OBJECTIVES of PRESENTATION: To introduce and explore ethical problems faced by Nephrology Fellows providing hemodialysis to chronically uremic patients:

1. Recognize complex stresses evoked by the decision to proffer maintenance hemodialysis to often frail and/or old patients with substantive comorbidities.

2. Appreciate the concept of futility and need for support for a uremic patient opting for death rather than further uremia therapy as the “best choice” in coping with renal failure.
The International Society of Nephrology, in 1960, at its Lake Geneva organizational meeting on “Life Prolongation by Dialysis in Renal Failure Requires an Ethical Basis for its Use”, convened 20 clinicians and scientists who presented papers on renal tubular micropuncture, urine acidification, natriuretic factors, the mesangial cell discovered with the electron microscope, an inventory of glomerular lesions, Balkan nephritis, and initial outcome reports of chronic dialysis and kidney transplantation to establish a new specialty called Nephrology. None of the presentations in any aspect of the program mentioned recognition of possible ethical stress induced in the medical staff treating kidney failure patients.

By 1967, it was evident to the newly established American Society of Nephrology that that a growing population of uremic patients wanted personal dialysis treatment to extend life after failure of their own “vital organ”. Remarkably, in retrospect, Willem J. Kolff who though under the German occupation of Holland, invented and applied the first practical artificial kidney in 1943, for a regimen termed hemodialysis was viewed as applicable for temporary, reversible acute kidney failure and not a means of extending life based on dialysis as a chronic therapy1.

**Life Extension by Hemodialysis Forces Rationing and Ethical Challenge**

Belding H. Scribner’s 1960 report that convincingly documented the reality that irreversible renal failure, a prevalent cause of death, had become treatable2 for which “proper” medical practice included hemodialysis. Life magazine3 and national news sources enthusiastically reported the success of “chronic hemodialysis.” Lacking equipment, trained staff, and any funding, the renal community was suddenly confronted by a population seeking treatment for family members in the throes of uremia. A year of twice-weekly maintenance hemodialysis, as originally designed by Scribner’s Seattle team, required more than $10,000 not including doctors’ fees (more than $280,000 for thrice weekly dialyses in 2016 dollars). Obviously, demand dwarfed capacity of Scribner’s pioneer small hospital acute dialysis unit.

Forced, by inadequate resources to turn away a growing number of patients both young and old, the Seattle team established an anonymous panel of
volunteer community members acting as a “Who Shall Live Committee.” Struggling with the enervating chore of screening applicants to select those most “deserving” of life sustaining treatment, the Committee set criteria including a restricted age range of 18 to 45 years. The world of uremia therapy shook when a 16-year old high school student whose renal failure was caused by lupus nephritis rejected her exclusion (meaning at that time, certain death), a small and portable dialysis system termed the minimonster, was designed by Dr. Albert “Les” Babb, the Seattle team’s chief engineer within 4 months, permitting the first “home hemodialysis” in July, 1964. Babb’s accomplishment was listed as one of the "Ten Wonders of Biomedical Engineering" by the Biomedical Engineering Society in 1990. Dr. Babb subsequently was elected to the National Academy of Engineering, the National Academy of Sciences' and the Institute of Medicine. Thus, a decision in medical ethics became a defining moment in Nephrology.

Questions generated by the need for fair allotment of insufficient lifesaving resources forced nephrologists, hospital administrators, academic deans, and legislators to deal with a new kind of triage. Coping with dialysis rationing (as well as other high cost regimens such as bone marrow replacement) ultimately sparked a change in thinking about accessibility of health care in the United States thus demarking the beginning of modern bioethics. As aptly stated by Alber Jonsen, professor of biomedical history and ethics at the University of Washington. it was the “Dialysis Committee” that forced open a new era for the ethics of medicine, as the health care profession faced "an issue that the traditional ethics of medicine had not previously faced and for which it had no ready response."

In a remarkable live performance of hemodialysis using an actual in vivo demonstration before the House of Representatives Ways and Means Committee, dialysis treatment for renal failure became a national legislative priority. To its great credit, the United States Congress, in 1972, amended the Social Security Act disability requirement to permit reimbursement for long-term dialysis. A further amendment in 1978 and related state legislation increased Medicare deductibles as well as co-payments to allow for home hemodialysis supplies. By these actions, the United States affirmed the principle that health care services should not be an exclusive right of the rich and privileged, of the
white-collar worker, the breadwinner, or any other selected "profile\textsuperscript{11}." Reflecting on the national impact of his introduction of dialysis, Scribner remarked that: "When the U.S. Congress enacted legislation in 1972 which made all patients with end-stage kidney disease eligible for Medicare, they set a precedent that led to Medicare’s extending funding of many of the very expensive technology-based treatments such as coronary bypass open heart surgery, and bone marrow transplantation." The ethical basis for universal dialysis in kidney failure became the foundation for “fair” organ allocation in kidney transplantation\textsuperscript{12} and other forms of modern high technology medicine. In 2016, however, neither dialysis therapy nor kidney transplantation has become generally available for the majority of patients noted in most countries to have life threatening kidney failure.

**Ethical Stresses when Deciding Whether to dialyze uremic patients in 2016**

Listed in Table 1, are generally expressed Ethical Concerns in coping with the major question of whether to initiate maintenance hemodialysis in “very old” (>75 years) geriatric patients with uremia. This issue was well explored by the Renal Physicians Association in their Clinical Practice Guideline, Second Edition, “Shared Decision-Making in the Appropriate Initiation and Withdrawal from Dialysis” published in 2010\textsuperscript{13}.

A vexing recurrent problem in provision of uremia therapy is the extent of obligation to continue dialysis care to a nonadherent, hostile, and even combative patient who may be senile\textsuperscript{14}. A landmark Civil Action No. 086-079 (B) in Jackson, Mississippi United States District Court on December 21, 1987, ruled that Dr. John Bower, Director of Nephrology at the University Medical Center, must continue dialysis of Michael Brown who had a ten year record of misconduct and staff abuse. Brown overtly injected narcotic drugs, missed dialysis treatments, and proffered verbal abuse to Dialysis Unit staff. Brown died in a motor vehicle accident after a police chase at 100 miles per hour and the enormous stress to Bower and his staff is told in Bower’s “Rest of the Story\textsuperscript{15}” recounting of a senior nephrologist’s unsuccessful dealing with a Court unable to help a renal program’s plea for relief from a vindictive and hurtful patient.

No clear evidence notes geriatric ESRD patients to be more nonadherent to their regimen than are younger adults. While the opposite may be true, no
report lists rates of nonadherence by age. Very old (75+) ESRD patients do extend life by dialysis and as a group, effect better psychosocial adjustment to dialysis than do younger patients, despite limitations in physical functioning due to arthritis and peripheral motor neuropathy\textsuperscript{16}. Current increasing emphasis on ethical questions generated by geriatric patients with kidney disease is the consequence of two realities: 1. While there were 33 million Americans aged 65 years or older in 2003, by the year 2030 this number is predicted to increase to 70 million\textsuperscript{17}. 2. More than 1 million Americans over the age of 65 years currently have advanced kidney disease and provision for their expensive care is still incomplete and without an overall plan. Elderly patients often suffer extrarenal comorbidity forcing the question of whether or not to commence costly regimens such as maintenance dialysis\textsuperscript{18}.

**Medical Ethics in Research: The Belmont Report**

Frequent criticism of the gradual inclusion of geriatric and patients severely ill with extrarenal disorders that serves as a resource to define the “boundary” between the practice of medicine and the conduct of research involving human subjects is The Belmont Report (1979)\textsuperscript{19,20} that established:

1. Boundaries between practice & research
2. Basic ethical principles
   a. Respect for persons
   b. Beneficence
   c. Justice
3. Applications
   a. Informed Consent
   b. Assessment of Risk and Benefits
   c. Selection of Subjects

Factors purportedly associated with poor adherence by geriatric ESRD patients include: confusing “too” frequent drug dosing, inadequate patient's perception of treatment benefits, poor patient-physician communication, lack of motivation, poor socioeconomic background, and lack of family and social support\textsuperscript{21}. Strategies advocated to improve regimen compliance lack scientific validation in dialysis and transplant patients include simplifying the treatment regimen, establishing a partnership with the patient, and increasing awareness through education and feedback.
Recurrent Ethical Issues in Providing Uremia Therapy to Geriatric Patients

Listed in Table 1 are recurrent ethical issues arising in the daily practice of proffering care for geriatric uremic patients. These issues have been the subject of protracted discourse explored in depth in a Case Manual\textsuperscript{22}, which also considered the marketing of live donor kidneys, will be explored in depth as illustrative examples of the complexity of conjoined legal-ethical stresses to demonstrate the extent of controversy and the absence of a single truth. Some of the unanswered stressful questions that are faced daily by Renal Fellows include:

1. Who determines the application of a life sustaining therapy (patient, family, physician)?
2. Does a patient have the \textit{right} to refuse a life sustaining therapy?
3. Can a family override a patient’s wish regarding life sustaining therapy?
4. When family conflict is brought to a hospital administrator’s attention, does the resolution shift from patient and physician to the administrator?

Generalization about refusal of long-term dialysis therapy for ESRD is limited by differences in cultural attitudes. In Japan, for instance, “Refusal of dialysis is not uncommon in elderly patients with chronic renal failure\textsuperscript{23}.” ESRD treatment rates that are half that of the US in Europe, the United Kingdom, and Canada most probably result from medical and ethical standards pertaining to futility and life extension that sharply diverge from those obtaining in the US. Discussions with nephrology trainees permitted formulation of a list of key issues that were generated by study of this case including:

5. Who determines the application of a life sustaining therapy (patient, family, physician)?
6. Does a patient have the \textit{right} to refuse a life sustaining therapy?
7. Can a family override a patient’s wish regarding life sustaining therapy?
8. When family conflict is brought to a hospital administrator’s attention, does the resolution shift from patient and physician to the administrator?

**Legal Analysis**

Based on consultation with medically oriented attorneys, and review of the concept of “Advanced Directives,” it is reasonable to assert that a competent patient’s decision to discontinue lifesaving medical treatment (including dialysis) be honored, despite objections from a responsible relative.

Assuming the patient was competent when deciding to discontinue dialysis treatments, a hospital director risks liability by ordering continuation of dialysis. In a case that reached the U.S. Supreme Court, a competent, non-terminally ill person was found under the Due Process Clause of the 14th Amendment to have the right to refuse unwanted medical treatment – even if death will result. Justice O’Connor wrote that there is a protected liberty interest in refusing unwanted medical treatment, including artificially delivered food and water. A federal appeals stated that “a liberty interest in refusing medical treatment extends to all types of medical treatment, from dialysis or artificial respiration to the provision of food and water by tube or other artificial means.” Subsequently, supreme courts in several states concluded that their state constitutional right of privacy encompasses the right to refuse life-saving medical treatment.

Other states have statutes providing that physicians need not accede to a patient’s request to withdraw or withhold treatment if it would be against their beliefs to do so, but must try to or successfully transfer the patient to another health care provider willing to comply with the request. Whether a competent patient’s decision to discontinue dialysis treatments must be honored was addressed by a New York State Court decision that a dialysis patient who
verbally and in a signed statement wished to discontinue dialysis treatments had made an informed, rational, knowing decision to forego the treatments. After the patient lapsed into uremic coma the court denied the hospital's petition to continue dialysis treatments.

Juggling and balancing State and individual interests in a dialysis context, Iowa determined that the State’s interest in preserving life corresponds directly to the degree to which the patient’s quality of life has diminished due to physical deterioration. Noting that continued dialysis would permit the patient to have “an otherwise normal and healthy life for perhaps twenty years,” the court concluded that the State’s interest in preserving life “weighs heavily in the balance.” Because the patient had minor children, the court found that the State’s interest in protecting innocent third parties from the impact of the patient’s death was invoked outweighing the patient’s interest in discontinuing dialysis treatments.

Determining whether a patient is competent can be a difficult. Patients who are senile, unconscious, traumatized, disoriented, excessively emotional, or minors may all be held incompetent. The general test for competency is the factual question of whether, "at the time and under the circumstances when his consent is required, [the patient has] the mental ability to make a rational, deliberate decision regarding the proposed treatment." Should a hospital director have uncertainty about a patient’s competence, he must protect the hospital and himself legally by continuing dialysis treatments until a court can address the issue. Incompetent patients retain their right to make decisions about their care, but that right generally must be exercised on their behalf by their surrogate, usually a member of the patient’s family.

Ethical Analysis:
The hospital director has an ethical obligation to honor the patient’s decision to stop dialysis treatments and thereby end her life. However, he also has an ethical obligation to make sure that discontinuation is the patient’s own, sincere, fully informed, conclusive decision, and that the son fully understands that decision.

Patients with decisional capacity have the moral right to either consent to, or to refuse, any treatment intervention offered to them, even if as a consequence of such refusal their death may result. Such decision making empowerment is based on the philosophic principle of autonomy, and the legal principle of individual self-determination. What is critical in this case is the recognition that despite her increasingly debilitated condition, the patient continues to possess decision making capacity to exercise such right of refusal, and her decision to discontinue treatment appears to be a well considered, authentic reflection of her wishes. Since the patient still has decisional capacity, the son has neither the legal authority to insist on treatment continuance nor any standing on which to sue the hospital and attending physician. Dialysis should be discontinued in accord with the choice of this capable patient.

When celebrities opt not to agree to dialysis, headlines usually follow as was true for James A. Michener, the universally celebrated Pulitzer Prize winning author, who at the age of 90 stopped hemodialysis treatments in Austin, Texas\textsuperscript{28}. Similarly, Australia’s richest man, billionaire media “mogul” Kerry Packer, at age 68, decided not to extend his life by dialysis after a failed kidney transplant\textsuperscript{29}. Packer’s cardiologist, said that Packer knew “knew he was on borrowed time. He could have opted for more dialysis, but he chose to go quickly and with dignity.” By contrast, death in renal failure untreated by dialysis or a kidney transplant is the typical ESRD outcome for geriatric patients.
older than 65 outside of the US. Yet, substantive life prolongation in ESRD patients of advanced age is attainable with transplant recipients evincing best outcome. Of the USRDS cohort of incident ESRD patients from 1994 to 2000, aged 75 or older, one year survival on dialysis was 62.6% compared with 81.7% after a deceased donor transplant. After five years, 40.3% of deceased donor kidney grafts and 12.4% on dialysis were alive connoting the substantive advantage of selecting the transplant option for uremia therapy. For the subset aged 70 to 70 years when given a deceased donor kidney, 34% were alive with a function kidney graft ten years later.

Nevertheless, bias against providing uremia therapy for the aged persists in Nephrology practice in the US. Illustrating this assertion, for ESRD patients age 80 or older, as reported by the USRDS, although survival permitted by a deceased donor allograft is astoundingly good, of 71,000 incident patients of age 80+ between 1994 and 2000, only 66 (1 in a 1,000) were waitlisted for a kidney transplant\textsuperscript{30}. Overcoming negativism toward the elderly ESRD patient’s prospects whether treated by dialysis or a transplant is a challenge especially in developing nations with limited budgets for healthcare. There are no simple answers to devising a fair method of treatment allocation when the reality is that resources are insufficient to treat all who might benefit.
Table 1
Ethical Stresses in Nephrology

Patient selection for/exclusion from long-term renal replacement therapy
a. How old is too old for renal replacement therapy?
b. Should young people be selected before old people for kidney therapy?
c. Should “important” people (Politicians [President], Clergy [Pope], Affluent [Billionaire contributor to hospital]) be placed ahead of ordinary people in allotting renal replacement therapy?
d. Are multiple deceased organ transplants ethical while a wait list exists?30

e. Must non-citizens be treated when therapy is scarce or expensive?
f. Are women to be assigned treatment on an equal basis as are men?
g. Is it reasonable to take race and religion into account when determining who shall be treated?
h. Is HIV infection a reasonable exclusion criterion?
i. Does absent insurance coverage and being poor mean denial of therapy?
j. Should prisoners be excluded from renal replacement therapy?

Who decides not to start life sustaining dialysis in ESRD?

a. Patient
b. Family
c. Futility
d. Financial

How should the medical staff cope with patient noncompliance31, hostility, or criminality?

a. Withdraw renal replacement therapy with death an obvious consequence
b. Consultation (psychiatry, social service, administration family, clergy, friends)
c. Role of Ethics Committee

Is it OK to instill comodification (buying and selling) of kidney transplants32?

a. Payment to deceased donor families
b. Concealed payment to donor
c. Open marketing of kidneys legally
d. Open marketing of kidneys concealed
### TABLE 2

**Everyday Examples of Individual Jurisdiction and Authority Over One’s Body**

1. **Consenting for federal (National Institutes of Health) studies that impart personal risk:**
   - a. biopsies of liver, kidney, muscle
   - b. invasive procedures, bronchoscopy, cystoscopy
   - c. participation in new drug trials

2. **Engaging in behavior risking serious injury:**
   - a. working on oil rigs
   - b. sky diving
   - c. bungi jumping
   - d. mountain climbing
   - e. swimming with sharks
   - f. Pamplona “Running of the Bulls”
   - g. professional boxing and football
   - h. ingesting high calorie diet when obese
   - i. cigarette smoking
   - j. motorcycle riding without a helmet

3. **Renting or selling body parts:**
   - a. selling semen and ova
   - b. surrogate uterus rental
   - c. whole body rental (prostitution)

4. **Enrolling in voluntary military service**

5. **Donating organs and portions of organs (pancreas, liver, lung) to relatives**

6. **Donating organs and portions of organs (pancreas, liver, lung) to friends**
References

Friedman: ETHICAL DILEMMAS IN GERIATRIC UREMIA THERAPY


27. Polk County Sheriff v. Iowa Dist. Court, 1999 Iowa Supp. LEXIS 105, *12 (Supreme Court of Iowa, April 28, 1999).


