The GMP Revolution – A breakthrough more than a decade in the making

By Sally Young, Wisconsin Alumni Research Foundation (WARF)

The story of medical foods – palatable, safe and validated by 70 years of research – can be described as a breakthrough in PKU management. For people living with PKU, the odds of a healthy future are stacked against them. Birth defects and mental retardation are inevitable if treatment is delayed or discontinued. However, of 370,000 babies being born every year in the world, only 30% of them have access to proper newborn screenings. Based on an incidence of 1 in 10,000, statistically PKU patients are born daily for one person to reach their teens. Despite this being globally every day, only 30% of them have access to proper newborn screenings. And until a cure is found, many PKU patients are born every day to reach their teens without a chance to be early diagnosed nor any access to care. This is unacceptable.

But it’s not too late to change this. We have the tools to better support families. And we can still create a better future for PKU patients. The story of medical foods began in Madison, Wisconsin, USA. In the ‘60s a food scientist named Harry Waisman gained an interest in a novel solution for PKU patients. His research led to the discovery of a naturally occurring protein – the amino acid alanine – that is harmful to PKU patients. However, it is naturally enriched in long-chain neutral amino acids.

For this reason, WARF sought the attention of a small, family-run medical foods company called CardioTherapeutics. The company believed it just might hold the key for improving the overall health and quality of life for PKU patients. Initially, synthetic amino acids, GMP represents all the known sources of low-phenylalanine whole natural proteins. And with the support from WARF, this goal became reachable. The amino acid is utilized by PKU patients as a natural alternative to their diet. It’s not just a diet for PKU patients. It’s a lifestyle change.

The vision of this new group is that people living with PKU, young or old, can be able to reach their full potential. This can be managed by strict adherence to a diet low in protein. The amino acid is harmless to PKU patients as a natural alternative to their diet. It’s not just a diet for PKU patients. It’s a lifestyle change.

This story of the medical food, the amino acid, and the PKU patient, is just one example of how a medical food can be integrated into a healthy, nutritious diet and provide a wide range of foods that are so many popular alternatives could not be included in a new food system. For example, it became the focus for a new line of products that would help PKU patients – especially children and teenagers – stick to their diet to stay healthy.

To find answers and explore the potential of the amino acid, CardioTherapeutics worked with the University of Wisconsin’s neuropsychiatrist, Penny Rey, PhD., R.D.N.

The story of the PKU community is that all people living with PKU, young or old, can be able to reach their full potential. This can be managed by strict adherence to a diet low in protein. The amino acid is harmless to PKU patients as a natural alternative to their diet. It’s not just a diet for PKU patients. It’s a lifestyle change.
How Arla Foods Ingredients is giving PKU patients a new formula choice

By Erik Jensen, Research Scientist, Arla Foods Ingredients, Denmark

Arla Foods Ingredients is one of the world’s leading suppliers of milk proteins. We are based in Denmark, but have an international mindset and supply ingredients to over 90 countries, from Latin America to Asia-Pacific and Africa. Our ingredients are used in all kinds of products – drinks, yoghurts, cakes, protein bars, infant formulas and textiles, among others.

Our raw material is whey, which is a by-product of cheese production. We carry out an extensive analysis of different proteins and in today acknowledged for its high nutritional value. The proteins found in whey have many beneficial characteristics, such as specific protein profiles and inferiorities. We are therefore focused on making these proteins commercially available to our customers, which are companies in the food industry. We have maintained this focus through several decades and it has resulted in a high level of expertise in purifying specific proteins and protein fractions through the use of various filtration techniques.

It was therefore an easy decision for us to invest in developing the production process for GMP (Glycin-Methionin-Protein or GMP for short), which is found in liquid whey. We agreed to put our efforts into this project after scientists had discovered that the GMP peptide chain was completely free from phenylalanine, thereby making it a potential gene-vector as a partial substitute for free amino acids in PKU patients.

Our aim was to produce a GMP ingredient with the highest possible purity in order to test medical protein originating from the gut in PKU patients. This very ambitious goal resulted in a long and challenging journey to develop a high-quality GMP product suitable for PKU patients. The project involved several investments in research and development as well as the building of a new production facility in Denmark. Finally, we achieved our goal in a very short period of time and production costs were optimal.

We are happy that it is now possible for PKU patients in many countries to consume GMP-containing formula, make their own impressions, and decide whether products containing the GMP ingredient can be worth the money.

The journey does, however, not stop here and we work not just for health but also for better PKU food and formula, as more and more people are now better informed about PKU.

Our story started in 2000 when Arla Foods Ingredients was set up. In 2003, we identified the project as a possible ROI and called it the ‘task force’ project. Each of them had their own tasks and the project was not only about making product but also about finding the best way to make it. In 2005, the team of Lynn, Sally and Virginia got a small product for testing and the project started in 2006. In 2007, we agreed to put our efforts into this project and during 2008 the project was completed.

In 2009, the dream of a PKU product became a reality. We are very proud of the new product and we believe that it is a unique opportunity for PKU patients to have a better quality of life.

The PKU project was started in 2000 and it took several years before we were able to produce a product suitable for PKU patients. The product was developed in collaboration with the University of Wisconsin–Madison and the latest chapter in a long and inspiring journey.

Today, we are very proud of the new product and we believe that it is a unique opportunity for PKU patients to have a better quality of life.

How GMP came to be...

By David Paolella, father of two PKU-children

On July 9, 1992, Lynn and I had our second child, Camerone Luke Paolella. We had a healthy 6-pound baby to nurture and very excited to introduce her to the world. As the months went by, we came to realize that our daughter had PKU.

For years, parents of PKU children have worked hard to find an acceptable alternative to synthetic AA medical foods for managing the disease. The medical community and families have been waiting for a PKU product that is safe and acceptable without being expensive.

Synthetic AA medical foods provide a safe and acceptable alternative to Cambrooke Therapeutics. “We provide evidence that GMP medical foods provide a safe and acceptable alternative to synthetic AA medical foods for managing PKU,” Ney said. “Our findings show that Glytactin GMP medical foods provide a safe and acceptable alternative to Kambooke Therapeutics. We provide evidence that GMP medical foods provide a safe and acceptable alternative to synthetic AA medical foods for managing PKU.” Ney told early reporters that Glytactin GMP medical foods provide a safe and acceptable alternative to synthetic AA medical foods for managing PKU.

The study was published in the Journal of Nutrition and Metabolism, indicating that the high acid loads of AA medical foods cause bone loss and become a nutritional and production cost burden. In the PKU mouse model, the study showed that GMP diets resulted in bigger and stronger bones compared to the high acid loads of AA diets. The study showed that Glytactin GMP medical foods do not have high acid loads.

The study, published in the Journal of Nutrition and Metabolism, indicates that the high acid loads of AA medical foods cause bone loss and become a nutritional and production cost burden. In the PKU mouse model, the study showed that GMP diets resulted in bigger and stronger bones compared to the high acid loads of AA diets. The study showed that Glytactin GMP medical foods do not have high acid loads.

The innovations of Dr. Ney and her colleagues at the University of Wisconsin–Madison are a source of pride for the entire campus, and the latest chapter in a long and inspiring journey.
GMP and appetite

By Kirsten Ahring, Kennedy Centre, Denmark

Since 1979, Kirsten Kian Ahring has worked as a metabolic dietitian at the Kennedy Centre, the national PKU center in Denmark, including Greenland and the Faroe Islands.

Comparison between casein/glycomacropeptide (GMP) and free synthetic amino acids (FSAA) in connection with standardized meal in selected biomarkers in phenylketonuric (PKU) patients

BACKGROUND: Phenylketonuria (PKU) is a metabolic disorder with elevated blood levels of phenylalanine (Phe) and a risk for intellectual disability. The diet of people with PKU is restricted to maintain a safe and effective alternative to this highly restricted diet. One of the main focuses in PKU care is to investigate what kind of impact GMP has on the body. The aim of this study was to investigate the influence of the following biomarkers related to appetite and food intake.

METHODS: Patients (f female, m male, age 13-46 mean 35.4 + SD 11.3) were matched on the following criteria: • age, • diagnosis of classical PKU confirmed by mutation analysis, • serum Phe levels < 360 mmol/l, • treatment with BH4 (coenzyme), • had received treatment with a protein restricted diet since neonatal period and were willing and able to participate, • nursing or planning to become pregnant. All the patients were living in Denmark, the national PKU centre database from the following criteria:

• BMI > 30, pregnant,

• obese or planning to become pregnant.

RESULTS: None of the seven nutritional parameters were measured at time 0 and 240 minutes. The data in this article has been presented as a poster at the SUDIN 2017 (http://www.sudin.org/cf/CF2017_Alund) and as an oral presentation at the E.S.P.K.U 2017 (http://www.espku.org).

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GMP and its use in children with PKU

By Anita MacDonald, Research Dietitians, Birmingham Children’s Hospital, UK

INTRODUCTION

Over the last few years there has been a lot of discussion about the use of GMP as a protein substitute.

Most of the research work has originated from Dr Denise Ney, from the Wisconsin University in America. This has led to it being a popular protein substitute throughout the USA. However, uptake of this protein substitute has been low across Europe, with many health care professionals needing to see more supporting research about the usage of GMP in children with PKU as well as studies into its usage in children over a longer time period (van Wegberg et al., 2009, Ney et al., 2008, Solverson et al., 2012a, Solverson et al., 2012b).

In this article we are going to examine some of the work being done in humans. Most of the human studies have been done in teenagers and adults over a short time period.

In the children taking the low Phe GMP, many children did not take the low Phe GMP at the sole source of the protein substitute. The low Phe GMP contained 48% (3-6%) of the total protein substitute intake, with the remaining amount (42%) supplied by amino acid supplements.

At the end of the 12 months (figure 2), no significant differences were found between or within the groups for median phenylalanine or tyrosine blood levels over the 12 months of close observation. Median phenylalanine and tyrosine blood levels remained within normal target reference ranges for age.

GMP is an abbreviation for glycomacropeptide. This sounds complex and sophisticated but when broken down into sections, its meaning becomes clearer.

A LITTLE BIT OF HISTORY

GMP is not a new protein. Spiurgy et al. (1954) examined its amino acids and structure ways over 60 years ago. However, because of an incomplete purification process, GMP was largely forgotten in the early days.

However, after the early research, the protein has been carried out and is now believed to have some unusual properties. It is associated with reduced inflammation within the digestive tract and is used as a protein source for people with autoimmune conditions. It has the ability to both inhibit the growth of unhealthy bacteria, but also help the growth of friendly gut bacteria (Bifidobacteria).

Properties of GMP

• Does not cause inflammation or repair
• May potentially reduce inflammation
• May reduce the growth of friendly gut bacteria (Bifidobacteria)
• Helps to protect teeth
• Supposed gastric anti-acids

PKU AND GMP

Almost 6 years ago, the first reports of GP being used with PKU appeared in the scientific literature.

When a GMP protein substitute is made, the essential/semi-essential amino acids that are missing in GMP are added back into the protein substitute, so it is not deficient in any important amino acids. Therefore, a GMP protein substitute is a combination of GMP and added amino acids. The GMP protein substitutes are also supplemented with all the other necessary nutrients such as vitamins and minerals. Many studies have shown PKU children and adults on a GMP protein substitute supply from PKU and unseen benefits provided by GMP as the sole protein source.

In the control group, the Pha-free amino acid supplement provided all their protein substitute requirements.

In both groups of children taking a median of 60g/day of protein from the GMP product contains 20g protein. If blood phenylalanine or tyrosine levels over the 12 months of close observation. Median phenylalanine and tyrosine blood levels remained within target reference ranges for age. Both groups of children were taking a median of 48% (3-6%) of the total protein substitute intake, with the remaining amount (42%) supplied by amino acid supplements.

CONCLUSIONS

• Blood phenylalanine and tyrosine levels remained stable in both groups of children taking the low Phe GMP protein substitute intake was given as low Phe GMP. Most children continued to take the only GMP low Phe amino acid supplement.

Conclusions and recommendations for PKU patients taking a low Phe amino acid supplement. Both blood phenylalanine and tyrosine levels were within the recommended target levels for the age group studied. No reduction in the intake of dietary phenylalanine was made even though a high-end phenylalanine intake was required by the children in the low Phe GMP group.

The GMP protein substitute was very well tolerated and accepted by the children who chose to take it.

REFERENCES


Figure 2. Median blood phenylalanine concentrations (µmol/L) over the 12 months (n=29). No significant differences were found between or within the groups for median phenylalanine or tyrosine blood levels over the 12 months of close observation. Median phenylalanine and tyrosine blood levels remained within target reference ranges for age.
New research: Bone health in Phenylketonuria (PKU)

By Denise M. Ney, PhD, RD; Professor of Nutritional Sciences, University of Wisconsin–Madison, USA

Skeletal fragility is a poorly understood complication that many people with PKU experience. Risk factors for bone fractures in PKU are not fully understood but may include low bone density (BMD), lower bone mineral content (BMC), and alterations in bone architecture. Skeletal fragility in PKU may be related to the PKU genotype or the amino acid load. PKU affects the ability to maintain a neutral pH. For example, a reduced urine pH increases the risk for fracture, but not everyone with PKU is affected.

Dietary interventions can help to maintain a neutral pH. Prebiotic foods increase calcium absorption, and in one study, BMD was increased in adolescents (without PKU) who were fed a prebiotic for one year. In summary, GMP is a prebiotic, low-acid, low-PHE dietary protein that reduces Desulfovibrio bacteria, increases cecal short-chain fatty acids and results in beneficial changes in the intestinal microbiota. Evidence from both human and animal studies demonstrates that gastrointestinal flora increase calcium absorption, and in one study, BMD was increased in adolescents (without PKU) who were fed a prebiotic for one year.

Calcium and vitamin D are the main building blocks for bone formation. Because animal foods including dairy products are restricted in the PKU diet, the amino acids that provide the building blocks for bone formation are limited. PKU patients may need to incorporate a low-PHE diet in order to maintain adequate bone health. 

Physical activity works together with the PKU diet to optimize bone health. Short-term exercise provides ‘mechanical loading’ which increases bone density. High-impact exercise can increase bone density and provide advice on how to maintain a neutral pH. For example, a reduced urine pH increases the risk for fracture, but not everyone with PKU is affected.

Over 50 research articles have discussed bone health in patients with PKU. Here we agree that PKU affects the bone, but there is controversy regarding the degree, implication and cause of the bone abnormalities in bone, but there is controversy regarding the degree, implication and cause of the bone abnormalities in bone. Most agree that PKU affects the bone. Most agree that PKU affects the bone. PKU affects the bone, but there is controversy regarding the degree, implication and cause of the bone abnormalities in bone. There is controversy regarding the degree, implication and cause of the bone abnormalities in bone. Most agree that PKU affects the bone. Most agree that PKU affects the bone. PKU affects the bone, but there is controversy regarding the degree, implication and cause of the bone abnormalities in bone. There is controversy regarding the degree, implication and cause of the bone abnormalities in bone.

References:
Wish it, Dream it, Find a way and DO IT

By Marketa Rysava, now living in Denmark

My dad truly is the outdoors type. He loves hiking, camping in the wild and spending the weekends in the mountains. From the age of 12, I needed to have 1-2 days free per week to do some activities with dad and the rest of the family. The only place that was suitable for us was the Dolomites, which we would always drive to. There, we would spend almost every Saturday and Sunday in a workcamp, doing all kinds of activities. We would make the AL supplement, it was so simple and wonderful. Now I am 32, but I still love going on these hikes, depots and workcamps in the countryside with my dad and my sister. I believe the AL supplement is so much more than just a supplement. It is a way of life. That I can do what I want and be responsible, creative, stronger and in particular, I learned to learn to compromise.

In the beginning of 2013, I was applying to universities for my master’s degree. For sure that there is a kitchen I can use.

Going backpacking to South Africa for the second time was a big step for me, as it was the first time I travelled alone. Before going, I was nervous, but on the way to the airport, I was very excited. I arrived in Cape Town and started to travel along the west coast, staying over in different campsites. I got myself a backpack, which I think was important for my AL diet. It helped me to decelerate and to get to know the locals. I also brought some AL supplements with me. The first time I travelled to South Africa, I was hard, but it gave me a lot of power and confidence.

Another amazing adventure happened a year later, when I went to South Korea for 3 months. That time I visited a lot of places and sick people. There, I discovered the interesting and unique nature of South Korea in a very special way. I stayed in Seoul for most of the time, but I also visited several places around the North Korean border and flew to Jeju Island for a few days. After I tasted the local food, I fell in love with it. Korean cuisine is based on rice, which is higher in protein therefore it was necessary to remember and lower the amount of protein. It can, however, so there were a lot of veggie side dishes available, I filled up with these. There were lots of different dishes in Korea: rice products such as sweet and spicy rice cakes, rice puddings, Kimchi Koons – options with vegetables, etc. and all of them were delicious. There was one倒霉的 nut several available – fried peanut, roasted and suitcase. The trips were very interesting to taste all the delicious, healthy dishes. One of my favorite side dishes was kimchi, which is a spicy pickled cabbage and Koreans have it with every meal. I got a recipe from the friend I stayed with and I made it many times myself since I came back to Europe as it is healthy and very delicious. Street food in Korea is amazing and I think I could not do without it. I would love to go to Korea again.

In the end, I was very happy with my choice of doing an AL diet. Even if it was hard, it was worth it. I met wonderful people. Thanks to them, I discovered the interesting and unique nature of South Korea in a very special way. I stayed in Seoul for most of the time, but I also visited several places around the North Korean border and flew to Jeju Island for a few days. After I tasted the local food, I fell in love with it.

I loved it so much that the year after I planned to go again, but I fell ill and my health condition worsened. I was in hospital in London and later on also in Brussels, but I was not in the country at all those times. I went back and forth to London, Brussels and to my village in the countryside. In the beginning of my second visit, I was a buffet, therefore a lot of fruits, vegetables, protein, etc. were available. There was always something to choose from. So, all I needed was my AL supplement and perhaps LP bread. I had never done this before, so I had to research and choose the right one. I was surprised when Elena (workcamp coordinator) accepted. Therefore, I returned the year after in May and I was very happy to do it. I know that I would not have been able to do it on my own, so I am very grateful for her help.

In July, I went to Italy for a month where I took part in a volunteer workcamp in a small village called Bolzano in the north-west part of South Tyrol. The workcamp was organized by a local non-profit organization and took only a few days. I spent the rest of the time with a friend I met at a camp and we travelled around and discovered some stunning places around the island. We spent our free time helping the personnel at the Kennedy Center was very helpful and friendly. Thanks to them, I got all the information I needed during my first visit. The start of my new life in Denmark was much less stressful than it was in the US. During these first months, I spend many of my evenings in investigations, including good information to the personnel at the Kennedy Center was very helpful and friendly. Thanks to them, I got all the information I needed during my first visit. This is the start of my new life in Denmark. I collected information and got ready to move abroad again. This time, I knew how to do it, and I was ready to get in touch with the clinic as soon as possible. Therefore, I got in touch with them about 3 months before I moved to Denmark. I received a lot of important information and was also contacted for a medical exam and tests. That is why I am now able to travel to South Africa, even though I have no citizenship and only a passport from my birthplace.

Another interesting experience was my own little trip to Europe. I went in summer 2015 with my friend and another couple. We were camping outdoors regularly and rarely visited cities. It was magical, but it took a lot of preparation. There were two big facts I had to consider: First, I had to research all the AL supplements in shops. Fruits or vegetables at best. I needed supplements in shops. Fruits or vegetables at best. I needed to find out how it worked, and I had access to both LP foods and AL supplements, but I did not use them that much. I could not do without it. The AL supplement is still my way of life. It makes me feel healthy and happy.

Wandering WOOL Sekelwane © Marketa Rysava


I mentioned only my most interesting adventures, but all experiences, even the ones I did not talk about bought me important lessons. They helped me to develop some qualit...
As a father of two adult PKU children, I am very thankful for the tremendous support our family has received from the PKU community. It remains our personal mission to help as many PKU families as possible who have been diagnosed with "tolerable Disease," even better known as PKU.

I have been raising family in Germany since 1995 and have a bond with the people and physicians. Our families are still very much engaged with us during our annual PKU meetings during the past 24 years. Each time families and individuals asked us as when we would bring our products to Germany. After several years of planning and evaluating the needs for what we do, I am happy to announce that Cambrooke’s products are now available in Germany beginning January 2018.

Reflecting on my experience as a PKU Dad, I am very thankful for the PKU medical pioneers in both the US and Europe. Their contributions and efforts are essential to our PKU support teams.

Cambrooke’s products are only as good as the people who use them. As a father of two young adults, I believe these products are well-suited for young adults, children and for our medical and academic communities. Our team is dedicated to develop our PKU products for our patients.

Family support is the cornerstone at every stage of our life. My wife and I have worked hard to teach our children that they are special, that they have many children and that this did not limit or define them. In our PKU family we have taught them to be the best. Cambrooke’s protein is the most thoroughly researched PKU formula ever created.
An innovative technology applied to amino acids for phenylketonuria is going to bring tangible benefits

For the first time, the application of a pharmaceutical technology to develop an innovative medical food has been proven with the aim of overcoming a real challenge to PKU management. A recent global survey by DSM Medical showed that physicians and dieticians’ concerns about PKU management is strongly impacted by patients’ adherence to the recommended dietary regimen. In this research, most patients reported that the palatability of medical foods on the market, especially in terms of taste and odor, still represents a significant barrier, causing poor compliance or strongly impacting their life, confining the odor and the taste of the free amino acids, which prolonged absorption could sustain the expected health benefits of this new product.1,2

An innovative technology applied to amino acids for phenylketonuria is going to bring tangible benefits for the first time. The application of a pharmaceutical technology to develop an innovative medical food has been proven with the aim of overcoming a real challenge to PKU management. A recent global survey by DSM Medical showed that physicians and dieticians’ concerns about PKU management is strongly impacted by patients’ adherence to the recommended dietary regimen. In this research, most patients reported that the palatability of medical foods on the market, especially in terms of taste and odor, still represents a significant barrier, causing poor compliance or strongly impacting their life, confining the odor and the taste of the free amino acids, which prolonged absorption could sustain the expected health benefits of this new product.

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