impacts on data analysis/results along with cost impact. As estimated by the Data
Warehousing Institute, the costs of low quality data exceeds $600 billion annually.
Data cleaning process includes querying for errors, typos, outliers, out-of-range
responses, missing data, deviations, etc. Paper: query data for erroneous/out-of-
range values, these values need to be cross-checked with original paper form to
identify errors in either patient entry or data entry staff. If associated with
patient entry, it may need to be set as missing. When original paper is lost, values
may need to be set to missing as accuracy cannot be confirmed. Time/dates may be
out-of-range or missing, which require cross-checking with original paper. If time/
date cannot be confirmed, the entire entry may need to be set as missing. Missing
values in data need to be identified and cross-checked with original paper to conﬁrm
if value was skipped by patient or by data entry staff. ePRo: can be implemented to
prevent entry of out-of-range values, includes time/date, patient/dentist data entry;
eliminates error by data entry staff; can be programmed to not allow skipped
responses to prevent missing data responses. End-of-study time is precious to
the pharmacoeconomics ﬁeld as very large datasets need to be created. Analysis
of data with paper can be labor intensive and ePRo can save time with preventing
errors from occurring, reducing time needed for data cleaning.

PRM153
RETHINKING COST-EFFECTIVENESS IN THE ERA OF ZERO HEALTHCARE SPENDING GROWTH
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OBJECTIVES: The global economic crisis imposes severe restrictions on healthcare
budgets, limiting the coverage of new interventions, even when they are cost-efﬁcients.
Aiming to develop a tool that can optimally compare the impact of medical intervention alternatives on the entire target population, under a pre-specified budget constraint. METHODS: We illustrated the tool by using a target population of 1,000 patients, and a budget constraint of $1,000,000. We compared two intervention alternatives: the current practice that costs $1,000 and adds 0.5 quality-adjusted-life-years (QALYs) per patient and a new technology that costs 100% more, and provides 20% more QALYs per patient. We developed a formula (ICER) = (C2-C1) / (QALY2-QALY1), for defining the maximum premium for a higher-cost/higher-effectiveness intervention that can justiﬁe its adoption under a constrained budget. RESULTS: Using the new therapy will result in a loss of 300 QALYs, compared to the lower-cost, lower-effectiveness intervention, despite a favorable incremental cost-effectiveness ratio (ICER) of $10,000. The maximum price for the higher-efﬁcacy therapy that will preserve the target population outcomes is 20% higher than the lower-cost therapy. CONCLUSIONS: Although an intervention associated with higher costs
and higher efﬁcacy may have an acceptable ICER, it could provide inferior outcomes in the target population under budget constraints, depending on the relative efﬁcience and costs of the interventions. The cost premium that can be justiﬁed for a high-effectiveness therapy is directly speciﬁc to the target population. An alternative
approach, which has never been explored, is to directly ask people to construct their
personal utility functions. Instead of asking people to value a selection of EQ-5D health states, and then using their responses to infer the utility functions with respect to EQ-5D dimensions and levels. The approach involves directly asking people about the relative importance to them of dimensions, levels and interactions between them. In this presentation, we will describe the development of an innovative new approach that is directly linked to personal utility functions of the general public. The approach is informed by “swing weighting” techniques in the multi-criteria decision analysis literature and by existing direct valuation methods
such as the short form individual quality of life measure. We will summarise the results of a feasibility study which tested the acceptability of the questions, and will
show how the results can be used to generate EQ-5D values. We will also discuss the
research that is required to further reﬁne and operationalise the method.

PRM154
THE ELECTRONIC AGE: INTEGRATING EPRO/ECAO TO REDUCE PATIENT, SITE, AND STUDY TEAM BURDEN
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While some have fully embraced and incorporated ePRo/eCAOs into protocol
design or development, commonly these tools are conceptual paper PRo/CoA forms.
REasons for paper PRo/CoA continued use, focusing on how PRo can be integrated into
the electronic trial solution to reduce the burden to participants/patients, sites, and
clinical teams in setting up, maintaining, and closing out a clinical trial. Assessing
risks and beneﬁts of electronic technologies will be identiﬁed and transitioning to ePRo/eCAO collection modes. Strategies recommended for successful transition to integrated electronic FRo/CoA solutions will be discussed. Integration of ePRo/eCAO provides several beneﬁts over paper, including improved compliance and higher data quality. Comparing the advantages of electronically captured PRo/CoA data vs. paper, the beneﬁts of ePRo/CoA far outweigh those of paper. Combine this with the support and advocacy of ePRo/eCAO in clinical trials by regulatory authorities and a shift of
the general population towards electronic devices; it raises the question why all clini-
cal trials are not using ePRo/CoA to optimize the integrity of data and trial results.
Common obstacles in the selection of a PRo/CoA electronic data collection mode include: paper instruments designed for a paper world, inability to determine true
risks, unknown total cost of electronic vs. paper administration, instrument author
has sometimes costly requirements for migration, unclear translation expectations,
and fear of the unknown. An assessment of methods of facilitating the transition to
electronic data capture will be performed. Examples include use of items/instruments
that are appropriate for electronic platforms and easily migrated and site and patient
training plans. In this age of technological advancements, including an integration
plan in clinical trials is important to mitigate potential risks and minimize the burden
to clinical trial staff and participants. Detailing this up front can help to alleviate many
of the obstacles in the transition from paper to electronic PRo/CoA.

PRM155
ADOPTING SOFTWARE ENGINEERING BEST PRACTICES IN THE FIELD OF PHARMACOECONOMICS: INCREASE IN TRANSPARENCY OF AND CONFIDENCE IN OUR HEALTH ECONOMIC MODELS
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The spreadsheet dominated the pharmacoeconomics software platform of choice for programming pharmacoeconomic models that are submitted to reim-
bursement agencies worldwide. Arguably, the spreadsheet represents a poor choice for model development and implementation as standard software development
tools to manage spreadsheet quality are non-existent. This paper will demonstrate
how the concept and principles of software engineering and adopting their best
practices in model development can increase model transparency and our conﬁdence
that our models perform as expected. We will also compare the advantages and
disadvantages of using spreadsheets versus other programming languages.
Brieﬂy, the primary advantage of the spreadsheet is that it’s universally available
and accessible to all. It’s universal in that a spreadsheet is available on most com-
puters. It’s accessible in that everyone can open the model, inspect it, and use it.
Beyond these advantages, the structure of the spreadsheet challenges our model
practices in increasing transparency and can introduce potential inaccuracies.
For example, generating an audit trail showing the history of what changes were made, when, and by who is not possible with spreadsheet ﬁles. Moreover, the spreadsheet
does not have available standard software tools for developing test suites. A test suite represents a series of tests that must be passed to conﬁrm software performs as expected. For models, this would mean the test suite conﬁrms a model computes what it purports to com-
pute. Hence, test suites serve a critical and foundational function in the lifecycle of
models. Lack of these features need to be similar to traditional software engineering.
In summary, adopting traditional programming languages and their software engineering support tools offers an opportunity to increase model transparency compared with spreadsheets. Reimbursement agencies should con-
sequently require the tools provided by our clinical agency and require supporting software guidance to include non-spreadsheet analysis tools to increase model transparency and our confidence that pharmacoecono-
metrics models perform as expected.

PRM156
DIRECTLY ELICITING PERSONAL UTILITy FUNCTIONS: A NEW WAY TO VALUE HEALTH-RELATED QUALITY OF LIFE
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The end product of EQ-5D valuation studies is an algorithm describing, on aver-
age, how people value each dimension and level. Within the EQ-5D descriptive system, and potentially a range of interaction effects between dimensions and levels. Standard methods for eliciting the preference data (standard gamble, time trade-off, and visual analogue scale) vary considerably in approach, but have in common an aim to ‘uncover’ these preferences by asking survey respondents to
value a sub-set of EQ-5D health states, and then using their responses to infer the
utility functions. These algorithms therefore include specific assumptions about the
levels from their responses, this approach involves directly asking people about the
relative importance to them of dimensions, levels and interactions between them.
In this presentation, we will describe the development of an innovative new
approach that is directly linked to personal utility functions of the general public. The approach is informed by “swing weighting” techniques in the multi-criteria decision analysis literature and by existing direct valuation methods
such as the short form individual quality of life measure. We will summarise the
results of a feasibility study which tested the acceptability of the questions, and will
show how the results can be used to generate EQ-5D values. We will also discuss the
research that is required to further reﬁne and operationalise the method.

HEALTH CARE TREATMENT STUDIES

MEDICAL DEVICE/DIAGNOSTICS - Clinical Outcomes Studies

PDM1
MAJOR AND MINOR ADVERSE EVENTS IN PATIENTS WERE SUBJECTED IN CARDIAC RHYTHM MANAGEMENT DEVICES (CRMD’s) THERAPY AND THEIR FINANCIAL IMPLICATION: A PROSPECTIVE SINGLE-CENTER TWO YEARS SURVEY
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OBJECTIVES: Cardiac rhythm management devices (CRMD’s) have proven their clini-
cal effectiveness for patients with heart rhythm disorders. Little is known about safety
and complication rates during implantations of these devices. This study demonstr-
ated the major and the minor complications related to implantations of CRMD’s,
and estimated the additional hospital stay and cost associated with managing these adverse events. METHODS: During a period of one year in total 464 consecutive recipi-
ents were subjected to CRMD’s implantation and furthermore were recruited and
followed up for 2 years. Finally, data were analyzed for 398 patients who completed the
two year’s follow-up, resulting in a total of 796 patient-years. RESULTS: From the
203 patients with initial pacemaker (PM) implantations, 6 (2.99 %) patients had seven adverse events, six major and one minor (5 patients had lead’s dislodgement, 1 of
them twice (minor adverse events) and 1 patient developed pocket infection (major
adverse event), while from the 177 PMs replacements 1 (0.58 %) patient developed a
major adverse event a pocket erosion. 2 patients with minor adverse event (1 with
an initial PM and 1 with replacement) died before they complete the follow up from
respiratory failure. From the patients we recruited there were 14 patients with one or
two major adverse events (69 patients) nor in replacements (11 patients) of implantable
cardioverter deﬁbrillator (ICD). The average prolongation of the hospital stay was 7
days ranging from 1 to 35 days, resulting in 17 411 € of total additional direct hospital
cost. CONCLUSIONS: This study provides relatively low rates of adverse events in