

CURRICULUM VITAE

Denise Cunningham, RN, MSN, CCRC, CIP

OFFICE ADDRESS:

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Department of Research
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Professional Experience

Manager

Research Department
Providence Hospital and Medical Centers, Southfield, Michigan
1991 – Present

- Coordinate clinical research
- Provide assistance to investigators conducting research
- Supervise Research Nurses
- Ensure compliance with Hospital and FDA Regulations
- Review research applications and informed consent
- Draft informed consents for clinical research studies
- Liaison between clinical research sponsors and Institutional Review Board
- Assist in patient recruitment for clinical research studies
- Collect and maintain required research data

Committee Appointments: Member, Institutional Review Board
Member, Research Committee

Acting Director

Research Department
Providence Hospital and Medical Centers, Southfield, Michigan
April 1, 2001 – July 1, 2002

- Manage professional research staff of nine individuals in the Divisions of Clinical Trials, Research Laboratory, Microvascular and Gross Anatomy Laboratory
- Management of department budget and restricted research funds
- Oversight of all research projects to insure compliance with hospital policies and federal and state regulations
- Consultant to residents, fellows and medical staff on research design and implementation
- Supervision of Institutional Review Board and Research Committee.

– Coordination of inservice education for researchers, departmental staff and hospital associates regarding hospital policies, procedures, federal and state compliance requirements (FDA, OSHA, and USDA), and research ethical guidelines, principles, and issues.

Research Nurse/Study Coordinator

Department of Physiology

Providence Hospital, Southfield, Michigan

1983 - 1991 (Part-time and contingent status 1979-1983)

- Provide assistance to investigators conducting research
- Coordinate clinical research
- Determine subject eligibility for research studies
- Collect and maintain required research data

Committee Appointments: Research Committee

Staff Nurse

American Red Cross, Detroit, Michigan

1981-1983

Paramedical Examiner

Meditest, Southfield, Michigan

1979

Staff Nurse

Kimberly Nurses, Southfield, Michigan

1979

Staff Nurse

Cardiac Care Unit

Providence Hospital, Southfield, Michigan

1973 -1979

Committee Appointments: Chairperson, CCU Nursing Audit Committee 1978

Staff Nurse

Medical-Surgical Unit

Providence Hospital, Southfield, Michigan

1972 – 1973

Education

1972 - R.N. Diploma

Providence Hospital School of Nursing.

Southfield, Michigan

1990 - B. S. N.
Wayne State University
Detroit, Michigan

1998 - M.S.N. Wayne State University
Community Health Nursing
Detroit, Michigan

Publications

Madhavan, T., Patel, J., & Cunningham, D. (1985). Timentin compared to tobramycin/piperacillin combination as empiric therapy in serious infections in hospitalized patients. In Jogi Ishigami (Ed.) Proceedings of the 14th International Congress of Chemotherapy, Kyoto, Japan, 1985, Recent Advances in Chemotherapy-Antimicrobial Section 3, (pp. 2693-2694). Japan: University of Tokyo Press.

Madhavan, T., Cunningham, D. (1985). Clinical and laboratory studies of cefbuperazone: A long acting cephamycin, in a suburban community hospital. In Jogi Ishigami (Ed.) Proceedings of the 14th International Congress of Chemotherapy, Kyoto Japan, 1985. Recent Advances in Chemotherapy - Antimicrobial Section 2, (pp. 1129-1130). Japan: University of Tokyo Press.

Madhavan, T., Cole, P., Cook, R., & Cunningham, D. (1985). Therapeutic substitution of cephalosporins, an effective cost containment measure in a community based teaching hospital. In Jogi Ishigami (Ed.) Proceedings of the 14th International Congress of Chemotherapy, Kyoto, Japan, 1985. Recent Advances in Chemotherapy Antimicrobial Section 3, (pp. 2685-2686). Japan: University of Tokyo Press.

Madhavan, T., Fitzsimons, B., Lewis W. F., & Cunningham, D. (1985). Role of the clinical microbiology laboratory in antibiotic cost containment: A community hospital experience with prior in vitro evaluation and reporting systems. In Jogi Ishigami (Ed.) Proceedings of the 14th International Congress of Chemotherapy, Kyoto, Japan, 1985, Recent Advances in Chemotherapy - Antimicrobial Section 3, (pp. 2693-2694). Japan: University of Tokyo Press.

Saba S., Duvernoy, W.F.C., Cunningham, D., Zaks, J. Does participation in multicenter trials change the practice pattern of private physicians? *Providence Hospital Medical Bulletin*, Volume 7, No. 1 (1994), 11-14.

Machado, C., Zarghami, J., Liddon, V., Cunningham, D. Intravenous procainamide: A facilitator for transthoracic cardioversion in recalcitrant atrial fibrillation. *PACE* 2000; 23;4.

Posters and Presentations.

Rahman, R., Madhavan, T., & Cunningham, D. (1983). Cefoperazone as empiric therapy in bacterial infections. American College of Physicians, Michigan Regional Meeting, Harbor Springs, Michigan, October 1983.

Patel, J., Madhavan, T., & Cunningham, D. (1984). A prospective, randomized novel approach in the treatment of bacteremia and pneumonia with the combination of an enzyme inhibitor clavulanic acid and ticarcillin. Fourth Mediterranean Congress of Chemotherapy, Rhodos, Greece, October 1984.

Madhavan, T., Cunningham, D. (1988). Critical clinical assessment of safety of ofloxacin and enoxacin in an ambulatory setting with special reference to CNS toxicity. Michigan State Medical Society Annual Scientific Meeting, Dearborn, Michigan, November 1988.

Madhavan, T., Cunningham, D. (1988). Critical clinical assessment of safety of ofloxacin and enoxacin in an ambulatory setting with special reference to CNS toxicity. American College of Physicians, Michigan Chapter, 34th Annual Michigan Scientific Meeting, Grand Traverse Village, Michigan. September 1988.

Andersen, B., Hawtof, D., Cunningham, D. (1989). Basal cell carcinoma: Analysis of factors for recurrence. 54th Annual Clinic Day for Resident Research, Providence Hospital, Southfield, Michigan, April 1989.

Osgood, G., Hawtof, D., Cunningham, D. (1989). Preliminary report of doppler laserflow measurements in patients undergoing rhytidectomy. 54th Annual Clinic Day for Resident Research, Providence Hospital, Southfield, Michigan, April 1989.

Dubay, L., Cunningham, D., Hawtof, D. (1992). Aesthetic changes following breast biopsies. 57th Annual Clinic Day for Resident Research, Providence Hospital, Southfield, Michigan, April 1992.

Saba, S., Zaks, J., Cunningham, D., Duvernoy, W.F.C. (1993). Heart rate variability (HRV) as a predictor of cardiac ischemia. 58th Annual Clinic Day for Resident Research, Providence Hospital, Southfield, Michigan, April 1993.

Nasir, I., Saba, S., Cunningham, D., Zaks, J., Duvernoy, W.F.C. (1993). Does participation in multicenter trials change the practice patterns of private physicians? 58th Annual Clinic Day for Resident Research, Providence Hospital, Southfield, Michigan, April 1993.

Hafford, T. K, Karamaii, A., Cassavar, D., Moran, M., Cunningham, D., David, S. (1995) Differences between young women and men in risk factors for acute myocardial infarction. 60th Annual Resident Research Day, Providence Hospital, Southfield, Michigan, April 1995.

Clinical Trials Experience

1979-1982 Lopressor-Placebo Myocardial Infarction Trial
Sponsor: Ciba-Geigy.

1988-1991 Nifedipine Peri-Operative Reduction of Ischemia Study (PORIS)
Sponsor: Wayne State University

1989-1991 Hemodynamic and Electrocardiographic Effects of Intracoronary Diltiazem during Percutaneous Transluminal Coronary Angioplasty
Sponsor: Wayne State University

1990-1991 Nicardipine After Percutaneous Coronary Angioplasty: A Randomized Prospective Double-Blind Placebo Controlled Study
Sponsor: Wayne State University

1990-1991 An Open Label Assessment of the Safety and Efficacy of Isradipine in The Treatment of Patients with Mild to Moderate Hypertension

1990-1995 Trial to Evaluate the Effect of Digitalis on Mortality in Heart Failure
Sponsor: NIH, NHLBI

1991-1993 Global Utilization of Streptokinase and t-PA for Occluded Coronary Arteries (GUSTO)

1993-1996 MATE Protocol: Medicine of Angioplasty for Thrombolytic Exclusion
Sponsor: William Beaumont Hospital

1992-1994 A One-Year, Multicenter, Double-Blind Comparison of the Effects of Once-Daily Dosing with Three Dose Levels of SK&F 105677 or Placebo in the Treatment of Symptomatic Benign Prostatic Hyperplasia
Sponsor: SmithKline Beecham

1993-1997 MATE Protocol: Medicine of Angioplasty for Thrombolytic Exclusion
Sponsor: William Beaumont Hospital

1996-2002 AFFIRM: Atrial Fibrillation Follow-Up Investigation of Rhythm Management
Sponsor: NIH, NHLBI

1996-Present PEACE: Prevention of Events with Angiotensin Converting Enzyme Therapy
Sponsor: NIH, NHLBI

1997-2001 Mode Selection Trial in Sinus Node Dysfunction
Sponsor: NIH, NHLBI

1997-Present SCD-HeFT: Sudden Cardiac Death in Heart Failure Trial
Sponsor: NIH, NHLBI

1997-1991 The Evaluation of Intravenous Amio-Aqueous at Electrophysiology Testing
Sponsor: Academic Pharmaceuticals

1998-1999 Clinical Evaluation of Sulzer Intermedics: 430-25 and 438-25 ThinLine II
Pacing Leads
Sponsor: Guidant

1998-1999 Efficacy of ATP in Terminating Fast Tachycardias
Sponsor: Medtronic

1998-1999 Evaluation of diagnostic features using the Guidant/CPI Discovery Models
1174/1175/1374/1275
Sponsor: Guidant

1998-2003 VALIANT
Sponsor: NIH, NHLBI.

1991-1992 TherOx Aqueous Oxygen System-Acute Myocardial Infarction with
Hyperoxemic Therapy Phase I Clinical Trial
Sponsor: TherOx, Inc.

1999-2001 RAMPART: Relative and absolute myocardial perfusion changes as
measured by positron emission tomography to assess the effects of ACAT inhibition: A
double-blind, randomized, multicenter trial.
Sponsor: Parke-Davis

1999-2000 Effects of adenosine on microvascular function in patients with acute
myocardial infarction
Sponsor: Wayne State University

1999-2000 Sulzer Intermedics: Steroid-Eluting ThinLine II Pacing Lead Models 43035S,
432-35S and 438-35S
Sponsor: Guidant

1999-2002 The Advanced Elements of Pacing Trial (ADEPT)
Sponsor: NIH, NHLBI

1999-2000 Phylax AV Clinical Investigation
Sponsor: Biotronik

2000-2002 A double-blind comparison of the incidence of hypotension with two formulations of intravenous amiodarone: Cordarone IV vs Amiodarone Aqueous IV injection

Sponsor: Wyeth-Ayerst Pharmaceuticals

2000-2002 Acute evaluation of autocapture in Bachmann's Bundle vs right atrial appendage using Affinity DR Device

Sponsor: St. Jude Medical

2002-2003 Evaluation of atrial arrhythmias utilizing the onset of electrogram capability of Discovery II and Ventak Prizm AICD

Sponsor: Guidant

2000-2001 Mode selection trial in sinus node dysfunction (MOST) substudy patient satisfaction questionnaire

Sponsor: NIH, NHLBI

2002-2002 Comparison of new stents for equivalency of reduction in vascular events (CONSERVE)

Sponsor: IVT

2001-2003 Pain FREE Rx II: Does PAcINg Fast VT REducE Shock Rx?

Sponsor: Medtronic

2001-2002 Tachos Atrial Conversion Therapy (TACT)

Sponsor: Biotronik

2001-2002 The open evaluation comparing stent thrombosis rate of the BX Velocity Heparin coated stent and the BX Velocity Stent

Sponsor: Cordis

2001-2003 TENAX XR Registry Investigational Plan

2001-Present TherOx Aqueous Oxygen System-Acute Myocardial Infarction with Hyperoxemic Therapy (AMIHOT) Phase II Clinical Trial: A randomized, controlled, multicenter trial of aqueous oxygen infusion for 90-minutes post-primary PTCA/Stent Intervention in Acute MI

Sponsor: TherOx, Inc.

2001-Present Synergistic effects of risk factors for sudden cardiac death (SERF) study

Sponsor: Guidant

2002-Present Pain FREE Rx II Expansion Study with GEM III AT ICD

Sponsor: Medtronic

2002-Present The pacing energy margin verification via intracardiac electrogram study
Sponsor: Guidant

2002-Present Optimal atrial lead placement for AF suppression
Sponsor: St. Jude Medical

2002-Present CAPTIVE: CardioShield application protects during transluminal intervention of vein graft by reducing emboli
Sponsor: MedNova

2002-Present Identification of protein markers for sudden cardiac death in VT/VF patients (IDEA-VF)
Sponsor: Medtronic

2002-Present Addressing the value of primary angioplasty after combination therapy or eptifibatide monotherapy in acute myocardial infarction (The ADVANCE MI Study)
Sponsor: Millennium Pharmaceuticals, Inc.

2003-Present Medtronic WAVE Study: Worldwide application study of Marquis VR enhancements
Sponsor: Medtronic

2003-Present Medtronic SAVE PACe* Study: *Search AV extension for promoting atrioventricular conduction
Sponsor: Medtronic

2003-Present A phase II, double-blind, randomized, exploratory, placebo-controlled study of the efficacy, safety and tolerability of MCC-135 comparing QD vs BID doses in subjects with congestive heart failure, NYHA Class II/III
Sponsor: Takeda Pharmaceuticals North America, Inc.

Professional Organizations

American Diabetes Association

American Heart Association

American Heart Association Council on Cardiovascular Nursing

Sigma Theta Tau International, Honor Society of Nursing

Association of Clinical Research Professionals

Applied Research Ethics National Association

Certifications

Basic Cardiac Life Support.

American Heart Association

Certified Clinical Research Coordinator (CCRC)

Association of Clinical Research Professionals

Certifications (continued)

Certification No. 02-547

Certified IRB Professional (CIP)

Council for Certification of IRB Professionals

Professional License

Registered Nurse: Michigan #4704097846