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► **To cite this version:**

Yaël Kolasa, Jean-Philippe Georges, Thierry Bastogne. Computer-aided design of ECG telemetry systems for online cardiac monitoring. Annual Meeting of Safety Pharmacology Society, SPS 2018, Sep 2018, Washington DC, United States. hal-01925675

**HAL Id: hal-01925675**

**<https://hal.science/hal-01925675v1>**

Submitted on 17 Nov 2018

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# COMPUTER-AIDED DESIGN OF ECG TELEMETRY SYSTEMS FOR ONLINE CARDIAC MONITORING

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**Background.** Telemetry is rapidly becoming standard practice for clinical studies. Remote monitoring may be performed at multiple locations of subjects over Blue-tooth, WiFi or 3G cell phone networks. Nevertheless, the accuracy and reliability of monitoring systems have still to be improved for clinical acceptability. Main challenges of wearable devices used in clinical trials have been identified in a very recent article (E. S. Izmailova et al., Clin. Pharma. Thera., 2018). They include scientific methodology as well as regulatory, legal, and operational hurdles.

## Objectives

The objective is to propose an in silico-based method able to prevent some of those issues during the design of clinical trials. To illustrate its applicability, a study case is developed in which we apply this proposed method to identify critical telecommunication parameters to control quality of transmitted ECG in telemetry systems.

## Methods

15 simulation parameters have been selected to test their criticality and four quality attributes have been examined: battery lifetime, number of received packets, transmission count and ECG distortion. The methodology framework relies on the Quality-by-Design guidelines (ICH Q8-Q12). Its partial implementation was based on two consecutive sets of simulations. In a first step, a screening design of numerical experimentations (Plackett-Burman design) was carried out to identify the critical network parameters. In a second step, an optimization campaign, based on a central composite design, was implemented to identify the design space, i.e. the region of interest in which all the telecommunication parameters have to be kept fulfilling the quality specifications. Simulations were carried out in Omnet++ and the statistical analysis in the software environment R.

## Results

For the number of packets received, two critical parameters were identified: message length and bit rate. For ECG distortion, the first two most critical factors are background noise power and energy detection of the radio receiver. For the battery lifetime, preliminary results tend to show that background noise power and bit rate are critical. For the transmission count, the bit rate and the max queue size of the message are decisive.

## Conclusion

This study demonstrates the relevance to use numerical simulations to design but also check the compatibility of a telemetry system with predefined specifications on quality of services in a given and constrained context. Such an approach can be implemented in the early steps of development and can save of lot of time and money by preventing malfunctions, scraps and posteriori restructurations of the telemetry networks.

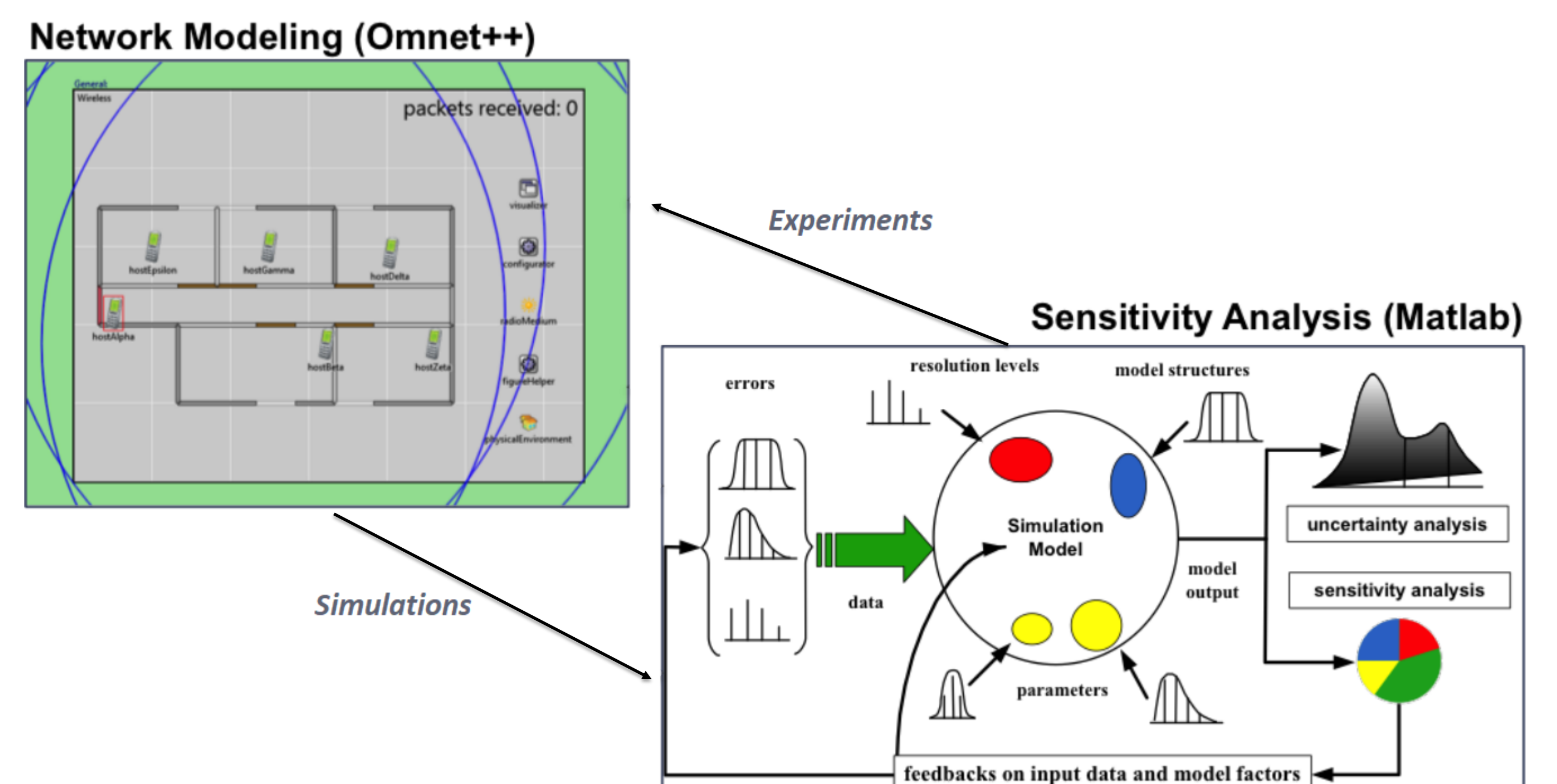


Fig.1: Design of numerical experiments for the robustness analysis of sensors networks

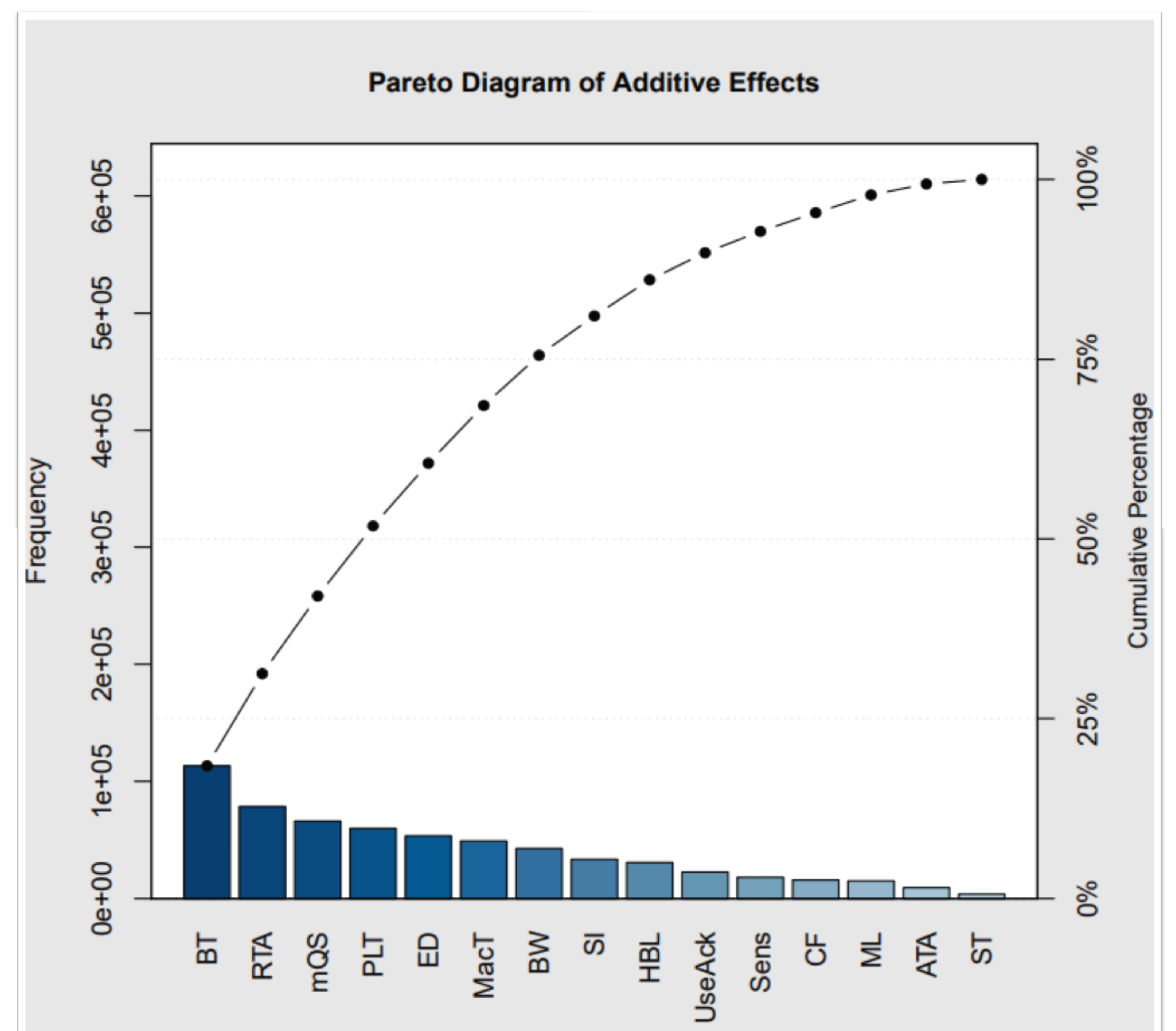


Fig.2: Impacts of the 15 simulation parameters on Transmission Count

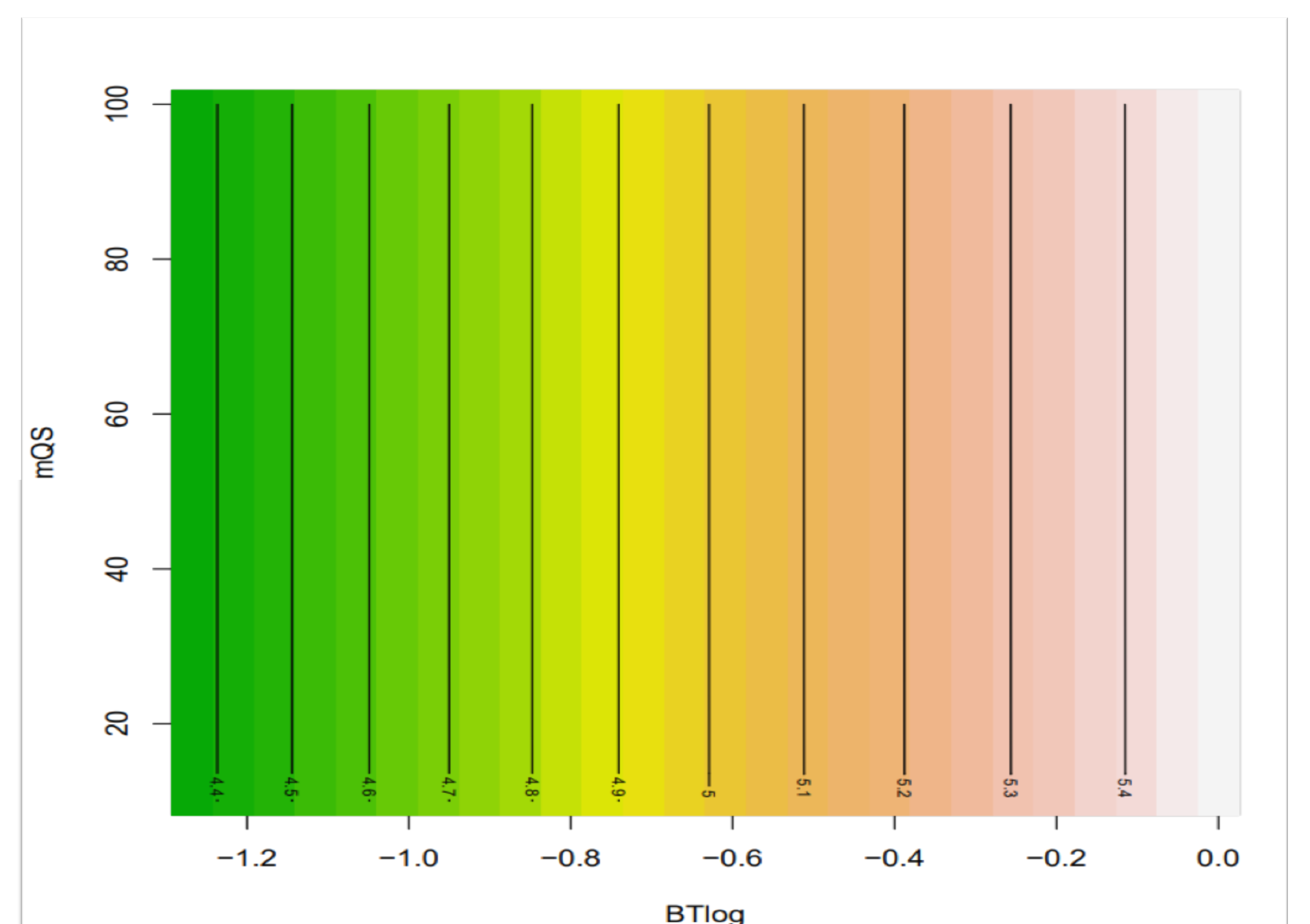


Fig.3: Response surface of Transmission Count for the 2 most critical parameters. It clearly appears that the impact of log(BT) is much more significant than the one of mQS.