EGYPTIAN PHARMACOECONOMIC UNIT
CENTERAL ADMINISTRATION FOR PHARMACEUTICAL AFFAIRS

INTRODUCTION TO
Risk Sharing agreements.

COST EFFECTIVENESS
OF Zoledronic Acid versus Alendronic Acid in the treatment of Osteoporosis in postmenopausal Egyptian Patients.

ECONOMIC EVALUATION
OF Lenalidomide plus Dexamethasone Versus Dexamethasone in relapsed or refractory multiple myeloma .

ECONOMIC EVALUATION
OF Bortezomib Plus Dexamethasone Versus Vincristine Plus Doxorubicin Plus Dexamethasone in previously untreated Multiple Myeloma patients.

ECONOMIC EVALUATION
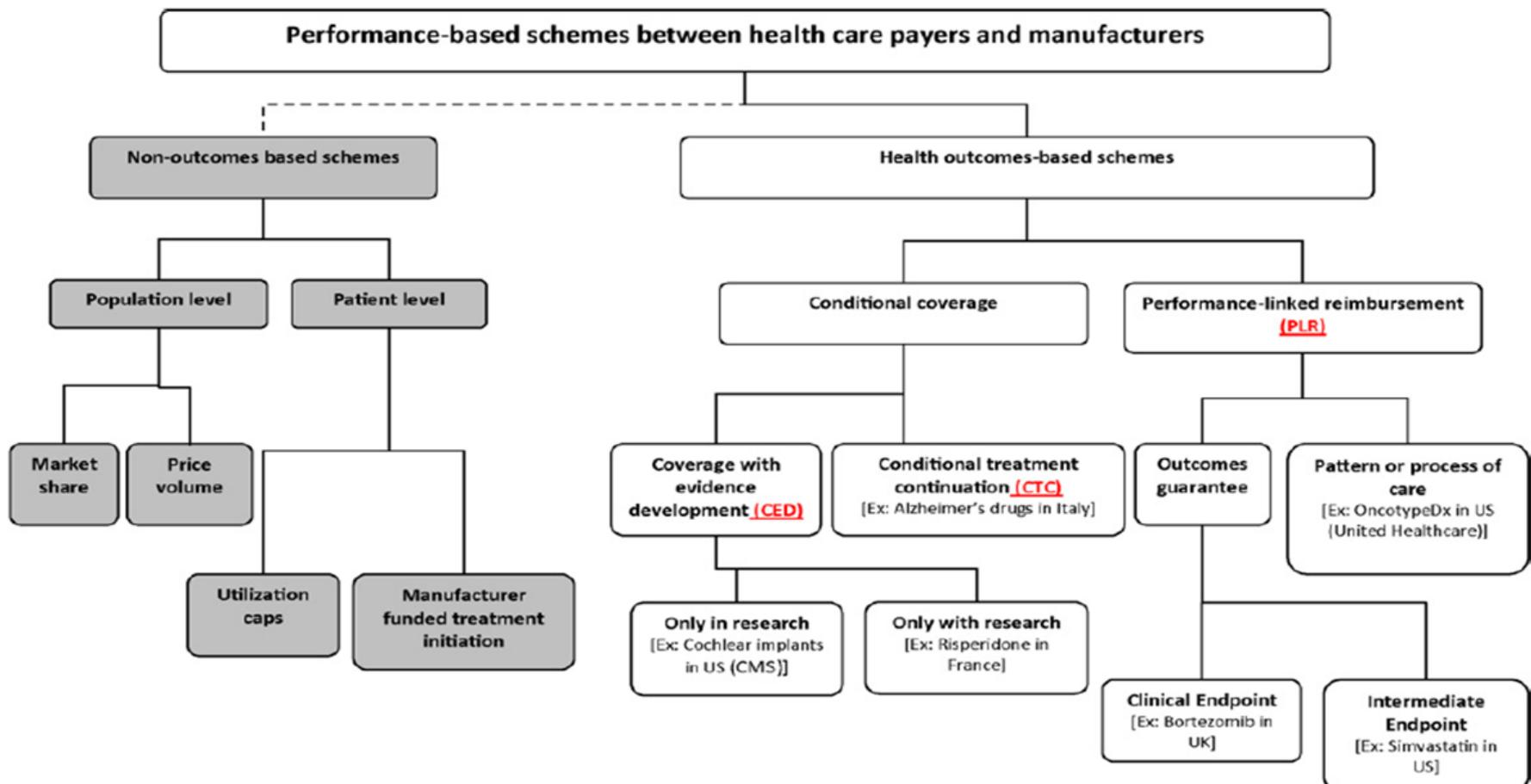Of Trastuzumab emtansine in HER-2-positive Advanced Breast Cancer.

Egyptian Drug Authority
Ministry of Health

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Introduction to risk sharing agreement

The rational and appropriate use of medical products must balance the interests of key stakeholders among the growing cost pressures and uncertainties that permeate the industry. Recently, there has been enthusiasm for linking coverage and reimbursement of medical products to the collection of additional evidence and/or to measures of health outcomes in the "real world". Risk sharing agreements schemes has been defined as those in which the price, level, or nature of reimbursement are tied to future performance measures of clinical or intermediate endpoints ultimately related to patient quality or quantity of life. There are a variety of health outcomes-based schemes that have been referred to as 'risk-sharing', 'pay for performance', 'coverage with evidence development', and 'performance-based reimbursement', among others. The following diagram presents the different types of risk sharing agreements.

Performance-based schemes between health care payers and manufacturers

- Non-outcomes based schemes
  - Population level
    - Market share
    - Price volume
  - Patient level
    - Utilization caps
    - Manufacturer funded treatment initiation
- Health outcomes-based schemes
  - Conditional coverage
    - Coverage with evidence development (CED)
      - Only in research [Ex: Cochlear implants in US (CMS)]
      - Only with research [Ex: Risperidone in France]
    - Conditional treatment continuation (CTC) [Ex: Alzheimer's drugs in Italy]
  - Performance-linked reimbursement (PLR)
    - Outcomes guarantee
      - Clinical Endpoint [Ex: Bortezomib in UK]
      - Intermediate Endpoint [Ex: Simvastatin in US]
    - Pattern or process of care [Ex: OncotypeDx in US (United Healthcare)]

Cost-effectiveness of Zoledronic Acid versus Alendronic Acid in the treatment of Osteoporosis in postmenopausal Egyptian Patients: Decision Analysis

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Abstract:

Background:

Osteoporosis is a major public health problem leading to an enhanced fragility of the skeleton.

The objective of this study was to evaluate, from the Ministry of Health perspective, over a five-year period, the cost-effectiveness of using zoledronic acid 5mg compared to that of alendronic acid in the treatment of osteoporosis in postmenopausal Egyptian patients who began therapy between the ages of 60 and 69 years.

Methods:

A half-cycle corrected Markov cohort chain model with five mutually exclusive health states (Well, hip fracture, spine (vertebral) fracture, wrist (non-vertebral) fracture, and death) was developed**.** A time horizon of five years was selected to reflect the long-term consequences of the use of a once-yearly intravenous infusion of zoledronic acid 5 mg was compared with the use of a once-weekly 70 mg oral alendronic acid. The transition probabilities between the five health states were derived from a previously published source. Health state utilities and major adverse events were obtained from published sources. Direct medical costs were obtained from the Ministry of health list. Costs (in 2014 EGP) and effects were discounted at 3.5% annually. One way sensitivity analyses were conducted.
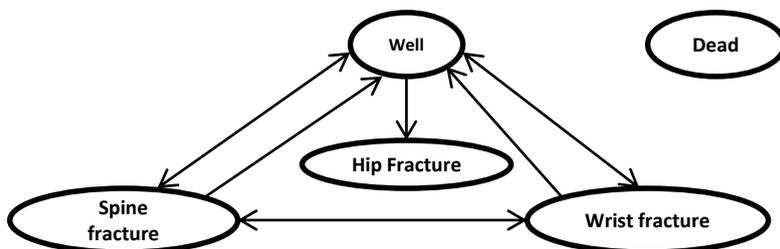
Results:

Across the overall population, the total QALYs of the Zoledronic acid group were estimated to be 194.4 compared with 194.1 for the Alendronic acid group, which resulted in a difference of 0.33 QALYs. The total costs over the 5-year timehorizon for the Zoledronic acid group and Alendronic acid group were LE 215,232 and LE 215,087 respectively (the difference was LE 145). These costs yielded an incremental cost-effectiveness ratio of LE 435 for the Zoledronic acid group. The odds ratio of zoledronic acid on vertebral & non-vertebral fractures was found to have the greatest impact on the results.

Conclusion:

Compared with our willingness-to-pay threshold stated by world health organization for middle and lower income countries, Zoledronic acid is cost-effective; and most likely to result in an ICER lower than the threshold limit. Thus, the new treatment (Zoledronic acid) should be recommended in the Ministry of health list.

Fig. 1: Markov State-transition Bubble diagram:
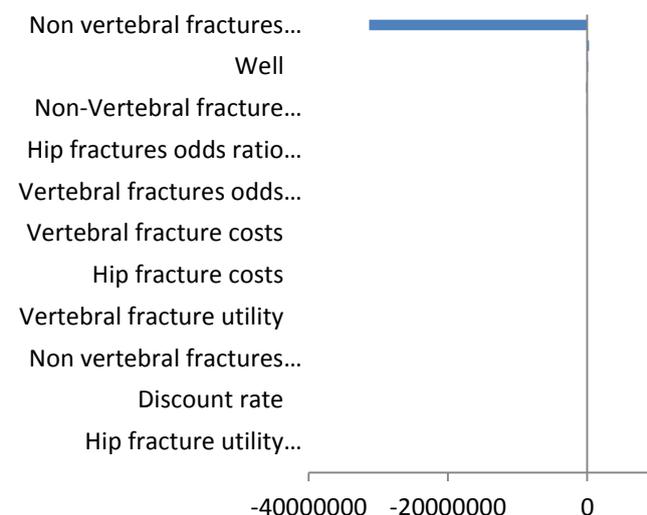
Tornado Diagram

Fig 2:Tornado Diagram

Economic Evaluation of Lenalidomide plus Dexamethasone Versus Dexamethasone in relapsed or refractory multiple myeloma .

Esraa said[1], Gihan Elsisi[1]

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Abstract

Background:

Recent clinical trials demonstrated that Lenalidomide plus dexamethasone is superior to placebo plus dexamethasone in patients with relapsed or refractory multiple myeloma.

The objective of the current analysis was to assess the cost-effectiveness of this combination from the Egyptian insurer perspective (PTES).

Methods:

A Markov model comprising 3 health states (stable disease, disease progression, and death) was developed to estimate the projected- economic implications of this therapy. The model used Markov chain model and included major adverse effects. Transition probabilities were estimated based on the results from pooled update of two large, multicenter MM-009 and MM-010 placebo-controlled randomized phase III trials. Health state utilities, major adverse events, and laboratory tests were obtained from published sources. Direct costs of the therapy, and costs of disease progression were obtained from PTES price list. All costs and effects were discounted at 3.5% annually, as recommended by Egyptian guidelines.
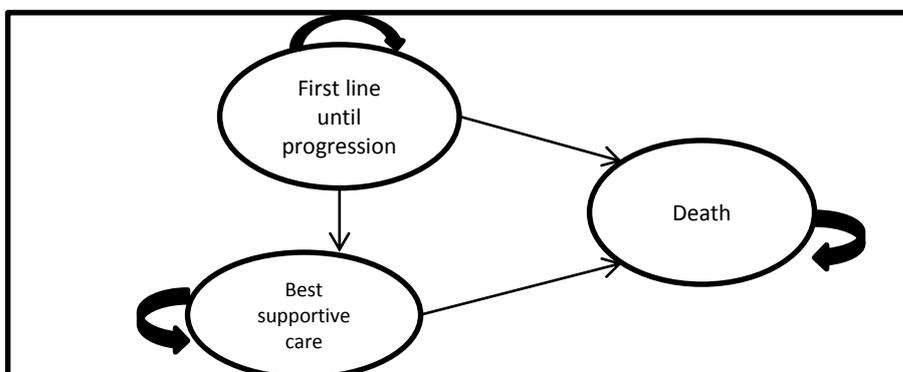
Results:

Over time horizon of 10 years, using Lenalidomide plus dexamethasone as combination therapy versus Dexamethasone resulted in an incremental cost-effectiveness ratio (ICER) of 1189452.7 EGP per QALY gained.

Conclusions:

Compared with commonly accepted willingness-to-pay thresholds using Lenalidomide plus dexamethasone is not clearly cost-effective; and most likely to result in an ICER somewhat higher than the societal willingness-to-pay threshold limits.
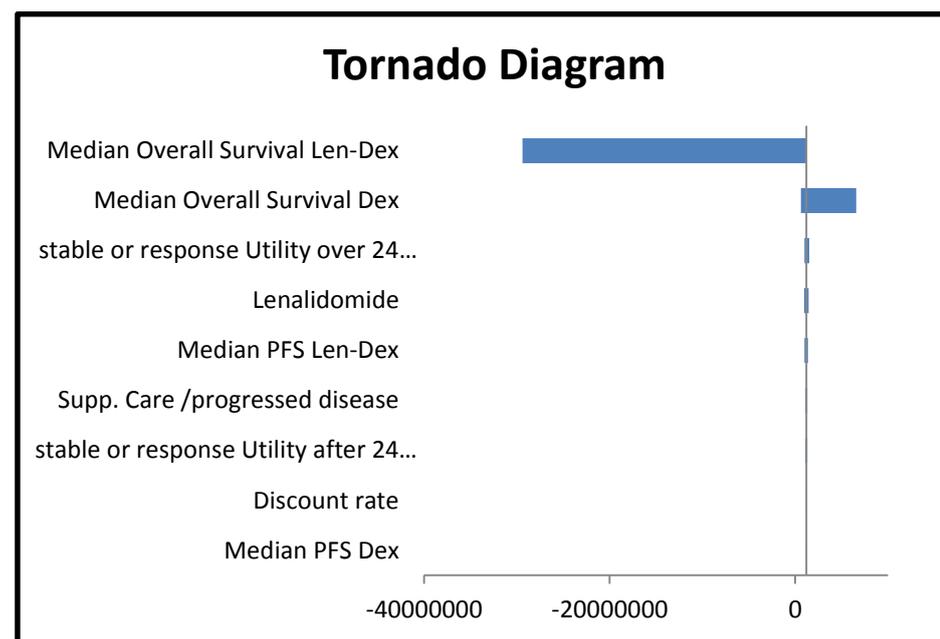
Fig. 2: Sensitivity Analysis

Fig.1 : Markov model Diagram

Economic Evaluation of Bortezomib Plus Dexamethasone Versus Vincristine Plus Doxorubicin Plus Dexamethasone in previously untreated Multiple Myeloma patients.

Esraa said[1], Gihan Elsisi[1]

[1] Pharmacoeconomic Unit, Central Administration for Pharmaceutical Affairs, Ministry of Health, Egypt.

Abstract

Background :

A recent clinical trial demonstrated that Bortezomib plus dexamethasone significantly improved post induction and post-transplantation CR/nCR and at least VGPR rates compared with VAD and resulted in a trend for longer PFS. Bortezomib plus dexamethasone should therefore be consider0ed a standard of care in this setting. The objective of the current analysis was to assess the cost-effectiveness of this combination from the Egyptian insurer perspective (PTES).

Methods:

A Markov model comprising 3 health states (stable disease, disease progression, and death) was developed to estimate the projected- economic implications of this therapy. The model used Markov chain model and included major adverse effects. Transition probabilities were estimated based on the results from the IFM 2005-01 Phase III Trial. Health state utilities, major adverse events, and laboratory tests were obtained from published sources. Direct costs of the therapy, and costs of disease progression were obtained from PTES price list. All costs and effects were discounted at 3.5% annually, as recommended by Egyptian guidelines.
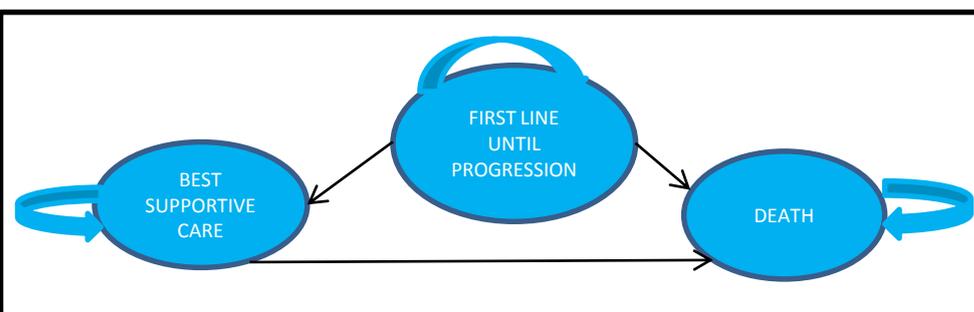
Results:

Over time horizon of 10 years, using Bortezomib plus dexamethasone as combination therapy versus VAD resulted in an incremental cost-effectiveness ratio (ICER) of 942,291.92 EGP per QALY gained.

Conclusions:

Compared with commonly accepted willingness-to-pay thresholds using Bortezomib plus dexamethasone is not clearly cost-effective; and most likely to result in an ICER somewhat higher than the societal willingness-to-pay threshold limits.
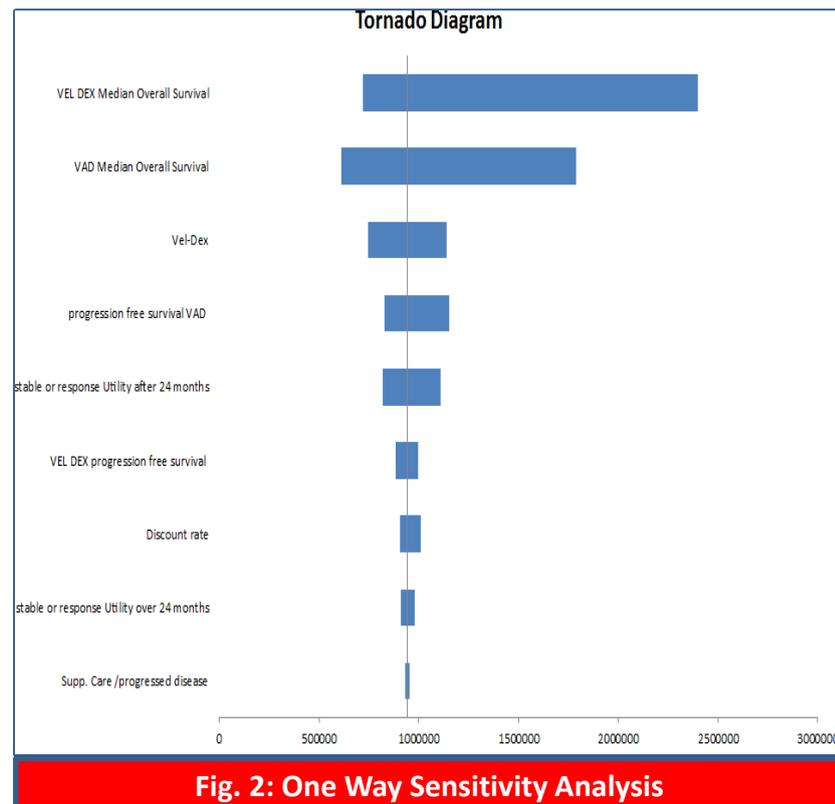

Fig. 2: One Way Sensitivity Analysis

Fig. 1: Markov State-transition Bubble diagram

Economic Evaluation of Trastuzumab emtansine in HER-2–Positive Advanced Breast Cancer

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Abstract

Background:

A recent clinical trial demonstrated that Trastuzumab emtansine significantly prolonged progression-free and overall survival with less toxicity than lapatinib plus capecitabine in patients with HER2-positive advanced breast cancer previously treated with trastuzumab and a taxane.

The objective of the current analysis was to assess the cost-effectiveness of this combination from the Egyptian insurer perspective (PTES).

Methods:

A Markov model comprising 3 health states (stable disease, disease progression, and death) was developed to estimate the projected- economic implications of this therapy. The model used Markov chain model and included major adverse effects. Transition probabilities were estimated based on the results from the EMILIA randomised controlled trial. Health state utilities, major adverse events, and laboratory tests were obtained from published sources. Direct costs of the therapy, and costs of disease progression were obtained from PTES price list. All costs and effects were discounted at 3.5% annually, as recommended by Egyptian guidelines.
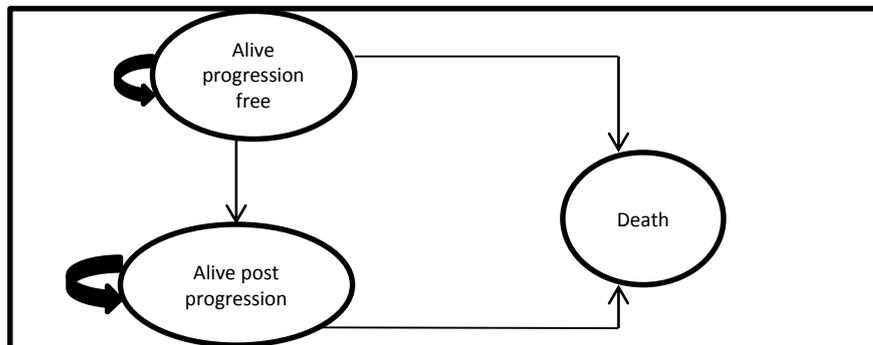
Results:

Over time horizon of 10 years, using Trastuzumab emtansine was estimated to cost an additional 515,845.25 EGP, with an expected gain of 0.442 quality adjusted life years (QALY) or an incremental cost-effectiveness ratio (ICER) of 1,167,881.21 EGP per QALY gained.

Conclusion:

Compared with commonly accepted willingness-to-pay thresholds using Trastuzumab emtansine is not clearly cost-effective; and most likely to result in an ICER somewhat higher than the societal willingness-to-pay threshold limits.
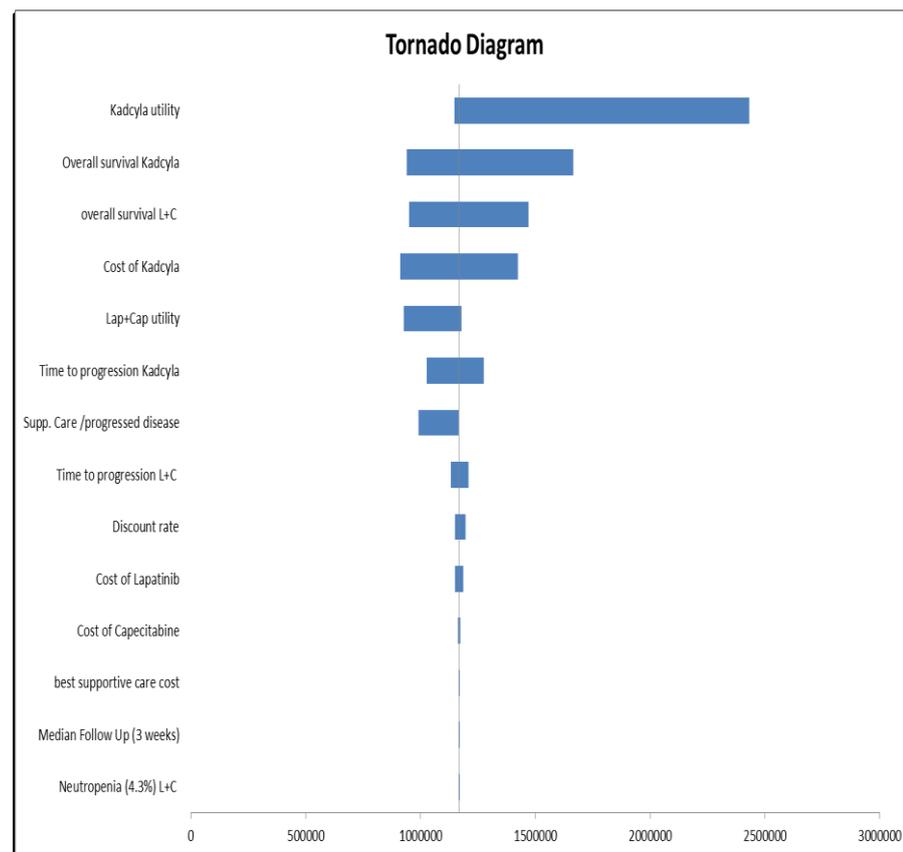

Fig. 1: Markov State-transition Bubble diagram

Fig. 2: One Way Sensitivity Analysis

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