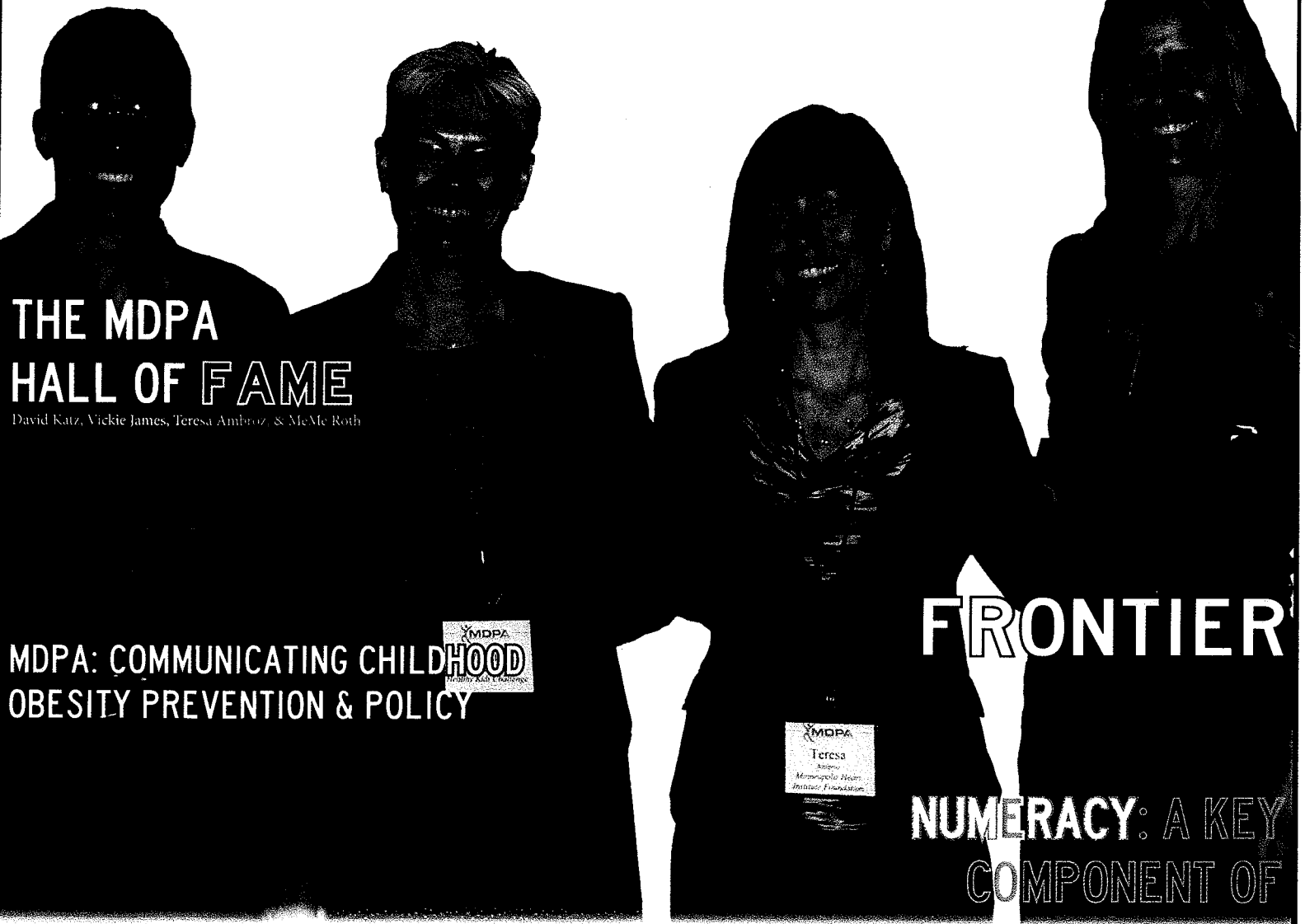




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Diabetes...The Next Frontier

By Tom Hayes and Brian Rassel

As is well known, diabetes is a highly complex disease with a wide array of causes, co-morbidities, and complication factors including age, weight, body mass index, high blood pressure, lack of exercise, income and a host of other significant issues. One could make the observation that the diabetes treatment algorithm is over-served in the U.S. with 40+ approved drugs in the physician's armamentaria and another 100 in clinical trials. However, virtually all are directed one dimensionally at the mass, monolithic patient base.

To the detriment of world healthcare and the proper treatment of hundreds of millions at risk, we, the industry and governmental bodies, tend to avoid the vital issue of ethnic impact on diabetes predisposition. Genetics and race have been overshadowed by the more obvious factors of obesity and lifestyle. And the distinction between parental influence, including hereditary and lifestyle, versus more pure racial genetics may be very important in more accurately researching and addressing diabetes.

Genetic Predisposition

There is a strong body of knowledge that while certainly not conclusive, does indicate a substantial influence of genetics and predominant ethnic/racial composition. Whether the relationship is correlative or causative, the observation has significant ramifications in the prevention, diagnosis, and treatment of diabetes. Relative to much earlier generations, genetic ethnic/racial analyses is more difficult today since the population in many countries tends to be multi-ethnic or the confluence of many genetic sources. Furthermore, the World Health Organization (WHO) collects and reports data most often by the entire country

and not by ethnic and racial sub-groups within those countries. As healthcare professionals and researchers, we must be much more cognizant of the genetic gravitational pull in health outcomes, and very specifically in diabetes.

Mid-Range Pigmentation

Skin pigmentation is perhaps the most obvious marker of ethnic and racial heritage and is a polygenic trait strongly based on evolution and sun exposure. And what human characteristic could be more related to evolution than the metabolic transformation of food into energy? Or the inducement of metabolic memory patterns in response to thousands of years of ethnic concentration? The WHO assigns numerical values for relative skin pigmentation by country on a scale of 1 (lightest) to 7 (darkest). Comparing some of the available diabetes data along with skin pigmentation values yields very interesting hypotheses. The high diabetes prevalence area spans the middle-range pigmentation countries sweeping from Portugal across the Arabic crescent all the way to India. Of considerable significance is that these countries most predisposed to diabetes are hardly the ones we might associate with obesity and an indulgent lifestyle . . . and certainly not the higher levels of diagnosis.

Of course there are a myriad of other factors that could and should be explored, but the striking relationship in the data shows as skin pigmentation becomes lightest or darkest at the extremes, diabetes becomes less prevalent. It is the populations rated by WHO with middle-range pigmentation that have the highest incidence of diabetes.

Region (all ages)	2000	2000-2020	Mid-Range Pigmentation (WHO)
	Number of people with Diabetes	% of Change in Number of People With Diabetes	
Former colonial countries	13,960	20	}
Established market economies	68,156	54	
Other Asia and Islands	58,109	148	
Latin America and the Caribbean	22,959	148	
India	79,447	151	
Middle Eastern Crescent	52,794	163	
World	324,064	115	

Source: World Health Organization

Even within Europe, the pigmentation impact and hypothesis is supported by the contrast of countries (Germany, France, Russia) with a pigmentation rating of 1 and a diabetes incidence of 4% versus Greece, Italy, and Spain with a pigmentation rating of 3 and an average diabetes incidence of 10%.

Extrapolating Implications

Quite interesting are the large number of emerging economies that often have a genetic ethnic/racial composition that features middle-range pigmentation. In some places, like the Middle East, diabetes rates are already extraordinary and range between 8-12% of the adult population.

Other distinct pockets representing a confluence of diabetes incidence and mid-range skin pigmentation include the United Arab Emirates, Mauritius, Seychelles, Malta, at the 20% incidence level. Add to these the populations of American Indians, Mexico, Hawaiians, and other Polynesian Islands. All are rated in the middle-range of skin pigmentation by the WHO and have a diabetes incidence level of 10-20%.

Areas experiencing escalating consumption patterns and lifestyle choices due to economic prosperity are potentially "activating" genetic predispositions to the disease. Nowhere has this been more true than with the Pima Indians of Arizona or the native islanders of Nauru. These two groups experienced a significant change to their food supply in the 20th century that included higher fat and calorie diets which "set-off" an explosion of diabetes diagnoses. Prevalence in Nauru now stands at approximately 28% while nearly 50% of the adult Pima Indian population are diagnosed with diabetes. These two groups may have an extremely active "thrifty" gene, which is an evolutionary response to survive extreme fluctuations in consumption, making populations able to store fat at times of feasting and survive famine on bodily reserves . . . but potentially greatly increasing the genetic predisposition for diabetes.

Further tipping the scales and the "weight of evidence" are the top ten countries in terms of diabetes population. The U.S. is the only exception. All others (India, China, Indonesia, Pakistan, Brazil, Bangladesh, Japan, Philippines and Egypt) have a mid-pigmentation rating. The "Indo" genetic connection may very well be a key factor. Some 24 million Americans have diabetes and an additional 57 million have high blood glucose levels that qualify them as pre-diabetic. However, the high number of diabetics is not evenly dispersed through ethnic groups in the community. Non-Hispanic whites have an incidence of 6.6%, as compared to 7.5% for Asian Americans and 10.4% for Hispanics. The latter are rated in the middle range of skin pigmentation.

And people with red hair and the lightest of pigmentation are proven to experience substantially higher levels of pain. Skin pigmentation is not the cause . . . but rather the most outward visual manifestation of ethnic and racial heritage.

Exhibit 2 Diabetes Prevalence



Conclusion

Clearly diabetes is a very complex disease with a great number of competing and contributing factors to its global prevalence. It has been observed that ethnic and racial groups with middle degrees of skin pigmentation appear to be much more susceptible to this disease. Though the reasons for this phenomenon may remain unknown for the foreseeable future, this is a major issue that needs to be much more fully addressed. As an industry, we need to open up the debate . . . even if sensitive in nature.

A great analogue for what could be executed in diabetes is BiDil. The drug is approved for use in addition to routine heart medicines to treat heart failure in black patients, (dark pigmentation of 6-7 on the WHO scale), to extend life, improve heart failure symptoms, and help patients stay out of the hospital longer. Only African-related patients were studied in the clinicals, so the FDA approval for BiDil is for "self-identified African American patients with heart failure" only.

Similarly, can we envision the "next frontier" coming to fruition with future clinical trials and the development of a diabetes drug specifically targeted to the middle-range pigmentation populations? At the New England Consulting Group, we sincerely hope so. This is a major business lacuna and opportunity . . . and great for the World! ✂

Tom Hayes, Managing Partner at the New England Consulting Group in Westport, Connecticut, has considerable experience across an array of therapeutic areas in healthcare with specific expertise on numerous diabetes and metabolic drugs. Tom is also the author of Maverick Marketing. He can be reached at th@necg.net.

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