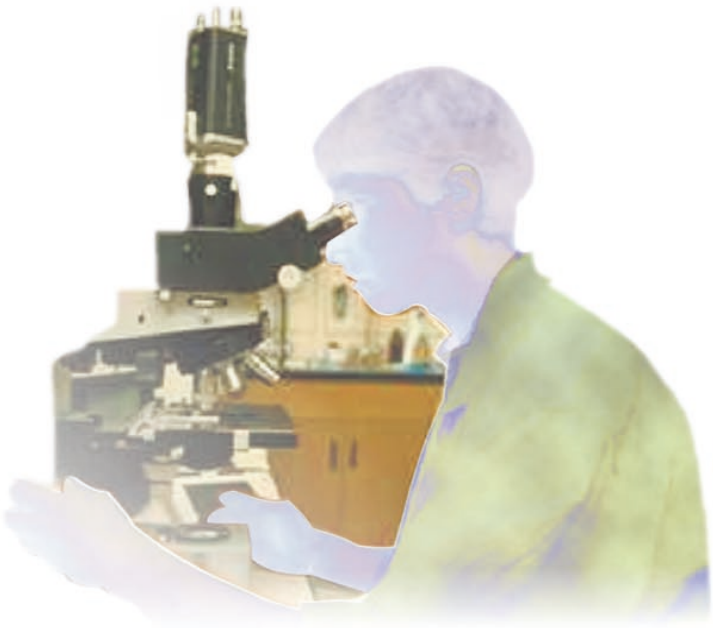
Recommendations from a Scientific Conference

Women and Renal Disease



September 14–17, 1999

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Women in Nephrology

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RECOMMENDATIONS FROM A SCIENTIFIC CONFERENCE

WOMEN AND RENAL DISEASE

September 14–17, 1999

PROGRAM CHAIRS

Christine K. Abrass, M.D.
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INTRODUCTION

More than 120,000 women in the United States have end-stage renal disease (ESRD), and many more women suffer from chronic renal insufficiency (CRI). Yet our knowledge about renal disease in women is limited. Epidemiologic data show that women are prone to develop certain renal diseases. Even in cases where disease risk is comparable between men and women, the rate of disease progression differs. Both sex- and gender-based differences in the response to pharmacologic agents and access to treatment modalities influence outcomes of renal disease in women.

To address these important differences in renal disease in women, four targeted areas were discussed.

- The first focused on the definition of sex-specific physiology, including the basic biology of estrogen and other sex steroids, their impact on immune system function, and their contribution to disease risk and progression.
- Specific effects of sex steroids on the vascular system were the second area of focus. The effects of estrogen on blood vessel development and function have important implications during glomerulogenesis, during development of the placenta, and during fetal growth. In addition, estrogen influences the development of vascular complications in women with renal failure.
- Clinical aspects of renal disease in women with CRI included discussions about diseases that do not usually progress to ESRD but do require sex-specific evaluation and treatment.
- The final section addressed the unique needs of women with renal failure, including complications and barriers to care. Targeted basic and clinical research is necessary to improve our understanding of sex-related differences in renal disease and its treatment and to improve women's health.

OVERVIEW OF RESEARCH PRIORITIES

Participants agreed on five overarching priorities throughout the conference.

Expand Research Beyond Estrogen Effects. Some information is available regarding the role of estrogen in renal disease risk and progression; yet estrogen is only one factor determining female sex. As studies define the influence of sex on renal disease, basic and clinical research should include studies of progesterone, gonadotropins and other hormones that differ between men and women.

Expand Research on Sex Steroids and the Vessel Wall. Given the profound influence of sex steroids on the vascular system, this area of research has broad clinical implications for women with renal disease. Sex steroids affect placental development and the intrauterine environment, which has recently been correlated with future risk for renal disease and hypertension. Knowledge of biology of the vasculature is essential to understanding normal renal development and the initiation of and response to glomerular disease. Finally, abnormalities in the pituitary–gonadal axis that accompany renal disease may contribute to accelerated atherosclerosis in women with renal disease. For these reasons, studies of the effects of sex steroids on the vasculature should receive special attention.

Expand Research on Pharmacokinetics, Pharmacodynamics, and Therapeutic Efficacy. Drug metabolism differs between men and women and is affected by changes in renal function. No guidelines exist for the specific adjustment of drug dosing in women with renal disease. Because of fundamental differences in the physiology and pathophysiology of hypertension and renal disease in men and women, the efficacy of standard treatment regimens must be assessed in women.

Expand Research on a Woman's Lifecycle. Studies related to women and renal disease must consider the woman's lifecycle stage. Puberty may be delayed in girls with renal disease, and women with renal disease may have amenorrhea or early menopause. Thus, chronological age is an inadequate predictor of the physiological lifecycle stage of women with renal disease. Standard criteria should be established to define the stage of the lifecycle so that data can be compared between studies, and so that treatments can be appropriately adjusted for lifecycle stage.

Expand Research on Barriers to Care. Current studies suggest that women with renal disease do not have equal access to certain treatment modalities. Thus, special attention must be paid to the care of women with renal disease. In particular, attitudinal and psychosocial barriers to care must be addressed because they influence treatment options and outcomes for women with renal disease.

AREAS OF RESEARCH NEED

Basic Biology of Sex Steroids in Renal Disease, Disease Risk, and Autoimmunity

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Observations in experimental models and humans indicate that sex influences the onset, course and rate of progression of renal disease. Male sex is a risk factor for more rapid progression in a variety of chronic nephropathies. Conversely, women have a higher incidence of autoimmune disorders associated with severe nephritis such as systemic lupus erythematosus (SLE). Our understanding of sex bias in renal disease and autoimmunity and interactions between sex hormones and the kidney is rudimentary. Fundamental research is needed to determine the precise hormonal, cellular, and molecular mechanisms for sex differences in disease initiation, severity and progression. The long-term objective is to identify and characterize mechanisms by which sex-linked factors affect normal renal homeostasis and modulate pathophysiologic processes. Characterization of these mechanisms will facilitate the development of rational, sex-specific interventions.

Specific Research Needs

Sex Steroids and the Kidney. The definition of estrogen's effect on the normal kidney should include its influence on hemodynamics, transport processes, growth and differentiation, and extracellular matrix metabolism. Differences in these responses during renal development and at different stages in the woman's lifecycle should be included. Renal estrogen receptor expression and the role of receptor modulators, both co-activators and co-repressors, must be defined. The field must also characterize the processes of transcriptional regulation and cell signaling within the kidney, as renal-specific mechanisms may exist. The examination of basic receptor biology in the kidney should not be limited to estrogen, as other sexually dimorphic hormones such as testosterone, progesterone, and prolactin may also have important effects.

Lifecycle Determinants. Investigators should define sex differences and distinctions among women with renal disease at various life stages for each area of study. Chronologic age may not reliably reflect the stage of the lifecycle for women with renal disease. Standard criteria should be established to define lifecycle stages, and studies should include staging and its impact on interpretation of data.

Sex Hormones and Immune Function. Basic research is needed to characterize the sex differences in immune responsiveness in humans. The effects of sex hormones on systemic immune function and the immune function of intrinsic renal cells need to be defined. As disease often disturbs the pituitary–gonadal axis, secondary disorders in sex biology may abrogate or compound the effects of sex steroids on immune system function. These effects, as well as the physiologic stage in a woman's lifecycle, must be considered when designing studies and interpreting data. When researchers examine gender differences in

kidney disease, they must study models of (1) autoimmunity such as SLE, Heymann nephritis and anti-glomerular basement membrane disease; (2) transplantation; and (3) acquired immunity.

Estrogen and Renal Injury. Investigators must elucidate the association of female sex and the risk of development and rate of progression of renal disease by identifying appropriate disease models that reflect human sex disparities. Using these models, the role of sex steroids (estrogen, progesterone and testosterone) in the cellular and molecular mechanisms of renal injury needs to be defined. Studies examining the effect of sex steroids on mechanisms of renal injury should include renal hemodynamics, transport processes, apoptosis, fibrosis, hypertrophy, hyperplasia, and growth factor and cytokine expression.

Pregnancy and Renal Disease. Pregnancy influences the rate of progression of certain pre-existing renal diseases. Thus, researchers must define the role of pregnancy-associated changes in sieving coefficients, lipid profiles, renal perfusion and other factors that influence the rate of progression. Conversely, certain renal diseases uniquely occur during pregnancy and influence fetal outcome and future renal function in the mother. It will be important to identify animal models to investigate the development and progression of pregnancy-induced renal disease.

Fetal Programming. Epidemiological data suggest that intrauterine development influences future risk for development of obesity, hypertension and renal insufficiency. Basic information is needed regarding the mechanisms of fetal programming of adult renal disease. It will be important to determine the role of genomic imprinting and effects of nutritional and hormonal status during pregnancy on the development of renal disease in offspring.

Transplantation. Additional basic information is needed about sex-specific immunology involved in graft rejection and survival. Sex-based differences in complications of immunosuppression and the implications of a woman's lifecycle stage on transplantation success and complications have not been defined. The potential special needs of pregnant women should also be a research priority.

Summary

Studies must characterize estrogen receptor biology in the kidney. Research should elucidate the interactions between estrogen and other hormones and their effects on the kidney in normal and pathophysiologic states. Sex stratification should be performed in experimental models and studies that include men and women. Studies should include *in vivo*, *in vitro* and human biopsy material when appropriate.

Role of Sex Steroids in Renal Disease Progression and Impact on the Vessel Wall

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The effects of sex steroids on the vessel wall play such an important role in nephrogenesis, normal renal physiology, pathophysiology, initiation and progression of renal disease, and the high mortality from cardiovascular disease in patients with ESRD that studies in this field are a priority. The limited availability of basic information about the fundamental physiology of the woman's lifecycle hampers understanding of the impact of estrogens on the vessel wall. It is essential to get fundamental data before mechanistic experiments can be well designed.

Specific Research Needs

Sex Steroids and Blood Vessels. Sex steroids play an important role in the regulation of blood vessel development. Angiogenesis is stimulated by estrogen and repressed by progesterone. Appropriately regulated angiogenesis is crucial to normal development of the renal vasculature and the glomerulus. Similar mechanisms may be important in the initiation and evolution of glomerular injury. Yet little is known about the specific effects of sex steroids on the formation and function of blood vessels in the kidney. As active angiogenesis sustains tumor growth, the role of sex steroids on blood vessels in the kidney has important implications for understanding and controlling the growth of renal tumors.

Blood Vessel Formation and Pregnancy. Sex steroids influence the development of the placenta, which influences the risk for pre-eclampsia. Little is known about the basic mechanisms leading to eclampsia and relationships to systemic abnormalities in the vessel wall and within the kidney. In addition to renal complications in women with eclampsia, placental abnormalities contribute to intrauterine growth retardation. As this is associated with future risk for renal disease and hypertension in the offspring, investigators should conduct basic studies of the impact of sex steroids on blood vessel development in the placenta.

Sex Steroids and Renal Disease Progression. The glomerulus is a specialized blood vessel unit that is physiologically and pathophysiologically influenced by insulin, insulin-like growth factor-1, angiotensin II, nitric oxide and other mediators that are modulated by sex steroids. Research is needed to define the mechanisms responsible for these effects in order to understand sex-based differences in rates of progression of renal disease.

Sex Steroids and Lipids. Lipids play an important role in the rate of progression of renal disease and in generalized vascular disease that is responsible for the high morbidity and mortality among patients with renal failure. Sex steroids modulate the synthesis, blood levels and clearance of lipids. Additional information is needed to define the role of these effects in renal disease progression. Improved understanding of these basic mechanisms is necessary for defining appropriate hormone replacement therapy for women with renal disease and estrogen deficiency.

Sex Steroids, Blood Vessels and Complications of ESRD. Basic researchers should elucidate the interrelationships of atherosclerotic cardiovascular disease and lipid/lipoprotein metabolism and renal disease in women. Studies defining the relationship of sex hormones and the impact of CRI on lipid metabolism and atherosclerotic disease will be crucial to outlining treatments. The choice of therapy and drug dose for women and men will likely differ. In women, vascular accesses for hemodialysis have a particular propensity to develop thrombi. Yet little is known about histological or other differences between men and women with access failure.

Summary

Considerable evidence shows that men and women differ in their risk for vascular disease. Yet there is inadequate understanding of the basic mechanisms responsible for this difference or the impact of these factors on the initiation and progression of renal disease. Research should focus on the role of sex steroids in blood vessel growth and atherosclerosis, and their implications for renal disease progression and the risk of complications.

Clinical Research Needs for Women With Chronic Renal Insufficiency

Bonita Falkner, M.D.
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In the field of nephrology there are many areas in which women have medical and psychosocial needs that differ from men. Early in the course of CRI, women develop abnormalities of the pituitary–gonadal axis that influence fertility and sexual function. In turn, abnormalities in sex steroid metabolism may contribute to the progression of renal disease and the development of other complications such as vascular and bone disease. Considerable work is needed to elucidate the manifestations of this relationship and to develop clinical interventions to preserve renal function. Moreover, women have a greater propensity to develop bladder dysfunction, interstitial cystitis, analgesic nephropathy and urinary tract infections, which make these important areas for clinical research.

Specific Research Needs

Drug Therapy. There are substantial gaps in research examining drug therapies in women with renal disease over the lifecycle. Research is needed on drug pharmacokinetics and pharmacodynamics related to the level of renal function, the stage of the menstrual cycle, exogenous hormone use, pregnancy, and body composition and size. Investigators must also better define drug safety during pregnancy. Further research must be conducted on the cytotoxicity of drugs in women with renal disease to determine the effects on fertility, teratogenesis, and perinatal development and outcome. A better understanding of gender issues regarding body image and communication may improve acceptance of treatment.

Biological and Psychosocial Consequences of CRI. Little is known about sex differences in systemic or extra-renal organ function in people with CRI. Research must define hypogonadism in women with CRI and examine sex differences in gonadal function,

including sexual function. The full range of benefits of hormone replacement therapy (HRT) and its influence on blood pressure and progression of renal disease is unknown. More information is needed to describe sex differences in the incidence and development of sleep apnea and cardiovascular disease (particularly hypertension) in people with renal disease.

Psychosocial issues must be considered in women with CRI. Women with CRI need special counseling about family planning, pregnancy and long-term outcomes in their children. Women with CRI also may need special counseling about body image, eating disorders, sexual function and libido.

Bladder Dysfunction. Nephropathy affects bladder function. More research is needed on the unique issues relevant to women and bladder dysfunction. Researchers must determine the factors that lead to incontinence; the role of pregnancy and delivery in the etiology of incontinence; and the roles of estrogen, exercise, and diet in bladder dysfunction in women. A better understanding of mechanisms underlying the development of urinary tract infection, new diagnostic tools and innovative preventive and treatment strategies are needed.

Diabetic Nephropathy. Research is needed on sex differences involved in the pathogenesis of diabetes and diabetic nephropathy. The possibility that target blood pressure levels should be lower in women with diabetic nephropathy requires investigation. Our understanding of whether the mechanisms and determinants of progression of diabetic nephropathy in men and women are different is rudimentary. To improve the outcome of diabetic nephropathy, the role of sex steroids in progression and the role of insulin resistance in disease pathogenesis in women need to be defined.

Analgesic and Lead Nephropathy. Underlying mechanisms and the treatment of specific nephropathies in women must be better understood. Research is needed on the role of gender as a risk factor for analgesic abuse. The role of sex steroids in the pathogenesis and progression of analgesic and lead nephropathy need to be studied.

Preventing Progression of CRI. The reasons for disparities in renal disease progression rates between men and women are unknown. Specific effects of estrogen or testosterone (or interrelationships between the sex hormones) on the determinants of proteinuria or renal cell responses to injury may explain sex differences in progression rate in patients with CRI. Alternatively, differences in treatment or responses to treatment may contribute to this difference. Research is needed to examine the effect of angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, spironolactone and calcium channel blockers on the progression of renal disease in women. Investigators should also identify effective markers that predict progression of renal disease in women.

Obesity, nutrition, and eating disorders might influence the progression of renal disease. The effects of body mass index and/or adipose mass, appetite suppressants, and weight loss–gain cycles on the progression of chronic renal failure are unknown. The relationship of birth weight and obesity on the development of renal disease should be examined. Finally, researchers should define psychosocial issues that influence adherence to dietary recommendations.

Bone and Cardiovascular Disease. Prevention of bone and cardiovascular disease are important issues for women with CRI. Although some data are available in women with ESRD, it is likely that these complications of renal failure begin much earlier in the course of the disease. Early detection of bone disease requires good markers and a better understanding of risk factors. More research is needed on treatment strategies for bone disease in women with CRI. Screening for cardiovascular disease in women with renal disease must be improved. Research to prevent the development of cardiovascular disease should focus on metabolic determinants of disorders of plasma homocysteine and lipids; the effects of diet, nutrition and drugs on homocysteine and lipid levels; and the change in incidence of cardiovascular disease associated with interventions.

Primary Care. Attention should be directed at health promotion and disease prevention in women in high-risk populations, including substance abusers, those who have experienced domestic abuse and depression, and those who are caring for others.

Summary

Women experience a variety of special forms of renal disease, which require research in order to improve their health. Each disease must be considered in the context of a woman's physiologic stage in life, as each stage may differentially impact the progression of renal disease. Furthermore, women metabolize and clear drugs differently from men, and therapeutic responses may differ also. For these reasons, research must specifically address the pharmacokinetics, pharmacodynamics, and therapeutic responses in women with renal disease.

Epidemiology, Management, and Complications of End-Stage Renal Disease in Women

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Women with ESRD are at increased risk for developing cardiovascular disease, bone disease, and cognitive dysfunction compared to the general population. Gender differences exist among dialysis patients with regard to modality choice, vascular access procedures and outcomes, and access to transplantation. Reasons for these disparities are not understood and interventions that may eliminate them have not been defined. The etiology of disparities is likely multifactorial, and may include hypogonadism, other biochemical factors, socioeconomic status and culture.

Specific Research Needs

Management of ESRD. Little is known about the management of ESRD in women. Current data suggest women treated with peritoneal dialysis are at higher risk of infectious and non-cardiac death compared to men. The causes underlying these differences should be investigated. Vascular access survival is lower among women than men. Although long-term outcomes for autogenous fistulas are superior to those for synthetic grafts, women are

more likely than men to have grafts. The smaller caliber of women's veins, delayed referral to the nephrologist and vascular surgeon, and physician choice may play a role in graft placement. The reasons for this and the secondary impact on long-term outcomes are not known.

Transplantation. Women are more likely to donate kidneys compared to men but are less likely to undergo renal transplantation. Women may donate organs more frequently than men because of family structure and dynamics, economic factors, or socialization differences. Gender disparities in transplantation could be the result of physical and social barriers for women, such as lower socioeconomic status, physician bias, patient preference, social biases, and medical factors such as higher comorbidity or anti-lymphocyte antibodies. Researchers should examine the special medical problems in women, including graft outcomes, optimal immunosuppression, complications of immunosuppressive therapy, disease recurrence, and the impact of transplantation on fertility, pregnancy outcomes, and teratogenesis.

Primary Care. There are no guidelines for the proper timing of routine screenings such as mammograms and PAP smears for women with renal disease. It is essential for researchers to determine if routine screening for breast, cervical and colon cancer are cost-effective and life saving in this population of patients.

Sexual Function. Women with ESRD have abnormal menstrual cycles and fertility, including dysfunction of prolactin, estrogen, FSH and LH. The cause(s) are unknown. Research should focus on the impact of hormone abnormalities on the menstrual cycle and fertility. In addition, research should determine if a higher dialysis dose, mode of dialysis delivery, or erythropoietin use and hematocrit level would improve menstrual irregularities and fertility. It is also not known if menstrual abnormalities and infertility result from abnormalities in hormones of the hypothalamic-pituitary-adrenal axis or have another cause. Studies are needed to determine if outcomes among women with amenorrhea differ from those in menopause. More research is needed to determine the contribution of psychosocial factors and cultural differences to menstrual abnormalities and in fertility.

Hormone Replacement Therapy. Women with ESRD experience premature menopause. However, little is known about the benefits and risks of HRT among women with ESRD. Although the pharmacokinetics of estrogen and progesterone have not been well studied in women with ESRD, data suggest that estrogen doses need to be reduced. Investigations of women with ESRD should determine if HRT improves quality of life and modulates the incidence and progression of cardiovascular disease. Other areas of potential interest include the effects of HRT on lipid metabolism, vascular reactivity, incidence of central obesity, dementia, and overall survival. HRT in women with ESRD might also decrease the incidence or severity of bone diseases such as osteoporosis and renal osteodystrophy and reduce the risk of hip and vertebral fracture. Because HRT might also increase the risk of vascular access thrombosis, pulmonary embolus and deep vein thrombosis, investigators should determine how to monitor women treated with HRT.

Incidence, Outcomes, and Barriers to Care. More information about the incidence of ESRD in women compared with men is needed. Researchers should determine whether observed gender differences are due to biologic factors, selection bias or patient preferences.

The characteristics of women with ESRD must be described. In addition, differences in outcomes of women with ESRD compared to men should be identified and the causes determined. Specifically, investigators should describe the impact of differences in physiologic mediators, hospitalization rates, and socioeconomic status between men and women on outcomes related to treatment.

Summary

Women with ESRD lose the protective effect from cardiovascular disease that most women enjoy compared to men. Sex steroid disorders in renal failure may be only partially responsible for the increased risk for cardiovascular complications. Research should address the clinical and therapeutic aspects of ESRD complications in women. Access to care and choice of treatment modalities differ between men and women. Differences need to be defined and interventions need to be developed to improve the care of women with renal failure.

CONCLUSION

This report outlines research that will improve our understanding of the pathogenesis and complications of renal disease in women. Our goal is to improve treatments and outcomes for women with renal disease. Both basic and clinical studies must consider (1) expansion of research beyond estrogen effects; (2) sex steroids and the vessel wall; (3) pharmacokinetics, pharmacodynamics, and therapeutic efficacy; (4) the importance of a woman's lifecycle; and (5) barriers to care.

Basic Research Tools Needed. Research on renal disease in women is critical, but the field faces many barriers. Research is hindered by the expense of performing studies on both males and females. New animal models that reflect the sexual dimorphisms exhibited by humans need to be developed and characterized. Spontaneous and induced animal models of renal disease, including animals with genetic variability in estrogen and progesterone responses, will be necessary to differentiate the effect of variables associated with sex. Improved approaches using cultured cells of defined male or female origin, especially cultured human kidney cells, and transfected cells should advance research on renal disease in women. Also, investigators need to develop methods to correlate *in vitro* and *in vivo* observations.

Clinical Research Tools Needed. Clinical researchers require access to large databases to advance our understanding of sex- and gender-related differences in renal disease. Sex-specific data on drug pharmacokinetics and drug interactions are needed. Improved markers of gonadal function in women with renal disease will allow researchers to establish the relationship between gonadal function, progression of renal disease and complications of renal failure. Methods to determine fertility are needed. Clinical research studies require reliable definitions of renal function relative to sex and body size and reliable definitions of blood pressure level versus risk for women across lifecycles. Standardized approaches to using HRT and selective estrogen-receptor modulators may enhance our ability to generalize results from clinical studies in women without renal disease. A central database for patients with CRI, tools to detect early bone disease, and gender-specific screening tools for lead and analgesic nephropathy are desirable.

Finally, training new basic science and clinical investigators will be fundamental to increasing the knowledge base and improving the care and quality of life of women with renal disease.

PLANNING COMMITTEE

WOMEN AND RENAL DISEASE

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The Impact of Pregnancy on Progression of Renal Disease* and Chair, *The Role of Sex in Progression of Kidney Disease

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The Role of Gender in Incidence, Treatment, and Outcomes of ESRD

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The Eve Within Each of Us: Mitochondrial DNA

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Interactions Between the Hypothalamic-Pituitary-Adrenal Axis and the Female Reproductive System in Women With Renal Disease: Clinical Implications

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Survival in Female and Male Dialysis Patients

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Special Problems in the Management of Hypertension in Women," **Chair,** ***Epidemiology of Renal Disease in Women*** **and Cochair,** ***"Clinical Research Needs for Women with Renal Disease (Other than ESRD)***

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September 14–17, 1999

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Administrative Document

April 2001

National Institute of
Diabetes & Digestive &
Kidney Diseases