VII. STANDING COMMITTEES

A. Academic and Student Affairs Committee

Clinical Trial Center Research Over the Last 30 Years

INFORMATION ONLY

Attachment
Research at the Clinical Trial Center. University of Washington, Department of Biostatistics

Research at the Clinical Trial Center Judy Powell
University of Washington, Department of Biostatistics November 8, 2012

Research at the Clinical Trial Center (CTC) has significantly contributed to this very important part of the University's mission for over 30 years (since 1982). I'm Judy Powell, I'm a Research Nurse and the Project Director for our current major project, funded by NIH, called the Resuscitation Outcomes Consortium, or ROC. Throughout our history, the CTC, as a unit of the Department of Biostatistics, has developed, coordinated and analyzed numerous studies in cardiovascular and emergency medicine. The CTC was directed by Al Hallstrom for the first 22 years and currently by Susanne May. The first CTC study, Cardiac Arrhythmia Suppression Trial (CAST), was a landmark study showing harm with the use of antiarrhythmic drugs in post MI patients who had abnormal heart rhythms and the study became synonymous with the hazard of using surrogate endpoints. Next, the Telephone CPR trial challenged the dogma that ventilations must be performed with CPR. Currently the American Heart Association has changed their lay person CPR practice to include chest compression only CPR. The Antiarrhythmics vs. Implantable Defibrillators Trial (AVID) showed that implantable defibrillators did reduce mortality but not as dramatically as predicted. The Public Access Defibrillation Trial demonstrated the efficacy of bystander defibrillation using Automated External Defibrillators using rigorous training and program monitoring. The AutoPulse Assisted Pre-hospital International Resuscitation (ASPIRE) Trial was one of the first real multi-community EMS collaborative efforts and was terminated due to a 50% reduction in survival in the mechanical CPR arm. Other CTC studies include the DAVID and DAVID II Trials. In every CTC research project, a key point is that Research Nurses were essential to the successful results.

In 2004, through intense nationwide competition, the UW CTC was chosen as the coordinating center for the Resuscitation Outcomes Consortium funded by the National Heart, Lung and Blood Institute in partnership with other public and private funding agencies. This grant is currently the largest amount of funding that the UW receives from NHLBI. Also, ROC was the first long term collaboration between EMS agencies throughout the US and Canada and includes over 200 EMS/fire agencies. ROC's essential mission is to provide infrastructure for clinical trials and outcome-oriented research in the areas of cardiopulmonary arrest and severe traumatic injury. The ROC was renewed in 2010 and has been awarded over 170 million dollars in support for various projects from 2004 through 2015. More than 14 EMS or hospital based projects within ROC were completed or are actively underway.

Integral to this research process is the role of the Research Nurse. One key point is the CTC recruits experienced clinical nurses from Harborview and UWMC. Prior to the late 1980s all nurses within the University organization were similarly classified and were paid on the same scale. After the late 1980s Research Nurses were classified differently than other nurses but were promised the same pay. This promise was maintained until approximately 4-5 years ago when pay scale differences occurred between research nurses and hospital based clinical nurses, and the differences continued to widen since then. Currently Research Nurses receive approximately 10-15% lower salary than hospital

nurses. Obviously, these pay differences adversely affect the ability to recruit clinical nurses for positions in research, and research is an absolutely essential and vital University mission element. Recently our own Clinical Trial Center lost an experienced research nurse to higher pay as a clinical nurse. Local departments are aware of the pay differences and are exploring ways to alter this. But more action is needed in order to assure that enough experienced clinical nurses are interested in moving to research and willing to help facilitate and complete the important research that made the University of Washington one of the highest recipients of research dollars in the country and perhaps the world.

Studies Conducted by the Clinical Trial Center in the Department of Biostatics

Name	**Years**	**Patient Numbers**	**Funding**
Cardiac Arrhythmia Pilot Study (CAPS)	1983-85	500 pts; 10 sites	
Cardiac Arrhythmia Suppression Trial (CAST)	1987-91	3000 pts; 30 sites	8.5 million
Telephone CPR (T-CPR)-non-inferiority	1989-93	500 pts; 1 site	
Telephone CPR (T-CPR)-superiority	1992-99	700 pts; 1 site	
Antiarrhythmics vs Implantable Defibrillators (AVID)	1993-98	1200 pts; 56 sites	12.5 million
Public Access Defibrillation (PAD)	2000-03	1000 facilities; 24 sites	17.2 million
Dual Chamber and VVI Implantable Defibrillator (DAVID)	2000-04	600 pts; 37 sites	9.6 million
DAVID II	2002-07	600 pts; 30 sites	Included in above
AutoPulse Assisted Pre-hospital International Resuscitation (ASPIRE)	2003-06	1300 pts; 5 sites	2.1 million
Resuscitation Outcomes Consortium (ROC) EMS Registry (cardiac arrest and trauma)	2005-2015	200,000 + pts; 12 sites	*Total funding for sites/CTC/protocols 60 million (2004 through 2009)
ROC Hypertonic Saline Trial-Shock	2006-08	895 pts; 11 sites	*
ROC Hypertonic Saline Trial-Traumatic Brain Injury	2006-09	1331 pts; 13 sites	*
ROC Prehospital Resuscitation using an Impedance valve and Early vs Delayed analysis (ROC PRIMED)	2007-09	17,153 pts; 10 sites	*
ROC CPR Feedback Substudy	2007-09	1586 pts; 3 sites	*
ROC Prospective Observational Prehospital and Hospital Registry for Trauma (PROPHET)	2010-11	3752 pts; 11 sites	+Total funding for sites/CTC/protocols 60 million (2010 through 2015)

ROC Dallas Resuscitative Endocrinology: Single dose Clinical Uses for Estrogen-Hemorrhagic Shock Pilot Study (RESCUE)	2010-12	50 pts; 1 site	+
ROC Dallas Resuscitative Endocrinology: Single dose Clinical Uses for Estrogen-Traumatic Brain Injury Pilot Study (RESCUE)	2010-12	50 pts; 1 site	+
ROC Biomarker Lactate for Assessment of Shock in Trauma (BLAST)	2011-13	600 pts; 9 sites	+
ROC Continuous Chest Compressions (CCC)	2011-15	23,000 pts; 9 sites	+
ROC Hypotensive Resuscitation (Hypo Resus) Pilot Study	2012	200 pts; 7 sites	+
ROC Amiodarone, Lidocaine, or Placebo Study (ALPS)	2012-15	3000 + pts; 10 sites	+
ROC Pragmatic, Randomized Optimal Platelet and Plasma Ratios (PROPPR)	2012-14	580 pts; 12 sites	52 million