

## *The Graphic Display of Quantitative Suicidality Data: S-Plots*

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### **What is the Methodological Issue Being Addressed?**

Suicidality data is currently organized and reviewed in complex tables, reflecting a categorical system, with a resultant loss of sensitivity and the risk of delayed detection of changes in suicidality, or of detection errors. Linking such data to study stopping rules is a complex multistep series of tasks, fraught with potential errors. In the interest of reducing error, speeding detection, protection of patients, clarity of data presentation and display, there is a need for a more efficient, clear, and simple system to display suicidality data. One solution is to graphically display the quantitative suicidality data in S-Plots to quickly visually identify individual patients at high risk and the suicidality disposition of all patients in a research study / clinical trial, and whether a clinical trial should be halted because of treatment-emergent suicidality. These S-Plots are customizable for the needs of different clinical trials and settings. A computer-generated version of these S-Plots is in development.

### **ABSTRACT**

**Introduction:** Regulatory agencies, pharmaceutical companies, clinical research organizations, data safety monitoring boards, medical directors of health care organizations, and medical safety officers are challenged with the difficulty of summarizing the suicidality status of patients under their care in a simple, clear manner. Currently, data collected using a dimensional scale are reduced to the categorical system at the completion of a study. Suicidality data is currently organized and reviewed in complex tables, reflecting these categories, with a resultant loss of sensitivity and the risk of delayed detection, or of detection errors. Linking such data to study stopping rules is a complex multistep series of tasks, fraught with potential errors. In the interest of reducing error, speeding detection, protection of patients, clarity of data presentation and display, there is a need for a more efficient, clear, and simple system to display suicidality data.

**Methods:** We explored and reviewed graphic displays of quantitative data in other medical and scientific disciplines to find suitable models. The selection criteria included simplicity, clarity, the ease of interpretation of the data, and how appropriate the displays would be for suicidality data, collected using a dimensional suicidality tracking scale. We applied a variety of graphic displays to a prospectively collected dataset using the Sheehan-Suicidality Tracking Scale (S-STs). The final displays are the result of this iterative process.

**Results:** Suicidality-Plots (S-Plots) display the data for groups of patients and for individual patients over time. Interpretation of these S-Plots can quickly identify patients at higher risk, and

provide a method to monitor the status of patients within a large sample over time. Interpretation of S-Plots can quickly identify the overall status of suicidality in the study over time in relation to the study stopping rules. Graphic display of quantitative suicidality data can be used to quickly visually identify individual patients at high risk, the disposition of all patients in a healthcare setting or clinical trial, and whether a clinical trial should be halted because of treatment-emergent suicidality. These S-Plots are customizable for the needs of different clinical trials and settings. A computer-generated version of these S-Plots is in development. It is designed to generate e-mails or phone alerts to site investigators and sponsors for subjects deemed at imminent risk, and who need immediate attention.

**Conclusion:** Use of S-Plots may reduce the potential medico-legal hazards from either the delayed analysis or delayed detection of suicidality in safety data, and the risk to patients in research trials and clinical settings.

### **DISCLOSURES**

David V. Sheehan is the author, copyright and patent holder of scales (including S-STs), structured interviews, phenomena definitions, classifications, and books on suicidality; a non-linear model and candidate drug treatments for suicidality; and a hypothesis for the mechanism of action of some anti-suicidality medications. DS is co-founder of Harm Research Institute and Harm Research Press. DS owns stock in Nview Health, which distributes the computerized versions of his scales and structured interviews.

Jennifer M. Giddens is the author and copyright holder of scales, phenomena definitions, classifications, and books on suicidality; a non-linear model and a candidate drug treatment for suicidality; and a hypothesis for the mechanism of action of some anti-suicidality medications. JG is co-founder of Harm Research Institute and Harm Research Press and is the editor of the Science of Suicidality. JG is a consultant for Nview Health.