 (33%) of 306 in the control group had influenza. 100 (100%) of 100 influenza-infected patients were diagnosed in the mPOCT group and 60 (59%) of 102 were diagnosed though routine clinical care (relative risk 1·7, 95%CI 1·7 to 1·7;p< 0·0001). 99 (99%) of 100 influenza-infected patients received antivirals in the mPOCT group versus 63 (62%) 102 in the control group (relative risk 1·6, 95%CI 1·4 to 1·9;p< 0·0001). Median time to antivirals was 1·0 hour in the mPOCT group versus 6·0 hours in the control group (difference of 5·0 hours, 95%CI 0 to 6·0;p=0·004). 70 (70%) of 100 influenza-infected patients in the mPOCT group were nursed in single room accommodation versus 39 (38%) of 102 in the control group (relative risk 1·8, 95%CI 1·4 to 2·4;p< 0·0001). Median hospital recovery scale score (an ordinal 6 point scale used to assess patient outcome) at 7 days was lower in the mPOCT group verses the control group (p=0·045).

Figure 1a: Time-to-event curve showing antiviral use over time in influenza-infected patients.

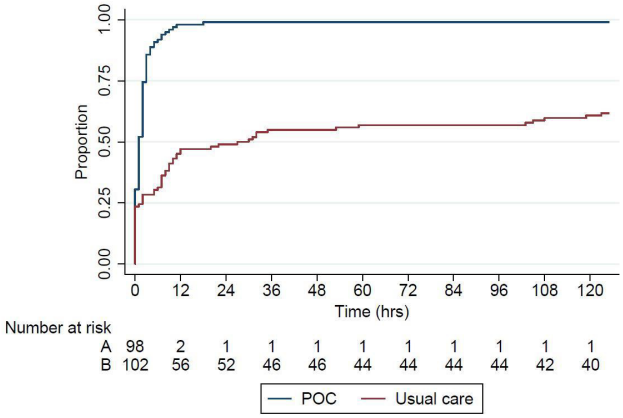
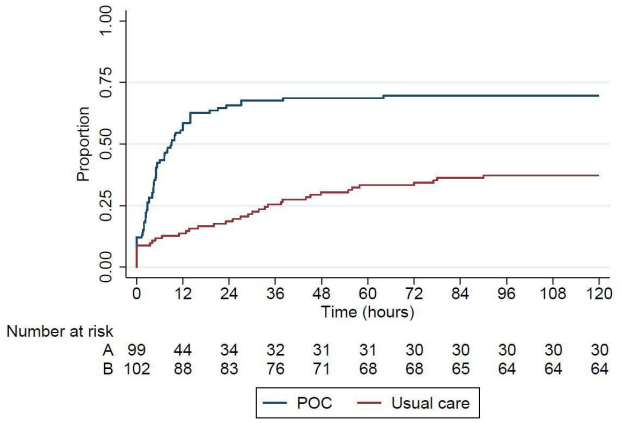


Figure 1b: Time-to-event curve showing isolation facility use over time in influenza-infected patients.



Conclusion: Routine mPOCT for influenza was associated with enhanced influenza detection, improvements in appropriate and timely antiviral and isolation facility use, and more rapid clinical recovery.

Disclosures: **Tristan William. Clark, BM MRCP DTM&H MD**, **BioFire Diagnostics** (Other Financial or Material Support, Equiptment and consumables for the purposes of research)**BioMerieux** (Other Financial or Material Support, Equipment and consumables for the purposes of research)**Qiagen** (Other Financial or Material Support, Discounted Equipment and consumables for the purposes of research)

121. A Respiratory Syncytial Virus Prefusion F Protein (RSVPreF3) Candidate Vaccine Administered in Older Adults in a Phase I/II Randomized Clinical Trial Is Immunogenic

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Session: O-23. Hot Clinical Trials

Background: RSV causes significant disease burden in older adults, since reinfections are common and may lead to severe disease presentations while only supportive treatment is available. We present immunogenicity of different formulations of an investigational vaccine (RSVPreF3) in young and older adults.

Methods: This is a phase I/II, placebo-controlled, multi-country trial (NCT03814590). Healthy adults aged 18–40 years were randomized 1:1:1:1 to receive 2 doses of either Low-, Medium- or High-dose of RSVPreF3 non-adjuvanted vaccine or placebo, 2 months apart. Following favorable safety outcomes, adults aged 60–80 years were randomized 1:1:1:1:1:1:1:1:1:1 in a 2-step staggered manner to receive 1 of the 9 RSV vaccine formulations containing Low-, Medium- or High-dose of RSVPreF3, non-adjuvanted or adjuvanted with $AS01_E$ or $AS01_B$, or placebo (same schedule). Humoral and cellular-mediated immune responses are assessed before and after each dose; results up to 1 month post-dose 1 are shown here.

Results: Of 48 adults aged 18–40 years and 1005 aged 60–80 years included in the exposed set, 42 and 933, respectively, were part of per-protocol set at 1 month post-dose 1. RSVPreF3 IgG geometric mean antibody concentrations were 8.4–13.5 and 7.2–12.8 fold-higher at 1 month post-dose 1 vs baseline in the 18–40- and 60–80-year-old vaccinees, respectively (Fig 1A). RSV-A neutralization activity significantly increased in all RSV vaccinees, geometric mean antibody titers being 7.5–13.7 and 5.6–9.9 fold-higher in 18–40- and 60–80-year-olds, respectively, at 1 month post-dose 1 vs baseline (Fig 1B). Geometric mean ratios of the fold increase between RSVPreF3 IgG antibody concentrations and RSV-A neutralizing antibody titers ranged between 0.9–1.1 in 18–40-year-old and 1.3–1.5 in 60–80-year-old vaccinees. A robust RSVPreF3-specific CD4+ T-cell response was elicited at 1 month post-dose 1 vs baseline in both 18–40- and 60–80-year-olds (Fig 2).

Figure 1. RSVPreF3 IgG geometric mean antibody concentrations (GMCs, enzyme-linked immunosorbent assay, panel A), RSV-A neutralizing geometric mean antibody titers (GMTs, neutralization assay, panel B)

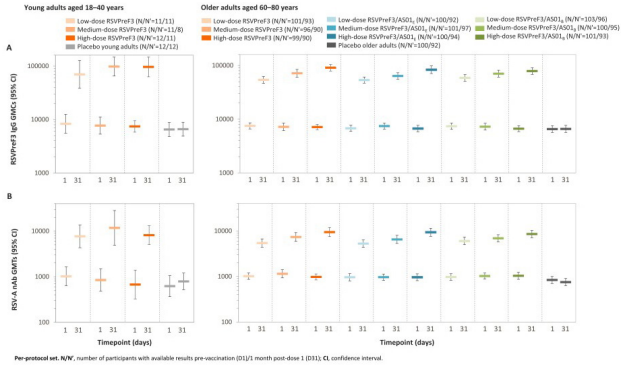
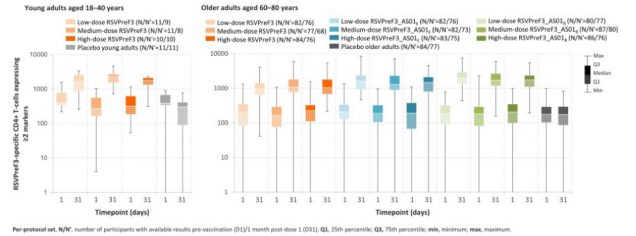


Figure 2. RSVPreF3-specific CD4+ T-cells identified as expressing ≥2 markers among IL2, CD40L, TNF-□, IFN-□ (intracellular cytokine staining assay)



Conclusion: One dose of RSVPreF3 candidate vaccine boosted humoral and cellular immune responses in all vaccinees. In older adults, higher humoral response, mostly neutralizing, was observed with increased RSVPreF3 antigen dosage and a tendency of higher cellular response was observed after adjuvanted formulations.

Funding: GlaxoSmithKline Biologicals SA

Disclosures: Javier Ruiz Guiñazú, MD MSc, GSK group of companies (Employee, Shareholder) Jelena Tica, PhD, GSK group of companies (Employee, Shareholder) Charles P. Andrews, MD, GSK group of companies (Scientific Research Study Investigator) Charles Fogarty, MD, GSK group of companies (Grant/Research Support) Edward Kerwin, MD, Amphastar (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)AstraZeneca (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Boehringer Ingelheim (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Chiesi (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Cipla (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)GSK group of companies (Employee, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Mylan (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Novartis (Employee, Advisor or Review Panel member, Research Grant or Support, Speaker's Bureau)other around 40 pharmaceutical companies (Other Financial or Material Support, conducted multicenter clinical research trials)Pearl (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Sunovion (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Theravance (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau) Isabel Leroux-Roels, MD PhD, GSK group of companies (Scientific Research Study Investigator) Corinne Vandermeulen, MD PhD, GSK group of companies (Other Financial or Material Support, My university only received Grant/Research Support) Marie-Pierre David, MSc, GSK group of companies (Employee, Shareholder) Nancy Dezutter, PhD, PharmD, RPh, GSK group of companies (Employee, Shareholder) Nathalie De Schrevel, PhD, GSK group of companies (Employee) Laurence Fissette, MSc, GSK group of companies (Employee) Narcisa Mesaros, MD, MSc, GSK group of companies (Employee)

122. Dalbavancin Use in Patients with Substance Use Disorders

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Session: O-24. Hot Issues in Clinical Practice

Background: Dalbavancin, a lipoglycopeptide antibiotic, has an extended half-life that allows for weekly dosing and is an alternative to daily intravenous (IV) antibiotics. The dosing interval has the potential to expand treatment options for more severe infections in patients with substance use disorder (SUD), houselessness, and other complex social determinants of health where treatment of severe infections with long courses of IV antibiotics can have a high risk of failure. Questions remain regarding clinical outcomes for this indication and patient population.

Methods: We conducted a retrospective review of dalbavancin use for any patient with documented SUD either by ICD-10 or in chart notes. We identified all patients > 18 years who received > 1 dose of dalbavancin via medication records.

Results: 53 patients with documented SUD received dalbavancin as part of their treatment regimen (Table 1). The most common indication was osteomyelitis, including 14 cases of vertebral osteomyelitis (Table 2). The most common causative organism was Staphylococcus aureus, 23 (43%) cases due to MRSA and 10 (18%) due to MSSA.

The majority of patients (41,77%) had a documented history of IV drug use (IDU) and 19% had alcohol use disorder. A structured, RN-lead multi-disciplinary discharge planning conference to discuss antibiotic options, risk factors for outpatient parenteral antibiotic therapy, and PICC safety in the community was held for 17 (32%).

Concern about outpatient PICC safety in patients with history of IDU, unsafe home environment, and prior non-adherence to outpatient antibiotics were common reasons for choosing dalbavancin. Ten (19%) patients were lost to follow-up. The 30 and 90-day readmission rates were 13% and 19% respectively but were due to relapse or recurrence of infection in only 3 (6%) at 30 days and 2 (4%) additional at 90 days. There was only one death at 90 days ant it was unrelated to infection. (Table 3)

Table 1. Patient Demographics

Age (years); mean	44.8 (STD 11.2)
Gender (Female)	17 (32%)
History of renal dysfunction	3 (6%)
History of hepatic dysfunction	6 (11%)
Substance Use History	**n (%)**
Intravenous substance use (opioids or methamphetamines)	41 (77)
Inhaled use (methamphetamines)	1 (2)
Opioid use disorder, unclear route	1 (2)
Alcohol use	10 (19)
Insurance Coverage	
Medicaid	37 (70)
Medicare	5 (9)
Commercial	2 (4)
Other	2 (4)
Multiple insurance providers	7 (13)
Uninsured	0
Addiction Medicine Involvement	
Addiction Medicine Consult	28 (53)
Multi-disciplinary discharge planning conference	17 (32)