



EXPLANATION OF THE HEALTH PROFILE

Ideal Protein's HEALTH PROFILE is clinical tool designed to assist the weight-loss coach in ensuring the client has a successful and enjoyable experience throughout the Ideal Protein Program. The following is an explanation as to why we ask certain questions and how to implement the information with respect to the dieter's individual program. It is essential that the dieter has sufficient time to thoroughly complete the form and it may be prudent to have he or she take it home to complete (you may chose to email the form to them) prior to their initial consultation (they may have to look at the prescription vials to accurately record any medications they might be taking for example). The "coach" should review the document, highlighting any areas where special considerations may be necessary. Remember, thoroughness on the client's part as well as the clinician's will result in a highly successful program.

CONTRA-INDICATIONS:

TYPE I DIABETES:

Dieters with a diagnosis of Type I diabetes mellitus may ***never*** be placed on the regular Ideal Protein Diet. This is due to the risk of the potentially fatal condition of ***keto-acidosis***. These individuals may however participate in the ***Alternative Diet*** and will experience about the same rate of weight loss. Their insulin requirements will generally decrease (good thing) and proper blood sugar monitoring should be observed. Many patients who have been diagnosed with Type I diabetes later in life may actually still be capable of producing insulin. As their insulin requirements decrease, it may be prudent for the physician to order a ***C-peptide level***. A positive result shows the pancreas is still able to produce insulin and a long-term goal of discontinuing insulin therapy may be contemplated.

SEVERE LIVER AND/OR KIDNEY DISEASE

Both of these organs are extensively involved in the metabolic processes of lipolysis and the oxidation of fatty acids, gluconeogenesis, and acid / base balancing. Either diet (regular or alternative) could result in a worsening of symptoms. In some cases where the severity of disease is not as great and a "risk vs. benefit" assessment seems to favor weight loss, ***explicit written consent must be obtained by the primary care physician as well as ongoing monitoring of liver and kidney function by the physician. In these exceptional cases, the Alternative Diet would be the one recommended.***

ACTIVE CANCER OR A HISTORY OF CANCER (INCLUDING SKIN CANCER)

These patients may not participate in either dietary protocol, but they may purchase Ideal Protein foods to supplement their diets. Although the Ideal Protein Protocol has some very beneficial aspects with regard to cancer (decreased insulin levels, insulin being a growth factor, decreased sugar load, cancer's "preferred food" and an emphasis on an alkaline pH) there could be a risk. Certain cancers may be stimulated by hormonal changes, particularly female reproductive cancers such as breast, ovarian, and uterine.

Because levels of estrogen may transiently increase during the weight loss phase of the program, estrogen receptor-positive tumors theoretically could be stimulated. Again, ***explicit written consent must be obtained from the patient's oncologist before contemplating the weight loss protocol.***

PREGNANT OR LACTATING FEMALE

This patient population should never be placed on ANY weight loss diet or a diet restricting complete food groups – unless specified by their OB / GYN. That being said, we would suggest their OB / GYN do a fasting insulin level and assess the mother's nutritional status with respect to carbohydrate intake. Insulin levels (fasting) above 10 micro units/ml may be indicative of insulin resistance and a restrictive carbohydrate diet may in fact be warranted. Again, ***explicit written permission must be obtained by the patient's OB/GYN managing physician.*** Of course, these patients may use Ideal Protein foods as a nutritional supplement, but not part of the calorie-restricted protocol. Nursing mothers must receive written permission from the BABY'S PEDIATRICIAN to participate in the Alternative Protocol.

CHILDREN (under 17 years of age)

Growing children, as a precaution, should never be placed on any calorie restricted diet or a diet restricting complete food groups ***without the expressed written permission of their pediatrician.*** Ideal Protein foods however, may be used as healthy snacks, as supplements, ensuring adequate protein intake with a minimum of calories, or as part of a physician supervised fat loss program.

HEART ATTACK (M.I.) OR HISTORY OF HEART ATTACK, CARDIAC ARRHYTHMIA (INCLUDING A PACEMAKER), ANEURYSM, BY-PASS OR STENT SURGERY.

When a weakened heart is abruptly subjected to decreased glucose levels, its mechanical function could be theoretically compromised. We therefore prohibit these patients from participating in our dietary protocol, again, ***except with written consent of their cardiologist.*** Patients with a history of cardiac arrhythmia should be started on the ***Alternative Program***, as it takes about two to three weeks for the necessary enzymes to be synthesized so that the heart may fully utilize *the ketonic bodies produced during the burning of fat, as a fuel source.* Abrupt decreases in glucose, without the necessary enzyme structure in place could theoretically precipitate an arrhythmic event.

CONGESTIVE HEART FAILURE (CHF)

Congestive Heart Failure is a progressive disease in which the patient's downward course is controlled / slowed by the physician constantly monitoring and adjusting a wide variety of many classes of pharmaceutical agents. These patients are very ***complicated and fragile*** and ***should never, as a rule, should never be placed on our diet.*** Electrolyte imbalances and fluid overload, particularly in the lungs, can occur suddenly and require emergency medical intervention. **REMEMBER:** Although medically and scientifically sound and backed up by decades of clinical practice in

institutions such as Harvard, Johns Hopkins, and Stanford, many lay people will have the perception that our diet is somehow unhealthy and even dangerous. ("You told Grandpa not to eat fruit and he died. Everybody knows fruit is good for you!"). We are here to help folks lose weight and regain their health and vitality; we are not here to practice heroics. No matter how noble or altruistic your intentions may be, this diet is NOT for everyone.

PARKINSON'S DISEASE

Parkinson's disease is a progressive neurological disorder where the dopamine producing cells of the *substantia nigra* area of the brain start to die. As these cells decline in number levels of dopamine (an important neurotransmitter) begin to fall. Motor skills are affected and symptoms like a rigid face, tremors, inability to begin walking or having a hard time to stop, and "pill-roller's syndrome" - the rapid rubbing of the middle finger with the thumb, begin to appear. These are mild at first and easily controlled with medication. As the disease progresses the dosage must be increased and other drugs may be added. The mainstay therapy is a combination of the drugs Levodopa and Carbidopa (Sinemet is the Brand Name). These drugs cross the blood-brain barrier and the levodopa is metabolized to dopamine (the carbidopa is given to inactivate an enzyme that degrades dopamine allowing for higher levels to be achieved).

The problem with giving protein is this: levodopa and carbidopa are amino acid-like substances and compete for absorption sites in the intestine with the amino acids derived from protein digestion. Basically when you eat protein with this medicine less of the dose gets absorbed. Furthermore the drugs that do get absorbed into the blood have to again compete with amino acids in crossing the blood-brain barrier. Bottom line: protein decreases the amount of drug the patient gets and symptoms become more severe.

Protein, as we know, is a necessary nutrient and dieticians specializing in Parkinson's frequently give diets in which the daily protein is given only at the evening meal. This allows for dosing during the day where the patient's symptoms must be controlled for a good quality of life. This practice was shown to be very effective by a recent Italian study. Therefore if you have a Parkinson's patient, you would NEVER place them on the protocol. You may however suggest our foods for a night-time supplement.

LITHIUM

Any person taking Lithium is not a candidate to be placed on either Ideal Protein protocol due to possible fluctuations in sodium levels which could cause lithium toxicity.

STRICT VEGAN LIFESTYLE

Due to severe restrictions in a strict Vegans' food consumption, they are unable to be placed on either Ideal Protein protocol.

HEALTH PROFILE

PROFESSION, WAKE TIME, BEDTIME

This information will give the coach an idea of the client's daily schedule. This will prove valuable in aiding the client to properly schedule his / her four *meals* each day. For example, if the dieter works a night shift, dinner may become breakfast. Also ask what facilities are available at their work place (micro-wave, stove, refrigerator) this may dictate what foods would be appropriate to have during lunch.

NUMBER AND AGES OF CHILDREN

Having young children at home or getting them ready for school every day is time demanding, to say the least. Couple this with housework and a "stay-at-home Mom" might find getting her 4 meals per day in to be a challenge. The coach should address this during the initial consultation. Also with children at home, there is a tendency to have a house filled with snacks. Parents, participating in the Diet, must be made aware of the temptation to absent-mindedly indulge. Coaches should recommend a pudding or drink to be kept in the refrigerator, ready to go if a sudden craving hits them. Stress can raise blood sugar and if their glycogen stores are depleted, the body will result to gluconeogenesis (or the break down of muscle) to accomplish this. It is therefore *imperative* for these parents *not to miss any meal!* ***We do not want to lose muscle!***

DIABETES

First, the coach should ask how many times a day the patient injects insulin and what type or types of insulin they use. The injections should ALWAYS be accompanied with a meal. The ***Alternative Diet***, which the Type I diabetics will use, provides **one serving of a) Fruit b) bread/grain c) dairy per day (i.e. not one of each at each meal!).**

If a patient injects twice a day, with the morning injection being the largest, a good plan would be to have a protein with the **bread and dairy group just prior to the injection.** Then he /she would have the **fruit with a meal just prior to the second, smaller injection.** If they inject 3 times a day, give one of the selections (bread, fruit, dairy) with a meal prior to each of the 3 injections.

If they use 1 injection of an insulin such as **Lantus** at bedtime, then a higher carb treat may be a good choice (this probably would only be with a Type II diabetic on the regular diet). So, the Type II's - if on Lantus- would save their "treat" (bar, chocolate soy crisp) until they inject their nightly insulin. Patients should be instructed to closely monitor their blood sugars and they should bring in their reading to the weekly follow-ups. Reductions in medication may then be recommended by the supervising physician.

Insulin pumps are a little more "tricky". Based on our clinical experience, we find reducing the basal rate of infusion by 15 to 20% beginning the day they start the program is a good place to start. Watch their weekly sugar readings and decrease insulin as needed. Patients should be instructed to carry a bag of chocolate covered soy crisps or a bar with them in the event of a hypoglycemic episode. Usually 1/3 to 1/2 of a bar or about 6 or 7 chocolate crisps will be enough to keep their sugars from becoming too low. Tell them to use these products, **not to drink a Coke, orange juice, or use a glucose tablet!!**

Those typical "rescue products" will contribute to wild blood sugar swings and compromise the effectiveness of the program!

There is a new class of injectables for diabetics called "incretin mimetics". The brand names are "BYETTA" and "SYMLIN". These increase the action of insulin and must only be used right before a meal. In addition the meal MUST consist of at least 250 Kcals. and contain at least 30 grams of carbohydrates otherwise the blood sugar will drop too low. For this reason these medications MUST be discontinued before the dieter starts either the regular or the alternative protocol.

Patients on oral medication will soon find these meds will have to be adjusted downward and eventually (in most cases) will be discontinued, as their insulin sensitivity improves...this is great!!! Advise the physician to decrease or discontinue the glyburide, glipizide, and "Januvia" first. These drugs cause the pancreas to secrete more insulin and glyburide can inhibit fat burning, as it somewhat inhibits the enzyme CTP-1 (which shuttles fatty acids into the mitochondria). The "glitazones" (Actos, Avandia) can be removed next. These drugs increase the insulin receptors sensitivity. Metformin in no way adversely affects our program and that one "can be the last to go".

CARDIOVASCULAR FUNCTION

Patients who have had a heart attack within six months are ***not to be placed on either dietary protocol.*** Patients with a history of cardiac arrhythmia should be placed on the ***Alternative Diet*** for about two to three weeks. If they have not experienced a tachycardic episode and have done well, they may at that time transition to the regular (ketogenic) diet. We recommend a fasting lipid profile be done before beginning the program and have a follow up one done in about 6 weeks. You will see remarkable improvements in triglyceride levels as well as significant improvements in cholesterol. Medications (statins, fibrates, etc.) may then be appropriately reduced or discontinued. **Again, written consent must be obtained by the Cardiologist prior to placing these candidates on either protocol.**

HYPERTENSION

Patients on anti-hypertensives (blood pressure meds / diuretics) should be instructed to monitor their BP's and to bring the readings in on their weekly or bi-weekly follow-ups. The coach should check BP as part of their follow-ups. When insulin levels drop (due to very few carbs in the diet) a tremendous diuresis may quickly ensue, sometimes in as little as 4 days. Most of these patients have been told to avoid salt; ***it is imperative that they understand this is a very low sodium diet and they must liberally use the sea salt provided in the diet.*** Weakness, dizziness (orthostatic hypotension) and headaches are almost ***always*** caused by dehydration and hyponatremia (low sodium). Insulin causes the kidneys to save sodium and retain water, therefore extracellular fluid accumulates. This will be released when the insulin levels drop, and the more insulin resistant a patient is, the greater will be the effect! Also remember caffeine is a diuretic, so for every cup of coffee, caffeinated tea, etc. they must drink an extra cup of water in addition to the ***mandatory 2 liters per day.***

Once in ketosis, patients will feel more energy. If a dieter suddenly complains of being tired, that should be a "heads-up" to see if meds should be decreased.

KIDNEY FUNCTION

The kidneys are extensively involved in acid / base balance and gluconeogenesis, two processes which play a major part in the Ideal Protein Diet. For this reason, severe kidney dysfunction is a contraindication for the program. Many patients with "Syndrome X" will present with *impaired* renal function (GFR < 60 ml/min). Patients with impaired function (between 38 and 60 ml/min) **may** be placed on the program, but GFR must be re-checked within 6 to 8 weeks. ***Most patients will show an improvement or at least will remain the same. If the GFR decreases, the program should be discontinued! If a candidate's GFR is not normal, written consent must be obtained from the primary care physician or specialist as is the case.***

Elevated uric acid levels are a common abnormality with "Syndrome Xer's". These levels will improve as insulin sensitivity and acid / base balance improves, as a result of our protocol. If a patient has a history of ***gout*** and/or ***kidney stones*** we should have them monitor the pH of their urine, particularly during the first 3 weeks of the program. Maintaining a urinary pH of about 6.5 to 7.0 is very important. You can check this with ***NITRAZINE (NitraTest) paper***. Should their urine be lower than that, prescribers may order ***PolyCitra-K*** (1 packet 2 to 3 times a day). Non-prescribers may recommend 1/2 tsp. of baking soda in 4-5 oz. of water 2 to 3 times a day. These folks should also be told to drink an additional liter of water per day (3 liters/ day). **See paper on Gout, Kidney Stones and the Ideal Protein Weight Loss Method.**

STOMACH/DIGESTIVE FUNCTION

The coach should note if the patient is prone to diarrhea or constipation. Diarrhea usually improves when beginning the Diet. An episode of diarrhea, although uncommon, is usually indicative of a "de-tox" or cleansing effect and is most often self-limiting. Make sure they are adequately hydrated. Should diarrhea persist, the physician should be consulted and appropriate therapy initiated. Constipation is a more common occurrence. This is generally caused by:

- 1) not drinking the minimum 2 liters of water daily,**
- 2) not eating the two green salads per day,**
- 3) not consuming the required 4 cups of vegetables daily or**
- 4) not taking all of the required supplements.**

If a patient finds themselves constipated, ***do not recommend a fiber laxative (like Metamucil)! These products invariably make the problem worse. Instead recommend a Fleet's enema, or magnesium citrate (1 teaspoon to 1 tablespoonful 2 to 3 times a day).*** Most Syndrome X patients are low in magnesium, and this represents a great and inexpensive way to supplement that mineral - plus getting the laxative effect. One 10 oz. Bottle costs about \$1.50 and they may get it in the laxative section of any pharmacy or grocery store. Each teaspoonful (5 ml) provides approximately 250 mgs of magnesium.

DIVERTICULITIS

Patients with a history of diverticulitis may (on rare occasions) experience a flare-up. The offending agent seems to be the large amounts of lettuce and/or fibrous vegetables required by the program. We have found an effective way to deal with this. One day a week (Sundays usually work well), have the patient assemble all of the vegetables that they like. They need 28 cups (4 cups per day x 7 days). To a soup pot add about a quart of fat-free chicken or vegetable stock and add the

vegetables, bring to a boil and season as they wish.....be creative and flavorful!!
Make sure they add plenty of their sea salt.

Reduce heat and simmer till vegetables are very soft, cool and puree the soup in a food processor. Now divide the mixture into 7 zip-lock freezer bags. One bag per day will provide all of their vegetables (they can add this to one of our soups, delicious) and this will be very gentle on their intestinal tract. Basically they can now "drink their veggies".

CROHN'S AND ULCERATIVE COLITIS

Our protocol is very anti-inflammatory (you will notice decreased levels of High sensitive C reactive protein and decreased IL-6) therefore these patients usually do very well. The highly absorbable protein isolates supply the needed building blocks to repair these tissues. These patients may take the above recommendations with regard to the vegetables and it is advantageous to add a good omega-3 oil supplement, which further enhances the inflammatory attributes of this program. Never start a patient on the program when they are having a "flare-up".

STOMACH FUNCTION

Patients with a history of acid reflux (GERD) will normally see their symptoms completely resolve within two weeks. If this is the case, advise the physician to discontinue PPI therapy (stop Nexium, Aciphex, Prilosc, etc) as these drugs have a negative impact on acid / base balance. If a patient's symptoms abate, but some GERD is still present occasionally, recommend an H2 antagonist such as Zantac, Pepcid or Tagamet, or even a liquid antacid such as ***Mylanta Supreme***, instead of a PPI (these drugs do not inhibit the proton-pump system and acid / base regulation will not be as negatively compromised). **WATCH SUGAR CONTENT OF LIQUID ANTACIDS!** (particularly generic brands, Mylanta Supreme is fine).

OVARIAN FUNCTION

If a woman is not yet menopausal, it is important you note what week she gets her period.

The reason for this is that she will retain water the week prior to her menses, thus when she weighs herself, she may not see a weight loss that week and will blame the program.

Explain that this is normal and she will see a great drop the following week, as she is still losing fat, but the additional water masked the change reflected on the scale.

Excess estrogen can be stored in fat cells and visceral fat cells produce estrogen (they are frequently nick-named "the third ovary". As women lose fat, free estrogen can be released into the blood stream and irregular periods may result. It is also common to see post-menopausal women start "spotting". Younger women may experience two periods a month or longer and heavier menses. Explain that all of this is perfectly normal and regularity will return once the "fat-loss" part of the program is finished (Phases I and II).

Because estrogen levels may affect the efficacy of oral contraceptives, women taking these medications should be advised to use an additional method of birth control during the weight loss phases. Peri- and recent postmenopausal females, who are sexually active, should be likewise advised - a pregnancy would be **rare**, but theoretically possible.

THYROID FUNCTION

One of the lesser known manifestations of "Syndrome X" is depressed thyroid function. This is particularly pronounced in females. The sub-group of patients will typically present with elevated **TSH levels and low T-3**. They will most likely already be on thyroid replacement therapy. Ideally, a thyroid panel should be obtained just prior to the start of the Ideal Protein Program, but this is not mandatory. Dispel the myth that a depressed thyroid will cause them not to have the success most dieters' experience. Insulin "trumps" thyroid hormone: once the insulin levels are normalized, they will burn fat like anyone else. Also explain that insulin mediates the conversion of **T-4 to T-3 (active thyroid hormone) and once insulin sensitivity is restored, normal thyroid function will likely ensue**. A thyroid panel should be repeated in 6 months and more often than not, thyroid replacement therapy will no longer be required, or at least the dose greatly decreased.

NEUROLOGICAL / EMOTIONAL FUNCTION

ANTI-DEPRESSANTS

Because the most commonly known side-effect of most popular anti-depressants is weight gain, many dieters will feel "this won't work because I take such and such". Explain that this is not true with this protocol. Their weight loss should be the same as a person not taking these medications. Also be forewarned, patients on multiple psych-meds will require patience on the coach's part, empathy and more time than those who are not. For this reason, it is highly recommended that a "rookie" coach avoid taking on such a client... these are "advanced patients" and a thorough, hands on knowledge of the program is necessary before undertaking a possible "tasking situation".

EPILEPSY

For over half a century the use of a "*ketogenic diet*" has been used as first-line therapy for refractory epilepsy (i.e. epilepsy that does not respond to pharmacological therapy) in children. Many hospitals, such as *Johns Hopkins and Stanford* have clinics devoted just to this treatment modality...this is nothing new and has been proven with the "test of time". Over 50% of children placed on a rigorous ketogenic diet **never** have another seizure, many more can greatly reduce the amount of anti-convulsants they are prescribed. Bottom line here is that a history of epilepsy is not a contra-indication and the Ideal Protein Protocol may actually improve these patients' quality of life.

MEDICATIONS

Remember, our protocol is just food: two green salads, 4 cups of fibrous vegetables, the minimum amount of quality protein and adequate minerals and vitamins. There is no interaction with any medication patients are currently taking, save the common practices they are now following with their current diet (for example: do not take the calcium/ magnesium supplement at the same time as a "floxacin or tetracycline antibiotic or thyroid hormone).

COUMADIN / PLAVIX/ ASPIRIN... VITAMIN K CONTENT OF VEGETABLES

Patients on anti-coagulant therapies should avoid vegetables that are high in Vitamin K. This vitamin will enhance the ability of the blood to clot and may compromise the patient's medical treatment. Lists of the vitamin K content of foods are readily available on the internet (Google) and giving these dieters such a list, highlighting foods with less than 25 mcgs of vitamin K per serving, is helpful. For example choose iceberg lettuce over romaine.

CURRENT EATING HABITS

When reviewing the patient's current eating habits, be vigilant for a high glycemic, carbohydrate laden diet. These individuals may experience a severe sugar withdrawal and it is possible for them to actually get sick to their stomachs (rare, but can happen). For these few individuals, the coach should recommend one week on Phase 4 or one or two weeks on the Alternative Diet. This will wean them off the sugar slowly, so when they start the regular protocol, these adverse reactions will not occur or at least be less severe.

Ask if they eat breakfast: if they usually do not, recommend a drink. Giving them a filling meal like our oatmeal, pancakes or omelet, may make them feel nauseous. Look at their favorite foods: suggest Ideal Protein foods that closely approximate what they like.

It is often helpful to give a "variety-pack" for the first week's food: a box of one each of the different drinks, different soups with chili, spaghetti, and stew and an assorted box of our "snack foods". No one will ever try to return anything if they only have one packet of a particular product. The next week, they will know exactly what they want. This is a very easy protocol, most dieters will settle on their "5 favorite foods": be supportive but strict!

Follow the proven protocol and the proven results will follow!

Don't let them make deals with you: **"can I eat this, it's low in carbs?"
IF IT'S NOT ON THE PHASE 1 SHEET, THE ANSWER IS NO!**

SWEET FOOD PREFERENCE

Likely to revert back to old eating habits... healthy sweet food choices should be emphasized (ex. grapes over raisins) and the use of low glycemic treats / fruits.

SALTY & FATTY FOOD PREFERENCE

These folks usually like quantity. In phase 4, focus on 3 to 4 course meals. Hot broth first (increases stomach acid production (better digestion), helps to fill stomach, slows down their eating time. Salad, or antipasto before the main course will help fill them up and now they will only need one serving of the main course, rather than 2 or 3 helpings of "meat and potatoes".