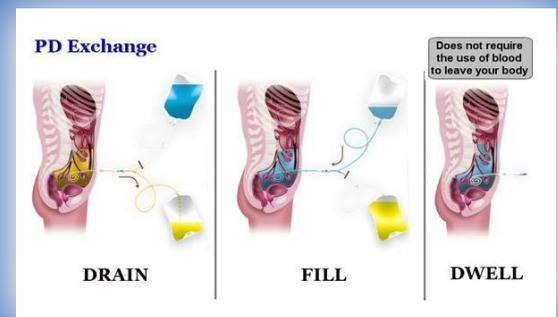


I was asked to help a company develop the launch plan for a significant peritoneal dialysis therapeutic advancement. The company had spent years and millions of research dollars to deliver protein to malnourished peritoneal dialysis patients. I identified three keys for a successful launch: 1) generate awareness of the underlying therapeutic challenge; 2) identify patient candidates for the new therapy; and 3) build belief in our therapeutic approach.

## The Need for Therapy Enhancements

Peritoneal dialysis treats patients who have lost their kidney function. The company's product, a sterile solution called dialysate, was infused through a catheter into a patient's abdomen. Through diffusion across the lining of the abdominal cavity (the peritoneum), the same constituents present in urine pass from the bloodstream into the abdomen filled with dialysate. After a fixed time period (the dwell time), this solution full of toxins is drained out and a new bag of dialysate is reinfused into the body for another dwell period.

Research indicated that most peritoneal dialysis patients suffered from protein malnutrition, attributable to several factors: a) many patients were prescribed a low protein diet in order to manage their toxin blood levels because the more protein consumed the higher levels of toxins generated, b) during dialysis, patients absorbed high quantities of glucose from the dialysate, resulting in reduced appetite, c) many dialysis patients could not afford protein from high quality sources.



## Generating Awareness

I quickly discovered that despite the existence of numerous research papers, nephrologists, the key prescribers, were quite unaware that a large percentage of their dialysis patients were protein-malnourished. Nor were they aware that protein malnutrition was highly correlated with poor treatment outcomes.

To address these knowledge gaps, I combined the best peer-reviewed articles on these topics into an educational brochure. This collateral contained summaries and article quotes, pulled directly from the papers. Since we provided the full reprints without company "editorializing," physicians treated the brochure as they would any clinical research paper. This information was distributed to the clinical community 12 months prior to launch, with the expectation that by the time our product arrived, nephrologists would already understand that many of their patients suffered from protein malnutrition and this affected their patients' outcomes.

### The Importance of Protein Nutrition in Sustaining Peritoneal Dialysis and Hemodialysis Patient Health

With Research by  
Edmond G. Levine, MD  
National Medical Care - Walling, Massachusetts  
P. MacKinnon, MD  
The Friedrichs Institute - Frederick, Denmark  
Reendan P. Techan, MD  
The Institute Hospital - Philadelphia, Pennsylvania  
Gerald A. Young, PhD  
The General Infirmary at Leeds - Leeds, England

And Clinical Commentary by  
Lee W. Henderson, MD, FACP  
Bayer Healthcare Corporation - Deerfield, Illinois

**Clinical Impact for Peritoneal Dialysis Patients**  
"Serum albumin is a powerful predictor of death (of patients) on CAPD."  
*Teaban*

Serum Albumin Level	Relative Risk of Death
< 3.5 g/dL	13%
> 3.5 g/dL	25%

Relative risk of death increases as the serum albumin of the peritoneal dialysis patient falls. The relative risk for a patient with a level below 3.5 g/dL is 5.5 times that of a patient with a serum albumin > 3.5 g/dL. Death occurred in 5 of 49 patients with serum albumin levels greater than 3.5 g/dL, and in 11 patients with levels below 3.5 g/dL.  
*Teaban, unpublished data, April, 1991*

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**Nutritional Status of Peritoneal Dialysis Patients**  
"Eighteen patients (8%) were severely malnourished, 73 (32.6%) were mildly malnourished, and 133 (59.4%) did not show evidence for malnutrition."  
*Young*

Degree of Malnutrition	Percentage of Patients
Severely Malnourished	8%
Mildly Malnourished	32.6%
No Evidence for Malnutrition	59.4%

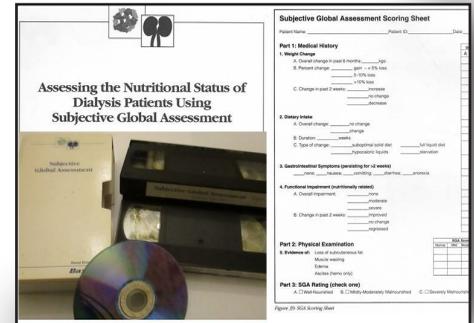
Over 40% of peritoneal dialysis patients are malnourished. Variation among centers is widespread. In one center the degree of malnutrition was 20% while the highest degree of malnutrition was 76%.  
*Young, 1991*

## Identifying Patient Candidates

We knew that creating awareness would not be enough to stimulate demand. Since the product would carry a premium price, our customers could not afford to place all of their patients on the company's protein dialysate. Therefore, helping the nephrologist correctly identify at-risk patients was critical. Unfortunately, the commonly used nutrition assessment approaches, like patient weight and serum albumen did not identify patients who would benefit from the company's new product.

Fortunately, a Toronto physician had developed a nutritional assessment technique, Subjective Global Assessment (SGA), which had been validated on dialysis patients. This technique was simple to perform, easily fit into staff workflow and required no capital outlay. However, the only description of the technique existed in a journal article; it was very difficult to understand the technique from the article.

I received permission from the SGA author to develop an SGA procedure video that would teach the technique step-by-step to clinicians so they could identify the protein- malnourished. I also designed an instruction manual to support the video and a score sheet that documented the patient's nutritional status for their chart. These materials were completed 3 months prior to launch so that the community had time to develop proficiency on the procedure.



## Building Belief

The last important step was building belief in our therapeutic approach. To address this, I organized a Physician Advisory Panel, comprised of dialysis and nutrition experts. During the panel meetings these experts reviewed such topics as: protein metabolism during renal failure and dialysis, biochemical role of amino acids, nutritional status of peritoneal dialysis patients, impact of nutrition on dialysis patient outcome, previous clinical studies with protein dialysate, and complications associated with protein dialysate. Our as-yet-unpublished clinical results were critically reviewed by the panel. The consensus development meetings generated a monograph which presented a holistic review advocating the diagnosis of protein malnutrition and treatment using the company's new dialysate, backed by scientific evidence and clinical results. This was completed in time for the product launch.

## The Results

All of these activities served to prepare the market and the company successfully launched the product globally. The product is still generating significant revenue 10 years later.

Foresight works with companies that are faced with marketing challenges like this company. We apply the clarifying lenses that help companies deliver improved marketing performance in such areas as: formulating advisory panels; designing positioning, messaging and branding; preparing product launches; integrating customer needs into product design; investigating customer needs and competitor tactics; developing digital and non-digital marketing campaigns; and creating compelling sales collateral.

