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Society for Clinical Trials Selects India's "Jharkhand and Orissa" trial as "Trial of the Year"

Study of birth outcomes and maternal depression in India to be recognized at Society's 2011 Annual Meeting in Vancouver, May 17

PHILADELPHIA — "The Ekjut Trial in Jharkhand and Orissa" earns recognition as "Trial of the Year" by the Society for Clinical Trials (SCT) as an extraordinary cluster randomized controlled trial, conducted with high quality in a very difficult setting, and achieving dramatic results of great public health importance. The trial's co-investigator, Dr. Prasanta Tripathy, will present an overview of the trial methods and findings during the SCT's 2011 Annual Meeting in Vancouver, BC, Canada on Tuesday, May 17.

Each year since 2008, the SCT has teamed with Project ImpACT to present an award to the randomized clinical trial published (either electronically or in print) in the previous year that best fulfills the following standards:

- It improves the lot of mankind.
- It provides the basis for a substantial, beneficial change in health care.
- It reflects expertise in subject matter, excellence in methodology, and concern for study participants.
- It overcomes obstacles in implementation.
- The presentation of its design, execution, and results is a model of clarity and intellectual soundness.

Published in *The Lancet* in March 2010 [Lancet 2010;375: 1182-92], the "Jharkhand and Orissa" trial was a cluster randomized trial in very poor communities in eastern India. The goal of this study was to reduce neonatal mortality rates and maternal depression. The investigators successfully randomised 36 clusters (10-12 villages per cluster) in three districts to a community intervention (vs. none) which involved using or organizing village women's groups, who engaged in participatory learning and action through play, stories and games. Group members themselves identified newborn health problems within the community and selected their own strategies to address the problems, which they then implemented. After three years of the intervention, neonatal mortality was reduced by 45% and maternal depression by 57%.

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Nominations for “Trial of the Year” came from SCT members, investigators, and interested scholars from around the world. The selection committee, headed by David Sackett of the Trout Research and Education Centre in Canada, included Kay Dickersin of Johns Hopkins Bloomberg School of Public Health, Kyungman Kim of University of Wisconsin, Steve Goodman of Johns Hopkins University and editor of *Clinical Trials*, and John Norrie of University of Glasgow. The committee was extremely pleased with the quality of nominations, reducing a slate of nine down to three finalists. The “Jharkhand and Orissa” trial stood out among its competition because, noted committee member Dr. Goodman, “Perhaps most importantly, the study gave the participants and their communities tools to continue the intervention after the study was over.”

Dr. Prasanta Tripathy will travel from India to present the study and represent the organization Ekjut (www.ekjutindia.org), whose mission it is to improve maternal and neonatal outcomes in the poorest areas of India. He explains that “ekjut” means ‘together’ in several Indian languages.

“This potential for continuation after the official end of the study was something that we thought about before the study began,” explained Dr. Tripathy. “We also agreed to extend the benefits of the intervention to the control areas if the intervention had an impact. We secured financial resources for the same, providing support to the groups through ‘facilitators’ from the same community and also disseminating findings for a possible roll-out by government.”

Professor Anthony Costello led the researchers from University College London Centre for International Health and Development, Institute of Child Health, and was a co-investigator on this study. He further explains the value of such a trial in the developing world: “The trial was designed as a community effectiveness trial rather than an efficacy trial of a perfectly implemented intervention which would be difficult to scale up in the real and resource-limited world in which these tribal populations live. Such trials are essential in the developing world so that we can really estimate the impact and cost-effectiveness of what we do.”

The “Jharkhand and Orissa” trial is an example of the sometimes vague concept of clinical trials being made relevant in the “real world.” As Dr. Tripathy illustrates, “This trial was a community-based intervention where we were testing the impact of a ‘process of change.’ It is recommended that such RCTs should also be accompanied by process evaluation, explaining the context, methods, how the intervention was carried out and possible mechanisms of change in the partnering communities so that the intervention can be adapted for scaling up in other locations keeping the ‘real world’ in mind. We have, therefore, published a process evaluation paper to explain the impact: [Explaining the impact of a women’s group led community mobilisation intervention on maternal and newborn health outcomes: the Ekjut trial process evaluation-Rath et al., BMC International Health and Human Rights 2010, 10:25doi:10.1186/1472-698X-10-25]. We have also scaled up our work with women’s groups to newer settings in eight districts of Jharkhand and Orissa states of India to gauge the impact.”

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Note to Editors: Journalists wishing to attend the presentation by Dr. Tripathy on Tuesday, May 17, 2011 at 5:00 PM should contact the Society's headquarters office at +1.215.564.3484, x 2213. A proof of assignment and photo ID will be requested.

About the Society for Clinical Trials: The Society for Clinical Trials, created in 1978, is an international professional organization dedicated to the development and dissemination of knowledge about the design, conduct and analysis of government and industry-sponsored clinical trials and related health care research methodologies. Visit www.sctweb.org.

About Project ImpACT: The aim of Project ImpACT (Important Achievements of Clinical Trials) is to identify and develop a comprehensive description of the most important randomized controlled trials (RCTs) performed in the fields of medicine and public health since 1948. Learn more at <http://www.projectimpact.info/Home/>.

Download Photos: View photos from Jharkhand and Orissa trial on the SCT website. Please provide photo credit to: Ekjut, Chakradharpur, Jharkhand, India, 2010.

About the Trial of the Year: Find a list of past [Trials of the Year](#) on the SCT website.