PS-82059-19 Requirements for multi-based data management systems for research

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Introduction: A well designed and managed database is essential in clinical research and therefore thorough database planning and design is required.
Aim and Methods: To investigate and document the challenges for a data team during planning of clinical research studies.
Results: The main challenges identified were:

a) Data team is not included during the planning of the proposal resulting in:
   i) Scope of study not clearly defined and database requirements changing
   ii) Database development resources (human and equipment) not catered for
   iii) Ethical aspects for database development unclear.
b) The decision to develop a data system vs a study management tool is not clearly defined, resulting in:
   i) Database requirements change during the study
   ii) Data forms do not cater for the management of the study.
c) Not enough time allocated to develop a Data Management Plan resulting in:
   i) Recruitment in longitudinal studies starts before preparations for follow-up visits are in place
   ii) Management processes to trigger follow up visits and process reports are not kept separate from the data required for outcome analysis.

Recommendation:

a) More time should be allocated to develop the database and data management plan including process management which will lead to the collection of standard, secure and complete data with a management system.
b) Scope of the project and documentation to be used for data collection should be approved by the principle investigators before development begins in order to eliminate misunderstanding between the clinical team and the data team.

PS-82119-19 Rehabilitation programme and quality of life in COPD patients

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Setting: The main goals of pulmonary rehabilitation in COPD are to maximize the functions of daily living and the learning of skills, which can be used to control the physical situation, to enhance quality of life (QoL).
Aim: To compare outcomes between a home-based rehabilitation program and a clinically based physical and kinetic therapy program.
Subjects: 96 subjects with COPD were randomly assigned to a clinic treatment group ($n = 46$; 61% male, 39% female; mean age [±SD] = 47 ± 10 years) or a home exercise group ($n = 48$, 71% male, 29% female; mean age [±SD] = 52 ± 9 years).
Methods: Subjects in the clinic treatment group received supervised exercise and a home exercise program over a 6-week period. Subjects in the home exercise group received the same home exercise program initially, reinforced at a clinic visit 2 weeks later. Measured outcomes were the distance walked in 6 minutes (6MWD) and the generic QoL scale SF-MOS (Short Form Medical Outcomes Study). Differences parameter values between groups were tested by Kruskal–Wallis, ANOVA and χ^2 tests.
Results: Both groups showed clinically and statistically significant improvements in 6-minute walk distances and SF-MOS scores at 6 weeks; improvements were still evident in both groups at 8 weeks. By 6 weeks, SF-MOS scores had improved by 48% in the clinic treatment group and by 23% in the home exercise group. 6 MWD had improved about 27% in both groups. At 3 months, both groups were substantially and about equally improved over baseline measurements.
Conclusions: Although both groups improved by 6 weeks, subjects in the clinic treatment group achieved about twice as much improvement in SF-MOS scores than subjects who performed similar unsupervised exercises at home. The results indicate that a home exercise program for patients with COPD provides important benefits. Subjects in the clinic treatment group were more satisfied with the overall outcome compared with subjects in the home exercise group.

PS-82206-19 Availability of DST results to clinicians between paper and the e-Chasqui laboratory information system

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Background: Communicating test results between TB laboratories and multiple health establishments can be complicated; technologies can facilitate timely transfer to improve patient care. In Peru acutely ill TB patients are taken to hospitals where first-line drug susceptibility tests (DSTs) may be ordered. Most patients are discharged with referral to a health center (HC) before results arrive at the hospital. These results are rarely forwarded to the treating HC.