Cade, MD, Gilead (Consultant, Research Grant or Support, Speaker's Bureau) Janssen Pharmaceutica (Consultant) Merck (Consultant, Research Grant or Support, Speaker's Bureau) ViiV Healthcare (Consultant, Research Grant or Support) Cynthia Brinson, MD, Gilead (Advisor or Review Panel member, Speaker's Bureau) ViiV Healthcare (Advisor or Review Panel member, Speaker's Bureau) Nisha Andany, MD, MPH, FRCPC, Gilead Sciences (Scientific Research Study Investigator) GlaxoSmithKline (Scientific Research Study Investigator) David Margolis, MD, MPH, GlaxoSmithKline (Scientific Research Study Investigator) David Margolis, MD, MPH, GlaxoSmithKline (Shareholder) ViiV Healthcare (Employee) Kenneth Sutton, MA, GlaxoSmithKline (Shareholder) ViiV Healthcare (Employee) Viviana Wilches, HBSc, MBiotech, GlaxoSmithKline (Employee, Shareholder) Jeremy Roberts, MSc, GSK (Employee) Cynthia C. McCoig, MD, ViiV Healthcare (Employee) Kati Vandermeulen, MSC, Janssen Pharmaceutica (Employee, Shareholder) William Spreen, PharmD, ViiV Healthcare (Employee, Shareholder)

## 117. Adjunctive Daptomycin in the Treatment of staphylococcus Aureus Bacteremia

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#### DASH

#### Session: O-23. Hot Clinical Trials

**Background:** Bloodstream infections (BSI) caused by methicillin-susceptible Staphylococcus aureus (MSSA) are associated with significant morbidity and mortality. The objective of our study was to determine whether daptomycin given in combination with an anti-staphylococcal beta-lactam improved outcomes in MSSA BSI.

*Methods:* A randomized, double blind, placebo-controlled trial was performed at two academic hospitals in Montreal, Canada. Patients  $\geq 18$  years of age with MSSA BSI receiving either cefazolin or cloxacillin monotherapy were considered for inclusion. In addition to the standard of care treatment, participants received a 5-day course of adjunctive daptomycin or placebo. The primary outcome was the duration of MSSA BSI in days.

**Results:** Of 318 participants screened, 115 were enrolled and 104 were included in the intention to treat analysis (median age 67 years; 34.5% female). The median duration of bacteremia was 2.04 days among patients who received daptomycin versus 1.65 days in those who received placebo (absolute difference 0.39 days, p=0.40). A modified intention to treat analysis involving participants who remained bacteremic at the time of enrollment found a median duration of bacteremia of 3.06 days among patients who received daptomycin versus 3.0 days in those who received placebo (absolute difference 0.06 days, p=0.77). Ninety-day mortality in the daptomycin arm was 18.9% vs. 17.7% in the placebo arm (p=1.0). There were no significant differences in the proportion of patients who developed renal failure, hepatotoxicity, or rhabdomyolysis between groups.

Conclusion: Among patients with MSSA BSI, the administration of adjunctive daptomycin therapy to standard of care treatment did not shorten the duration of bacteremia.

Disclosures: All Authors: No reported disclosures

## 118. Eliminating Blood Culture Contamination with an Initial-specimen Diversion Device

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### Session: O-23. Hot Clinical Trials

Background: Blood samples obtained via traditional venipuncture can become contaminated by superficial and deeply embedded skin flora. We evaluated the hospital-wide use of an initial-specimen diversion device (ISDD) designed to shunt these microorganisms away from the culture bottle to reduce blood culture contamination (BCC) and sequelae: false-positive central line-associated bloodstream infections (CLABSIs), repeat blood culture draws, inappropriate antibiotic usage, increased patient length-of-stay and misdiagnosis. The study aimed to show the proportion of blood cultures containing contaminants drawn by phlebotomy staff using the ISDD versus those drawn using traditional methods. Nursing staff continued to use traditional methods to draw blood cultures in the emergency department (ED) and from inpatients.

Methods: Over a four-month trial at Stanford Health Care (SHC), 4,462 blood cultures were drawn by phlebotomy staff using the ISDD (Steripath Gen2, Magnolia Medical Technologies) in the ED and from inpatients; 922 blood cultures were obtained by phlebotomy staff using standard methods. Additionally, 1,413 blood cultures were drawn by nursing staff using standard methods. The number of matched sets (2 bottles [aerobic/anaerobic] plus 2 bottles [aerobic/anaerobic], with total volume 40 ml) obtained through traditional methods and by the ISDD were recorded. Contaminants

were defined by the National Healthcare Safety Network (NHSN). In addition, sets in which 1 out of 4 bottles contained vancomycin-resistant *Enterococcus* (VRE) or *Candida* sp. were also recorded, even though these are not considered contaminants by the NHSN.

**Results:** Of 4,462 blood cultures obtained using the ISDD there were zero contaminants found (BCC rate 0%) versus 29 contaminated sets using traditional methods (BCC rate 3.15%). Twenty-eight contaminants were observed from nursing staff blood culture draws (BCC rate 1.98%). Zero false-positive CLABSIs were associated with use of the ISDD for the trial period. No matched sets containing 1 of 4 bottles with VRE or *Candida* sp. were observed.

Table: Stanford Health Care blood culture collection methods and contamination events (March 15, 2019 - July 21, 2019)

	Matched Sets	Contaminated Sets	Contamination Rate	False-Positive CLABSIs
Standard Method (Nursing Staff)	1,413	28	1.98%	0
Standard Method (Phlebotomy)	922	29	3.15%	1
Standard Method (Combined)	2,335	57	2.44%	1
ISDD (Phlebotomy)	4,462	0	0.00%	0

 $\it Conclusion:$  The trial results encourage adoption of the ISDD as standard practice for blood culture at SHC.

Disclosures: All Authors: No reported disclosures

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

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### Session: O-23. Hot Clinical Trials

**Background:** RSV is a common cause of respiratory acute illness in older adults (OA). We evaluated safety and reactogenicity of RSVPreF3 candidate vaccine in young adults (YA) and OA.

*Methods:* In this phase I/II, placebo-controlled, multi-country trial (NCT03814590), YA aged 18–40 years were randomized 1:1:1:1 and received 2 doses of Low-, Medium- or High-dose of RSVPreF3 non-adjuvanted vaccine, or placebo, 2 months apart. Following favorable safety evaluation, a staggered enrolment with 2 steps followed in OA aged 60–80 years, who were randomized 1:1:1:1:1:1:1:1 to receive 1 of the 9 RSV vaccine formulations containing Low-, Medium- or High-dose of RSVPreF3 non-adjuvanted or adjuvanted with AS01<sub>E</sub> or AS01<sub>B</sub>, or placebo (same schedule). Safety/reactogenicity up to 1 month post-dose 1 are reported here.

Results: Exposed set was comprised of 48 YA and 1005 OA. Within 7 days postdose 1, any solicited/unsolicited adverse event (AE) ranged from 58.3% to 83.3% across YA vaccinees (placebo YA: 58.3%) and from 29.9% to 84.2% across OA vaccinees (placebo OA: 33.7%) (Fig 1). Pain was the most common solicited local AE, being reported in  $\leq$  58.3% of YA (placebo YA: 0.0%) and at higher rates in the adjuvanted groups ( $\leq$ 75.7%) vs non-adjuvanted groups of OA (≤ 14.1%) and placebo OA (4.1%) (Fig 2A). Of solicited general AEs, fatigue (YA: ≤ 41.7% in vaccinees vs 50.0% in placebo; OA: ≤ 48.5% in vaccinees vs 16.3% in placebo) and headache (YA: ≤ 33.3% in vaccinees vs 16.7% in placebo; OA: ≤ 27.7% in vaccinees vs 8.2% in placebo) were most commonly reported (Fig 2B), while fever  $\geq$  38.0 °C was observed in  $\leq$  3.0% of OA vaccinees (placebo OA: 0.0%). Grade 3 solicited local and general AEs were observed in OA only, with erythema ( $\leq$  4.9% in vaccinees vs 0.0% in placebo) and fatigue ( $\leq$  2.0% in vaccinees vs 1.0% in placebo) being most common (Fig 2). No serious AEs (SAEs) were reported in YA. A number of 11 OA reported a SAE within 1 month post-dose 1, but none was fatal or assessed as vaccine-related. No clinically significant abnormalities occurred in hematological/biochemical parameters in any group.

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

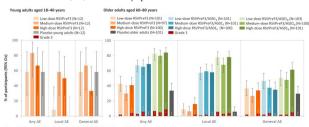
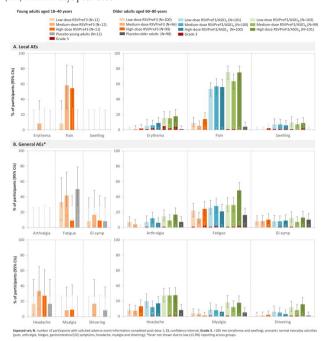


Figure 2. Percentage of participants with at least one type of solicited adverse event (AE) within 7 days post-dose 1  $\,$ 



**Conclusion:** First dose of RSVPreF3 candidate vaccine is well tolerated. AE rates tended to be higher after  ${\rm ASO1}_{\rm p}$ -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.

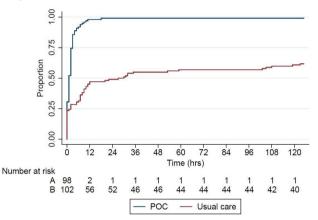
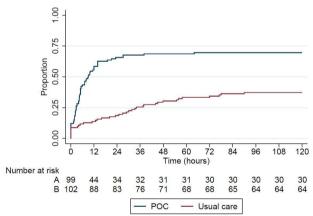


Figure 1b: Time-to-event curve showing isolation facility use over time in influenza-infected patients.



**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

Javier Ruiz Guiñazú, MD MSC¹, Jelena Tica, PhD¹, Charles P. Andrews, MD², Matthew G. Davis, MD³, Philippe De Smedt, MD⁴, Brandon Essink, MD CPI⁵, Charles Fogarty, MD⁶, Edward Kerwin, MDˀ; Isabel Leroux-Roels, MD PhD՞<sup>8</sup>,