this population. Results also suggest that the knowledge gap is greater among males than females. This in mind, FPPP included culturally sensitive elements such as a skit developed by community members and small group discussions to engage the population in conversations about pneumonia.

PIN3

DEVELOPMENT OF A PATIENT-REPORTED OUTCOME INSTRUMENT (SKINFECT-PRO) TO STANDALONE AND QUALIFY SYMPTOMS OF ACUTE BACTERIAL SKIN INFECTION (ABSSSI)

OBJECTIVES: The purpose of this study was to develop a patient-reported outcome (PRO) instrument to assess Acute Bacterial Skin and Skin Structure Infection (ABSSSI) symptoms in patients in clinical trials of antibiotic drugs, consistent with the FDA guidance. METHODS: A comprehensive review of the literature and interviews with nine US and European clinical experts informed the development of a concept elicitation (CE) interview guide, and a hypothetical conceptual framework and disease model. Exploring patients’ experience with symptoms of ABSSSI. CE was based on telephone interviews with 34 patients, after which saturation of emergent concepts was reached. Items and response options were generated based on the qualitative data and a draft instrument was prepared with input and refinement from an international panel of academic and industry experts. Subsequently, cognitive debriefing interviews were conducted with 15 ABSSSI patients and 3 clinical experts to assess item readability, relevance, comprehensiveness, and content validity. Items were edited based on feedback from the patients. RESULTS: CE subtypes were evaluated and consisted of 13 (38.2%) patients with major abscesses, 12 (35.3%) with wound infection, and 9 (26.5%) with cellulitis. The majority of the symptoms were experienced by a majority of patients to some degree described by clinicians. The mean age of patients was 38.8 years; 64.7% male. Symptoms were common across all ABSSSI subtypes and supported the saturation of concepts. Items were generated for the PRO Instrument using patient terminology. Limited country-specific data exist on health-related quality-of-life (HRQoL) impacts of hepatitis C virus (HCV) infection. The aim of this study was to develop a patient-reported outcome instrument (PRO) to stand-alone and qualify symptoms of acute bacterial skin and skin structure infections (ABSSSI) in patients with HCV. The purpose of this study was to develop a patient-reported outcome instrument (PRO) to stand-alone and qualify symptoms of acute bacterial skin and skin structure infections (ABSSSI) in patients with HCV.

PIN8

COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP): DEVELOPMENT OF A NEW PATIENT-REPORTED OUTCOME (PRO) FOR ABSSSI BIOMARKERS CONSORTIUM (CAB-ABSSSI PRO) PROJECT TEAM 3

OBJECTIVES: To determine in clinical studies with documented evidence of content validity. Qualitative data were common across all ABSSSI subtypes and supported the saturation of concepts. Items were generated for the PRO Instrument using patient terminology. Limited country-specific data exist on health-related quality-of-life (HRQoL) impacts of hepatitis C virus (HCV) infection. The aim of this study was to develop a patient-reported outcome instrument (PRO) to stand-alone and qualify symptoms of acute bacterial skin and skin structure infections (ABSSSI) in patients with HCV.

PIN6

SIGNS, SYMPTOMS, AND EXISTING PATIENT-REPORTED OUTCOME (PRO) MEASURES IN HOSPITAL-ACQUIRED BACTERIAL PNEUMONIA (HABP): A COMPREHENSIVE LITERATURE REVIEW

METHODS: A comprehensive review of the literature and interviews with nine US and European clinical experts informed the development of a concept elicitation (CE) interview guide, and a hypothetical conceptual framework and disease model. Exploring patients’ experience with symptoms of ABSSSI. CE was based on telephone interviews with 34 patients, after which saturation of emergent concepts was reached. Items and response options were generated based on the qualitative data and a draft instrument was prepared with input and refinement from an international panel of academic and industry experts. Subsequently, cognitive debriefing interviews were conducted with 15 ABSSSI patients and 3 clinical experts to assess item readability, relevance, comprehensiveness, and content validity. Items were edited based on feedback from the patients. RESULTS: CE subtypes were evaluated and consisted of 13 (38.2%) patients with major abscesses, 12 (35.3%) with wound infection, and 9 (26.5%) with cellulitis. The majority of the symptoms were experienced by a majority of patients to some degree described by clinicians. The mean age of patients was 38.8 years; 64.7% male. Symptoms were common across all ABSSSI subtypes and supported the saturation of concepts. Items were generated for the PRO Instrument using patient terminology. Limited country-specific data exist on health-related quality-of-life (HRQoL) impacts of hepatitis C virus (HCV) infection. The aim of this study was to develop a patient-reported outcome instrument (PRO) to stand-alone and qualify symptoms of acute bacterial skin and skin structure infections (ABSSSI) in patients with HCV.

PIN7

ASSESSING THE IMPACT OF FEGYELATED-INTERFERON/RIBAVIRIN THERAPY DURATION VERSUS VIRAL RESPONSE ON HEALTH-RELATED QUALITY OF LIFE (QOL) OUTCOMES IN CHRONIC HEPATITIS C VIRUS (HCV) PATIENTS, USING MULTIVARIATE MIXED-EFFECTS MODELING

OBJECTIVES: Fegyelated-interferon/ribavirin (FR) is commonly used to treat HCV genotype 1 (G1)-infected patients, both as dual therapy or triple therapy, combined with a direct-acting antiviral (DAA). FR-based treatments are associated with high levels of toxicity and decreased QoL. Adding simprevir as DAA to FR reduces duration of FR therapy and increases significantly the proportion of patients reaching viral response (VR). The objective of this analysis was to explore the impact of duration of FR therapy and of having VR on the level of impairment of QoL and other patient-reported outcomes (PRO). METHODS: Longitudinal QoL/PRO outcomes were analyzed for patients that completed the three randomized clinical trials comparing both FR- and DAA-based treatment. Abbreviations (Q) infected patients, both as dual therapy or triple therapy, combined with a direct-acting antiviral (DAA). FR-based treatments are associated with high levels of toxicity and decreased QoL. Adding simprevir as DAA to FR reduces duration of FR therapy and increases significantly the proportion of patients reaching viral response (VR). The objective of this analysis was to explore the impact of duration of FR therapy and of having VR on the level of impairment of QoL and other patient-reported outcomes (PRO).