

**NORTHERN ILLINOIS UNIVERSITY**

Investigating Barriers to Celiac Disease Diagnosis and  
Patient Wellbeing in the U.S.: A Comparative Study of  
the United States and Italy

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## **A. Abstract**

This study compared awareness of and attitudes toward celiac disease (CD) among American and Italian medical professionals, patients, and the general public in order to better understand and identify barriers to celiac disease diagnosis and patient wellbeing in the United States. Although the U.S. prevalence of the disease is somewhat higher than in Italy, the rate of diagnosis in the United States is significantly lower. One of the biggest differences between the two countries is awareness level (Guandalini, 2012 & Fasano, 2001). Factors that impact awareness are an important topic for study because of the strong relationship between awareness level and successful celiac disease diagnosis. Untreated celiac disease is associated with reduced quality of life and increased healthcare costs (Biagi, 2010 & Hershcovici, 2010). In addition, screening for celiac disease is inexpensive and reliable treatment is readily available (Reddick, 2006). The main issue in the United States in under-diagnosing celiac disease is awareness of medical professionals and the public.

The topic of how awareness level as well as social and medical support systems affect celiac disease diagnosis and wellbeing of patients with celiac disease in the United States and Italy was investigated by interviewing patients and celiac disease professionals from the two countries and comparing their perspectives. Data were also collected through social observation, visiting stores and restaurants that provided gluten-free products, and comparing information provided by awareness organizations from each country. Lack of awareness among both patients and medical professionals, the social environment surrounding celiac patients, and a lack of governmental regulation for the gluten-free food industry all proved to be significant barriers to patients with celiac disease in the United States. Fully identifying these barriers is the first step to addressing the issue of celiac under-diagnosis in the U.S. and will facilitate the development of more effective and efficient solutions.

## **B. Glossary/Abbreviations**

- AIC: Associazione Italiana Celiachia (Italian Celiac Disease Association)
- CD: Celiac disease
- CDF: Celiac Disease Foundation
- EGD: Esophagogastroduodenoscopy
- GF: Gluten-free
- GFD: Gluten-free diet
- NDDIC: National Digestive Diseases Information Clearinghouse
- PPM: Parts per million

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## **E. Introduction**

Celiac disease (CD) is a genetically-linked digestive disorder where the lining of the small intestine is damaged by an autoimmune reaction when gluten is ingested (Nelson, 2002). Gluten is a protein found in all grains of the wheat family (NDDIC, 2008). Although medical professionals from around the world once believed celiac disease was extremely rare, it has been proven that this is not the case. CD affects nearly 1% of the general U.S. population (Guandalini, 2012 and Fasano, 2001). Although the disease itself is not rare, successful and timely diagnosis of CD in the United States is very uncommon. According to a large national screening study, CD affects 1 out of every 133 Americans. However, only 1 out of every 4,700 Americans with CD is diagnosed. This means that out of the estimated 3 million cases in the country, only about 3% of them are diagnosed, leaving the rest undiagnosed and untreated (University of Chicago Medical Center, 2003).

The research conducted during this project explored the previously unstudied topic of how awareness level and social support system affect celiac disease diagnosis and wellbeing of patients with celiac disease (CD) in the United States and Italy. The goals of this project were a) to gain a better understanding of how awareness and attitudes of medical professionals and the public affect celiac disease diagnosis b) to identify barriers to timely diagnosis and treatment of celiac disease that patients with CD encounter in both countries and c) to discover possible ways for the United States to improve current awareness programs. The hypothesis was that lack of awareness and social treatment of celiac disease would prove to be significant barriers to patients with CD in the United States.

## **F. Literature Review**

The under-diagnosis of celiac disease in the U.S. is a major cause for concern for professionals and patients alike because of the damage to patient health and quality of life associated with untreated CD. Because this disease damages the small intestine lining, nutrient malabsorption is a major problem in untreated cases. Long-term complications in uncaught celiac cases may include delayed growth and short stature in children, and osteoporosis, arthritis, seizures, infertility, recurrent miscarriages, iron-deficiency anemia, depression, and intestinal cancers in adults (NIH, 2008). A strict gluten-free diet is currently the only treatment for CD and some studies have shown that overall mortality in celiacs not on the therapeutic diet is 4.5 - 6 times higher than the average rate (Biagi, 2010).

Having a low rate of CD diagnosis in the United States is also costly from a financial standpoint. Overall, healthier patients lead to lower healthcare costs. Currently, fast, inexpensive, and accurate screening technology is available, around 50\$ a blood test (Reddick, 2006). While Americans are not routinely screened for CD (NIH, 2008), there are currently a growing number of medical professionals who support a mass screening approach. One study has shown through statistical models that if the time-delay from onset to diagnosis is longer than 6 years, then a mass screening approach is a more cost-effective method for diagnosing CD than using an individual case-finding method alone

(Hershcovici, 2010). The current disease onset to diagnosis delay time in the United States is an average of 11 years (University of Chicago Medical Center, 2003).

Another significant factor in favor of pursuing increased celiac disease diagnosis in the United States is that there is also an effective and known treatment available. After a patient has undergone an intestinal biopsy to confirm the disease, treatment consists of a strict and life-long gluten-free diet (GFD) and patient health improvement can begin within days (NIH, 2008). Some studies have shown that the previously elevated mortality rate of patients who follow a strict GFD returns to that of the general population after some time (Biagi, 2010).

The final reason why increased celiac disease diagnosis should be aggressively pursued within the United States is the sheer potential for what we can learn as researchers and healthcare professionals. The greater the number of patients that are diagnosed, the greater the number of cases we have to learn from. Celiac disease is the only autoimmune disease with a clearly identified trigger, gluten, making it a good model to study other autoimmune diseases (University of Chicago Medical Center). CD also has strong links to multiple other autoimmune disorders, such as type 1 diabetes and rheumatoid arthritis. There is growing evidence showing genetic connections between these diseases, but it is still an area about which science understands very little (NIH, 2008).

There are a few different factors believed to be behind the under-diagnosis of CD in the United States, but they all lead back to awareness and education. One of the challenges of diagnosing CD is that it can be tricky to notice if a doctor is not specifically looking for it. However, the screening tests make this condition easy to detect once suspected. An inaccurate but still prevalent perception among many U.S. physicians that CD is rare is one possible explanation for under-diagnosis (Hamilton, 2005). Another factor involved in this issue is that celiac disease is a chameleon. It comes in multiple forms and the disease presentation is different depending on life-stage. In addition, many of the classic symptoms of CD can easily be attributed to other conditions. It is not uncommon for individuals who have CD may also have other disorders that distract from CD diagnosis (Pruessner, 1998; Catassi, 2008). The lack of physician education and the misconceptions surrounding this disorder hinder the successful diagnosis of celiac disease in the United States (Zipser, 2005), making proper education and increased awareness a significant need. The awareness issue is not isolated to the medical profession however; it also extends to the United States general population. Currently, there are a few major awareness campaigns and many smaller organizations in the United States slowly gaining ground, but there is still a long way to go in this movement (NIH News, 2006 and Celiac Disease Foundation, 2011).

Much can be learned by studying how Italy approaches celiac disease. Italy is an excellent country for comparative study because of its similarities to the U.S. in disease prevalence and testing techniques. Based on screening data, the prevalence of the disease is similar in the two countries, about 1:184 people in Italy (Fasano, 2001), while the U.S. CD prevalence is slightly higher, between 1:133 to 1:111 people (Guandalini, 2012 and Fasano, 2001). The screening tests and diagnostic criteria used are also the same in both countries (NIH, 2008 and Ministero Della Salute, 2008). The United States can learn from Italy concerning celiac disease because of the multiple things that Italy does differently that affect its diagnosis rate. According to screening studies, the Italian ratio of known cases to unknown cases is 1:7 (Fasano 2001) and the U.S. ratio of known to unknown cases is about 1:33 (University of Chicago Medical Center, 2003).

Italy's national screening system is a major factor that influences its approach to CD. In this program, all children are screened before the age of 6 (Mahnke, 2007) and then anyone who tests negatively after the initial screening is re-screened if they begin to show symptoms and CD is suspected by a specialist (Ministero Della Salute, 2008). Under Italy's universal health care system (Maio, 2002), the cost for all documented celiac-related medical care and testing, as well as a monthly stipend to pay for gluten-free food products is covered by the government (Ministero Della Salute, 2008 and Associazione Italiana Celiachia). In the U.S., there is neither a national universal insurance program nor a government screening program in place. Although the government recommends screening of symptomatic individuals, those having other autoimmune disorders or first and second degree relatives of diagnosed celiacs (National Consensus Development Program, 2004), insurance coverage for CD care and testing in the United States is inconsistent and complicated. Coverage differs

greatly between providers (Atlantic Health System). The lack of reliable coverage in the U.S. is a major issue because while the screening for celiac disease is inexpensive, the intestinal biopsy required to confirm the diagnosis is not. This procedure normally ranges between \$2000 and \$3000, which is out-of-reach for many patients without insurance coverage (New Choice Health Medical Cost Comparison, 2010). There is also no coverage in the United States for the added expense of gluten-free products and some of them cost almost as much as their gluten counterparts (Alderman, 2009).

## **G. Methods**

### ***Project Hypothesis***

Lack of social and professional awareness will prove to pose significant barriers to timely and effective celiac disease diagnosis and treatment in the United States.

### ***Study design***

This project was designed with 3 main goals at the forefront: 1) to better understand how awareness and attitudes of medical professionals and the public affect celiac disease diagnosis 2) to identify barriers to timely diagnosis and treatment of celiac disease that patients with CD encounter in both countries and 3) to discover possible ways for the United States to improve its current awareness efforts.

Data were collected through literature analysis, cultural and social observation, and interviewing. Semi-structured interviews lasting 30-60 minutes were conducted with one adult and pediatric patient from each country, a dietitian and an awareness organization representative from each country, and a U.S. primary care provider, and two Italian gastroenterologists. This research was done in part with the help of a translator who translated all consent/assent forms and recruiting documents into Italian. The primary investigator contacted celiac disease centers (University of Chicago Celiac Disease Center in the U.S.), hospitals (Policlinico, Sacco, and Humanitas hospitals in Milan), and awareness organizations (Celiac Disease Foundation in the U.S. and Italian Celiac Association Lombardia in Milan) by phone or email and provided informational letters to recruit medical professionals and awareness organizations. Celiac patients were given informational letters by their medical doctor or celiac awareness organization and requested to contact the primary investigator if they were interested in participating in the study. Recruitment letters in Italy were also distributed to English for Business class participants by an American celiac contact of the primary investigator.

Sessions began with each interviewee being requested to fill out a questionnaire concerning his/her opinions about perceived prevalence and awareness of CD among professionals and public. Interview questions related to attitude barriers, and methods for diagnosing and coping with celiac disease. No identifiable information was collected or stored and all possible precautionary measures were taken to protect the privacy and confidentiality of the interviewed patients.

Data were also collected in the form of educational materials from each celiac awareness organization and digital photographs were taken to document items such as restaurant menus, gluten-free products and stores, awareness brochures, and buildings. Data were evaluated qualitatively using the interview recordings and completed questionnaires, and educational material provided by the two awareness organizations, such as brochures and online resources. Analytical techniques included listening to audio recordings, taking notes, making tables to compare features, and contrasting awareness organization physical and online resources.

## **H. Results**

### **1. Patient Interviews: Barriers to celiac disease diagnosis and patient well-being identified.**

One of the most significant barriers to patient wellbeing in both countries proved to be a lack of effective celiac disease diagnosis. The negative symptoms of celiac disease, when left untreated, proved to significantly affect patient quality of life pre-diagnosis. Related to this, one of the main barriers identified for patients in the U.S. was a lack of awareness and knowledge among medical professionals about celiac disease. For the U.S. adult patient, who knew almost nothing about CD before her diagnosis, low awareness among medical professionals led to a delayed diagnosis time and years without answers. The U.S. adult patient described seeing numerous specialists over a period of multiple years and feeling tired and frustrated with feeling sick without any explanation. On the other hand, the Italian patients interviewed were both diagnosed within a matter of months. The adult Italian patient also described having moderately high awareness of celiac disease before his diagnosis. Although his was an asymptomatic case; he was diagnosed during routine screening after another family member was diagnosed.

Another significant barrier to patient wellbeing discovered in the U.S. was a lack of patient knowledge and education about the gluten-free diet in the months immediately following diagnosis. Both U.S. patients described that it is very difficult to always completely avoid gluten because of "hidden" gluten not clearly specified by food labeling and cross-contamination at restaurants. Negative symptoms that occur upon accidental gluten ingestion continue to be a barrier to patient wellbeing even after patients become more familiar with the GFD. The Italian patients expressed that the adjustment to a GFD post-diagnosis was a smooth and supported process.

Shopping also poses a barrier to celiacs in the United States because, in many locations, gluten-free products are only low to moderately accessible and are also more expensive than their gluten-containing counterparts. In Italy, both patients shared that they did not feel limited in any way by the GFD. Gluten-free products are clearly marked and often widely available even in smaller grocery stores. Even though gluten-free products are more expensive, celiacs in Italy are provided with a monthly stipend to offset the additional cost of GF products. One patient shared, in his home city of Milan, there is a small chain of entirely gluten-free specialty stores.

Barriers to patient wellbeing also proved to be social in the United States. A lack of knowledge among friends, colleagues, and restaurant staff about the GFD may put celiacs in uncomfortable or awkward situations where explaining or asserting their needs becomes an unpleasant experience. In Italy, because celiac disease is such a well-known issue, the Italian patients shared that friends, coworkers and restaurant staff are very familiar with CD and the needs of a gluten-free diet.

### **2. Health Care Provider Interviews: Barriers to celiac disease diagnosis and patient well-being identified.**

The U.S. primary care provider and a registered dietitian who were interviewed reported that awareness is easily the biggest barrier to celiac patient diagnosis and wellbeing. Because awareness is so low, many doctors do not diagnose celiac disease because they are not looking for it, according to the interviewees. In one U.S. doctor's opinion, the lack of awareness among medical professionals is due to a lack of education during medical school. The Italian professionals discussed a similar issue. While Italy's approach to CD is strong in the areas of diagnosis and treatment because of the long-running CD research in this country, one Italian interviewee still reported that an area for significant improvement included educational unification among medical professionals. He explained that this disunity currently results in regional differences in diagnosis and treatment. One Italian medical professional stressed that to improve the diagnostic rates for celiac disease in Italy, it is important that medical professionals be educated on the importance of not underestimating the signs and symptoms of celiac disease. She shared that the signs of CD are subtle and diverse, and it is important to be vigilant. The other Italian clinician shared that he believes Italy's rate of CD diagnosis is higher than that of the United States because of greater knowledge and awareness among Italian physicians.

However, Italian health care professionals also reported that even though there is a greater awareness of CD in Italy, there are still barriers to overcome. Both clinicians report they believe that while their colleagues are moderately familiar with CD, the general population of Italy is only slightly aware of this condition. Like Italy, the U.S. professionals report that the issue of low awareness also extends to the general population. To raise awareness among the public and food industries, the U.S. general practitioner interviewed reports that education should start with the people and be consumer-driven. He explained, by educating the public, people will know to ask their health care provider about CD. He reported this is one of the most impactful things that can be done to improve diagnostic rates for CD in the U.S.

Even after a patient is diagnosed, the quality of post-diagnosis support greatly varies based on where the patient lives in the United States, resulting in another possible barrier to patient wellbeing. Also as reported by one U.S. medical professional, the complications involved in getting insurance coverage for celiac disease testing are a frequent hurdle to celiac disease diagnosis. All professionals interviewed agreed that the issue of insurance coverage in the U.S. likely poses barriers to CD diagnosis and treatment.

Both Italian professionals agreed that the quality of life and post-diagnosis support for celiacs in Italy is very strong. One physician explained this is largely because of the Italian Celiac Disease Association's efforts. While one Italian clinician reported that quality of life for celiacs in Italy is very good, one of the Italian physicians shared that there is still room for improvement, sharing that one of the most significant things to improve life for celiacs in Italy would be increased access to GF products at social events. The U.S. professionals described less favorable conditions for celiacs in their country. In addition to the medical and diagnostic barriers that celiacs may face, challenges are also socioemotional, such as the frustration and embarrassment many celiacs face when having to ask several questions about ingredients or discussing their dietary needs in various social situations. Talking about dietary needs can be uncomfortable and may draw unwanted attention. Other challenges reported in the U.S. by medical providers include the higher cost of gluten-free foods, cross-contamination at restaurants, low awareness of restaurant staff, and difficulty reading food labels to find allergy information.

### **3. Celiac Awareness Organization Representative Interviews: Barriers to celiac disease diagnosis and patient well-being identified.**

The U.S. celiac disease awareness organization representative also identified under-diagnosis of celiac disease, related to low awareness in all segments of the U.S. population, as a significant barrier to patient wellbeing in the United States. She also explained that once patients are diagnosed, advocacy and support are necessary to enable patients to follow a gluten-free lifestyle, but often patients do not get the support they need. She reported that other barriers to patient wellbeing and diagnosis include an overall lack of unity and organization; there is no national database or data collection system, no screening system in place, and medical education also varies. Many doctors in the U.S. currently practicing were taught that CD was rare, a common misconception that affects how medical professionals approach celiac disease. Barriers among medical professionals to celiac disease diagnosis are mainly in the education category, including an overall lack of knowledge about CD, gaps in original training and being open to learning new things. The U.S. representative reported that research into the area of CD is greatly needed and has possible far-reaching implications; CD is not the only autoimmune disease where the elimination of gluten has beneficial effects, making it an issue with the potential to influence many.

Because this issue influences many, she reported that much change is needed. She explained that awareness is crucial and the factors that play the biggest role in awareness levels are funding, research, and government recognition. She reported that the most significant change that could be made to address barriers celiac patients face would be Food and Drug Administration regulation of the term "gluten-free." Currently, there are no government-regulated standards for the concentration (PPM) of gluten that can be found in a product for it to still be considered gluten-free.

She explained that government regulation gives a lot more weight to the cause. This would increase awareness and customer demand for products. Food industries also would take more interest due to increased awareness levels. She proposed that an overall increase in awareness would lead to high diagnostic rates.

Like the medical professionals interviewed, the U.S. representative also agreed post-diagnosis support is an area that may pose barriers to celiac patients. She explained that CD is unique in that a patient is essentially cured if he/she follows the GF diet. Often, if a patient starts feeling better, he/she is much less likely to seek out much follow-up care with his/her health provider. However, she reported there may be room for improvement in the follow-up care that professionals do provide. She explained that patients are not always being strongly advised against eating gluten again. Consequently, "cheating" on the diet is a significant issue for many patients, because of low education about the long-term negative effects of not adhering strictly to the GFD.

The U.S. representative reported that costs of celiac disease diagnosis and treatment may also be a hurdle in the United States. Although it does exist, insurance coverage is often limited. Initial blood testing is not expensive, but the biopsy to confirm diagnosis as well as following a GFD long-term is. Life at home for a celiac is also a little more complicated at first; making sure house is safe, avoiding cross-contamination, and finding substitutions are some of the challenges. Celiac students also face many challenges at school and eating out due to low awareness about the GFD.

According to the U.S. representative, Italy has recognized that CD is not rare, and consequently has a national database and a program for gluten free products on prescription. According to the Italian representative, the Italy's national celiac disease association, AIC, (Associazione Italiana Celiachia) is the main reason why quality of life is so comparable to those without CD in Italy. Through the efforts of AIC, celiacs are provided with a stipend for gluten-free products, exemption from military service, a quarterly newspaper, and a network of restaurants educated about celiac disease has been created throughout the country. AIC also provides many other services to celiacs living in Italy. One of the most significant is that AIC maintains a listing of and oversees certification for all the companies, restaurants, and hotels that provide gluten-free products or services. This organization also plays a large role in CD awareness, through magazine articles about CD, distribution of new research to its members, and hosting an annual meeting where celiac specialists speak. This event is attended by many doctors and patients alike. AIC also has a related foundation that supports research. In the United States, the Celiac Disease Foundation (CDF) is also active in the areas of education and awareness by hosting conferences, facilitating peer-to-peer medical education, and sponsoring a national awareness campaign about the symptoms of celiac disease. CDF also plays a role in the areas of advocacy and support as founding member of the American Celiac Disease Alliance, a legislative lobby in Washington DC that works with National Institutes of Health, the Food and Drug Administration, and Congress on celiac-related issues. There are local CDF chapters and support groups in many of the larger cities around the U.S. CDF also provides a hotline and information packets to patients free of charge, as well as information for physicians and a quarterly newsletter.

The representative of AIC reported that his organization's role in the management of celiac disease is as a voice and presence for celiac issues in the government. Part of this is providing gluten-free products and/or a stipend to patients, making it possible for celiacs to eat in public settings such as hospitals and universities. It is vital that an individual have the security that they will be able to eat something even though they are celiac.

He shared the strengths in Italy's approach to diagnosis and treatment of celiac disease are because the doctors are very aware of CD and can effectively diagnose patients. Even though his country's approach is overall strong, even he reported that there are some doctors with low awareness and outdated knowledge about CD. Unlike in the past, the difference now is that training is available if a doctor would like to get it.

He said that celiac disease awareness associations play the biggest role in celiac disease awareness levels in a country (especially in Italy), because they can work cooperatively with the government on behalf of celiacs. Through this, a celiac disease association has the power to influence government legislation in favor of celiac laws and research, to spread information and news, and to work closely with contacts in the Ministry of Health. Essentially, AIC is able to work as a united force across the country to improve training for doctors, care for celiacs, and increase awareness among the public.

In this interviewee's opinion, post-diagnosis support is strong for celiacs living in Italy. Celiac patients, certified by the country's ministry of health, are eligible to receive a stipend to help offset the increased cost of gluten-free products. AIC plays a major role in educating new patients about how to follow a gluten free diet with informational packets. Celiacs can also get information from the AIC website. This representative believed that there may be a relationship between improved post-diagnosis celiac support and increased rate of celiac diagnosis. If industries and restaurants are aware of CD, the public will be more aware, and there will be more help available to guide undiagnosed patients to a diagnosis. He reported that attitude barriers among medical professionals in Italy to celiac disease diagnosis are few, if any. The only possible barrier is a lack of knowledge about CD.

He reported that life at home for a celiac in Italy is very simple because there are so many gluten-free products available, although it was not like this 10 years ago. Today there are many more resources available to celiacs that there were not a decade ago, including a book of all gluten-free supermarket products, and free or stipend-available products at pharmacies. In the last decade, conditions for celiacs in Italy have significantly improved. Life at school for a celiac in Italy is not as simple. While there is a law that mandates schools to prepare GF meals for celiac students (as in the United States), it is not always an ideal situation because the celiac option is sometimes very different from what the other students are eating. In addition, there are people who do not know or understand the requirements of a GFD, so they may make mistakes in preparing the GF meal. Normally in schools, the celiac receives the different foods packed in a box with his/ her name and identification number on it. Sometimes the family brings bread, pasta, or crackers for the student, because the school does not provide these items. Today, shopping for a celiac in Italy is very simple; gluten-free products can be widely found at pharmacies, supermarkets, and completely gluten-free stores.

The biggest challenges people with celiac disease face in Italy are involved with eating outside of the home. Although AIC has 2,000 restaurants across the country certified, there are still many who do not know about the gluten-free diet and therefore cannot provide high-quality service. For a restaurant or hotel to be certified, they must go through an AIC education program. They are then inspected 2 times a year. Certification is voluntary; there is no law obliging restaurants or hotels to provide gluten-free food in Lombardia, the region Milan is located in. In some regions, there are regional laws that require restaurants to provide gluten-free meals. In this interviewee's opinion, following a gluten-free diet does not generally have strict dietary limitations that significantly impact quality of life. With so many gluten-free products available, many celiacs do not find the gluten-free diet to be very restrictive. However, it depends on the person; some people find it harder to change their habits than others. The gluten-free products are not exactly the same, but they are acceptable. This interviewee shared that one way to improve life for people with CD in Italy would be to have restaurants everywhere that can offer a GF meal so then no celiac has to worry about eating away from home.

#### **4. Restaurant and Grocery visits**

##### **Italy:**

In the restaurants and ice cream shops (gelaterias) visited, staff members were very knowledgeable about the ingredients in their products, aware of cross-contamination, and were very easy to work with. If they were not sure about ingredients (a rare occurrence), they quickly and willingly provided a list of ingredients or a recipe to be inspected. In the chain grocery store visited, products were clearly marked and easy to find. Even as a relatively small store, a selection of gluten-free products could be found in the dairy and deli section, in the dry goods section, and in the freezer section. At the gluten-free speciality store visited, an extremely wide selection of gluten-free items and brands was available including some fresh and frozen pastry items that were made by the in-store bakery. The store had multiple locations around Milan.

##### **United States:**

In the restaurants and cafes visited in the United States, knowledgeability of staff was in general very low. While some staff were willing to work to accommodate a gluten-free request, others either did not have either the knowledge, resources, or willingness to do so. Awareness of the gluten-free diet and cross-contamination was also low. In the United States, as expressed in the interviews, shopping for a celiac varies. At one small-town grocery store visited, there were almost no gluten free products, other than those that were naturally gluten-free. However, there are a growing number of specialty/health food stores that carry a small selection of GF products, but selection is limited and cost is often a limiting factor. At one very large grocery store visited, the store had a completely GF aisle and freezer section. However, this high level of product selection is exceptional for stores in the midwestern United States.

**Table 1. Top Barriers Identified to Patient Diagnosis and Wellbeing in the United States**

By Patients:	By Medical Professionals:	By Awareness Organization Representatives:
<ul style="list-style-type: none"> <li>• Awareness among medical professionals</li> <li>• Education about gluten-free diet post-diagnosis</li> <li>• Negative symptoms that occur upon accidental gluten-ingestion</li> <li>• Awareness among friends, colleagues, &amp; restaurant staff</li> <li>• Understanding of the seriousness that a celiac must avoid gluten</li> <li>• General low accessibility of gluten-free products</li> <li>• Traveling with CD because the availability of GF products is inconsistent</li> <li>• Higher cost of gluten-free products</li> </ul>	<ul style="list-style-type: none"> <li>• Health care provider awareness</li> <li>• General population awareness</li> <li>• Medical education to identify subtle signs and symptoms as CD</li> <li>• Frustration and embarrassment of explaining needs for celiac patients</li> <li>• Inconsistent post-diagnosis support</li> <li>• Insurance coverage for celiac testing</li> <li>• Cross-contamination at restaurants</li> <li>• Low restaurant staff awareness</li> <li>• Increased shopping time to read labels</li> </ul>	<ul style="list-style-type: none"> <li>• No FDA regulation of the term "gluten-free"</li> <li>• No clear standard for parts per million (PPM) of gluten that can be found in a product to still be considered gluten-free</li> <li>• Inconsistent medical education</li> <li>• Lack of awareness among medical professionals</li> <li>• Inconsistent quality of post-diagnosis support and education about the gluten-free diet</li> <li>• Lack of research (and a distribution of research funds)</li> <li>• Limited insurance coverage</li> <li>• Cost and invasiveness of biopsy to confirm CD</li> </ul>

## I. Discussion

Identifying the barriers to celiac disease diagnosis and treatment in the United States is the first step to addressing this issue of underdiagnosis and patient wellbeing. Fully identifying the barriers enables development and implementation of more focused, effective, and cost-efficient solutions.

Long-term outcomes for celiac disease patients depend heavily on whether or not a GFD can be followed successfully. In some ways, the celiac condition is unique in that if a celiac strictly follows a GFD, they are essentially cured. This is one of the biggest reasons that effective diagnosis is of utmost importance in the United States. Once a celiac has been on the GFD for a period of time, previously increased mortality often returns to that of the normal rate, the intestinal lining heals, and negative symptoms related to gluten consumption cease (Biagi, 2010; NIH, 2008).

Therefore, much depends on if a celiac can adhere to the GFD with a high rate of success. If a celiac cannot strictly comply with a lifelong GFD, he/she faces the risk of developing further health complications, including osteoporosis, arthritis, infertility, anemia, depression, certain cancers (NIH, 2008). These complications may have a significant effect on health care costs as well as patient quality of life. For example, in 2010 medical costs associated with lymphoma, a cancer that has increased incidence in CD patients, totaled \$12 billion nationally (Pruessner 1998; NIH News, 2011).

This research analyzed previously un-compared perspectives of individuals from diverse backgrounds to discover a wide range of solutions to and a more accurate picture of the barriers that

celiacs in the United States face. Currently, there is not a great deal of research being done on CD in the United States, an issue potentially related to low awareness. While the body of research has grown in the past two decades, there is still a long way to go. In addition, most of the research being done addresses celiac disease from a medical perspective, studying topics such as treatment, pathology, and clinical presentation. While this research is valuable and needed, CD diagnosis and treatment is also an issue with strong social components. Little research has been performed in this area and this is a void that I have sought to address with my study.

Findings were significant because they have implications for how we will approach celiac disease in the United States in the future. During this project, many tangible and addressable barriers were identified. These barriers also had widespread relatability and applicability to celiacs across the United States. Main barriers identified fell into three main categories: 1.) Education and Awareness, 2.) Lack of Supportive Social Environment, and 3.) Governmental Regulation.

While education and awareness was an issue that significantly impacted all segments of the population, the lack of education and awareness among medical professionals seemed to be the most damaging to effective celiac diagnosis in the United States. However, the importance of awareness and education among members of the food industry, among school professionals, public policymakers, and the general public also cannot be underemphasized.

Lack of a supportive social environment was the barrier that most affects celiac patient quality of life in the United States. Because celiac quality of life and future health greatly depends on the patient's ability to adhere to the GFD, it follows that an environment that enables the celiac to comply with the GFD would be crucial to patient wellbeing. Currently issues such as cross-contamination in restaurants, low availability and increased cost of gluten-free products, having to identify oneself as "different," and the negative symptoms that come with accidental gluten consumption are common barriers related to the social environment that celiacs face in the United States.

Governmental regulation also plays a significant role in celiac patient wellbeing. In the United States, legislation in this area is extremely limited. As of this writing, there are no clear guidelines for what "gluten-free" means. As discussed in the interview with the U.S. awareness organization representative, Food and Drug Administration regulation of the term "gluten-free" and the setting of standards for the maximum concentration of gluten that can be found in a product, would increase general awareness for celiac disease as well as food industry recognition of celiac issues.

## Proposed Solutions

Table 2. Top Solutions Discussed during Interviews		
By Patients:	By Medical Professionals:	By Awareness Organization Representatives:
<ul style="list-style-type: none"> <li>• Improvement of social situation for celiacs, especially greater accessibility to gluten-free foods when eating outside the home</li> <li>• Research into early and effective diagnosis and treatment for CD</li> <li>• Celiacs should educate others by talking to them about CD to raise general awareness</li> </ul>	<ul style="list-style-type: none"> <li>• Enhancing medical curricula across all specialties with topics related to CD.</li> <li>• Continuing education that targets medical professionals of many disciplines</li> <li>• Consumer-driven awareness efforts</li> <li>• Greater standardization for celiac testing and diagnostic procedures</li> </ul>	<ul style="list-style-type: none"> <li>• FDA regulation of the term "gluten-free" - set clear standards</li> <li>• National database and data collection system</li> <li>• Greater cooperation between awareness organizations and government</li> <li>• Peer-to-peer educational events for medical professionals</li> </ul>

While many possible solutions were suggested by interviewees, one response that echoed throughout the interviews was the call for a multi-disciplinary approach that involves medical professionals from a variety of fields, patients, and industry professionals. Because the signs and symptoms of CD are often nonspecific and affect many systems within the body (Pruessner, 1998; Catassi, 2008), a team approach to celiac disease case-finding is required.

The U.S. general care provider also had a very interesting and sustainable approach to celiac disease awareness. He explained that change must be driven by the demand of the celiac population in the United States. He continued by saying that businesses will listen to consumer demand, so combining marketing of GF products with education about CD symptoms would be a profitable way for companies to help their celiac client base to grow through raising awareness about celiac disease.

### ***Limitations of the study design***

Because of the small sample size (n=12), the majority of the data was qualitative, rather than quantitative. The research team was also very small and time constraints were a significant limitation. There were also limitations in comparing the views of the medical professionals from the United States (a general care provider and registered dietitian) to those from Italy (two gastroenterologists) because of the difference in professional position. An improved research design is planned for future work. It was also somewhat challenging to compare perspectives of different medical professionals because the medical systems in which the respective professionals work are so different.

### ***Problems that may have occurred that affected the outcome***

Many people were on the annual vacation period taken by many in Italy. Medical professionals, especially, were difficult to get in touch with. Some interviews were necessary to conduct by distance but were somewhat complicated by the language barrier.

Interviewees in Italy were all from a similar geographic location (Lombardia/ Milan) and interviewees from the U.S. were more spread out, from multiple states (including Midwestern and West Coast regions). Interviewees were not selected randomly, so this affected their representativeness of the entire population. Volunteer bias may have also affected the results. It is possible that patients in Italy and the U.S. who had a bad experience with celiac disease would probably be less likely to offer to talk about it.

### ***Strengths of the study***

The research was well funded through the Expand Your Education (EYE) and Undergraduate Special Opportunities in Artistry and Research (USOAR) grants. Another strength of this study was that it was primary research. Being able to travel to the site and talk to people in person was a vital component of the research from a cultural standpoint, especially in Italy. This also helped to minimize information being lost in translation. An additional strength was that this study explored previously un-compared perspectives, filling an information gap in currently available research. Diversity among interviewees was also a strength: interviewees provided a broad range of perspectives for a more complete picture of barriers to patient diagnosis and wellbeing in the United States. Interviews came from a variety of different life situations, backgrounds, and nationality. Another strength was the multidisciplinary approach of study design: drawing from nutrition, public health, anthropology, epidemiology, sociology, and medical perspectives.

### **Areas for Further Research**

While I did succeed in answering the research questions that this study centered on, in some ways, I conclude this project with more questions than I started with about the social situation surrounding CD. One of the most interesting areas for future research was the impact that awareness organizations can have. While all interviewees agreed quality of life for celiacs living in Italy is currently high, multiple interviewees reported that this has not always been the case. They reported that the situation for celiacs in Italy has significantly improved in the last 10-12 years, a change with a start-time that correlates to around the time AIC restructured in 1999 to become a federation of regional associations. In the years after that, celiac census data also started increasing in availability (Associazione Italiana Celiachia). I believe there is a potential connection between the restructuring of the organization for a more nationally unified approach and the current high quality of care that celiacs receive in Italy. There are many areas for future research into this topic of celiac disease awareness and social structure including:

- What has changed in Italy over the past 10 years to cause this significant increase in celiac awareness?
- How do the awareness organizations in the United States function and cooperate with the government versus those in European countries as it relates to celiac awareness and quality of care?
- How is training about celiac disease integrated into medical curricula in Italy and other European countries versus that of the United States?
- What is the correlation between United States post-diagnosis patient support/education and degree of compliance with the GFD?

### **J. Lessons Learned & Conclusion**

As I boarded the plane to fly out of O'Hare International Airport on July 23, 2012, I was both nervous and excited to be leaving the country for the first time. Now that I have completed my research, I realize that I have changed and grown a great deal. I feel that the world is a much bigger place because the situation I studied in Italy is just one country's approach to celiac disease and there are hundreds of countries in the world. I also feel that the world is smaller in some respects. At one point traveling to Italy for research seemed so far out of reach, but now that I have been able to do this, I feel more confident in my potential to accomplish even greater things in my field in the future.

Being able to conduct this research has impacted me in more ways than I can count. To start, it has given me a broader understanding of cultural differences and diversity. This project has also given me more understanding of celiac disease-related issues and more respect for the resilience and strength of celiac patients. I also have gained invaluable experience working with professionals in my future field. Through this, I have grown significantly in the skills of diplomacy, communication, negotiation, and assertiveness. I have learned an incredible amount about grant proposal and professional writing, institutional review board procedures, ethics in research with human subjects, patient confidentiality issues, interviewing, and interacting with people who come from different cultures. This project has also strengthened my skills in professional conduct, public speaking, and organization.

Through completing this project, I have become even more sure in my chosen career path. Conducting this research has helped me to reaffirm where my passions are: working and talking one-on-one with people and helping individuals with food allergies and autoimmune disorders. Some of the experiences of this project also helped me to decide that I want to pursue a master's degree with an emphasis in clinical and counseling psychology. Visiting Italy also helped me realize how much I love to travel, see new places, and experience different cultures. It has also broadened my curiosity about other topics related to celiac disease I would like to research further. Overall, I feel that this project has opened me up to a whole new world of possibilities, including traveling to other countries to explore other cultures, and increased my capacity to overcome challenges, ask questions, and search for solutions.

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