It's the Unknown Unknowns That Matter

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In the book "The Black Swan" by Nassim Taleb, the author introduces the concept of an ovine miracle which had previously been deemed an unassailable European belief, the existence of a living black swan.[1] The living evidence of this Australian phenomena was a concept whose very existence was thought to not only be improbable but completely impossible, an unknown unknown. This finding caused great excitement within ornithological circles.[1] These fantastic occurrences are very different from the known unknowns, which represent phenomena that occur with a predictable frequency, whose mechanism is understood, and are recognizable and quantifiable. The response is easy to craft and the downstream impact is rarely dramatic and unique. We understand these phenomena: a patient with a fever on postoperative day 5 may have atelectasis, a urinary tract infection, pneumonia, an intraabdominal abscess, or an anastomotic leak. We can sort these dilemmas out.

To qualify as a true black swan, the event must be dramatic in and of itself. The magnitude of the event however is defined not by the occurrence itself but predominantly by the response and sequelae of the phenomena. While it would be presumptuous to claim clairvoyance in selection of a theme for this talk, my term as president of the American Society of Colon and Rectal Surgeons (ASCRS) has been bracketed by two dramatic and unexpected events, the international monetary crisis last Fall and now the potential impact of influenza A (the PC term to avoid offending the porcine contingent). As a result, I would like to put this metaphor of the "Black Swan" in context for the things I have experienced thus far in my career and what this may mean to our specialty and professional medical association, the ASCRS.

According to Taleb, the major deficit the human species faces regarding "Black Swans" is our inability to adapt to them. Instead we implement the normal human responses of: prediction; attempted prevention (typically misguided); and that ultimate skill of blame. The last several months have provided ample opportunity for pundits to define all 3 responses, sometimes simultaneously. The three key components of a "Black Swan" are: the fact must be an outlier; the impact of the fact must be extreme; and as a result human nature forces a retrospective analysis and "explanation" for the fact. Throughout history we can all think of examples of "Black Swans" beginning with the founding of this country. The American colonists protested and ultimately went to war over a 2% value added tax rate, which truly perplexed the English Parliament at the time as it was far less than the internal English tax rate. Fundamentally, it was the lack of understanding, on the part of Parliament, that is was not the tax but rather that the colonists believed they **were** English and wanted equality of representation regarding the issue on par with citizens residing in England. The inability of Parliament to recognize this desire by continuing a paternalistic colonial power strategy, ultimately led to a long bitter struggle, the loss of a valuable colony, and our independence. Similarly, the French army **learned** from the awful lessons of World War 1 the benefit of secure fixed battlements only to face and immediately succumb to a disruptive technology called Blitzkrieg. This was despite the French superiority in both tanks and combat aircraft at the time. It was strategy that failed not technology. The most recent example, and unfortunately for many of us the recognition of direct and personal financial loss, is the recent world wide economic debacle. The entire system was predicated on a single mathematical formula (consisting of long forgotten calculus for me) that the inventor and

many colleagues felt certain would lead to a Nobel prize. However the simple fact was that "the experts" did not factor in a significant and broad devaluation in home prices. This is yet another inherent stigmatum of a black swan, the **experts** must all **know** that these phenomena are not possible and therefore clearly represent unknown unknowns. As one can see, all of these events had clear and dramatic historical impacts, however it was primarily failure to assess and attempt to understand the event more broadly that drove the downstream significance and impact of the event. I raise these examples as an attempt to redefine how we find ourselves in our current position with respect to the practice of medicine. We can only avoid the pervasive negativism by embracing our "Black Swan" so that we can develop a series of positive responses and avoid the typical pitfalls mentioned previously. Remember that black swans can be a positive depending on how you respond. Clearly, we Americans enjoyed the benefits of the "Black Swan" better than our English colleagues. To begin this journey first requires that we understand what Taleb refers to as the "triplet of opacity" which must be made transparent to adapt to a "Black Swan"

1. The illusion of understanding, which refers to the human frailty of believing we fully comprehend a world that is far more complex and random than we realize. The world is far more variable than we often give credit and many events are out of our direct span of control.
2. The impact of retrospective distortion. A retrospective analysis always confirms a clearer and more organized process than the empirical assessments of the time. Historians can always apply a sobering explanation of why the event should have been anticipated or how the response should have been better crafted.

3. The overvaluation of factual information and the handicap of authoritative and learned people. During an event, there is usually no lack of experts capable of rendering clear paths of response that will fix all. Do we know if the TARP or TALF plans have actually fixed or will fix our banking crisis?

We currently face a number of intersecting challenges for medicine in general and colorectal surgical practice more specifically. I submit to you, my colleagues, that all these "black swans" have the same parentage and that is the perception that medical care is too expensive, too dangerous, and in the final analysis a poor value proposition that must be remedied. I clearly do not agree with the two initial conclusions, however the final conclusion is always defined by the consumer not the provider. We must recognize the financial impact of how we deliver care to transform our "black swan", so that we can regain our status as the final arbiters of quality medicine. Patient satisfaction data across the globe have identified minimal correlation between higher levels of health spending and levels of satisfaction with care or how well individuals believe the health care system responds to their own needs.[4,5] This is further exemplified by a growing literature that demonstrates that, when provided with independent, unbiased information on the risks and benefits of interventions, an individual patient may not select the newest, most expensive, or most aggressive mode of treatment. So lets identify some of these swans and determine how best to avoid the trap of misinterpretation so that we can respond in a beneficial and productive manner.

The impact of reimbursement changes has altered the economics of colorectal practice and our interactions with our colleagues in medicine. Unfortunately, this topic

would require a several day long seminar to address and define all the implications of repairing the current zero sum process called the Physician Fee Schedule and the Orwellian process known as the Sustainable Growth Rate. This latter process is neither sustainable nor growth, as it has accumulated an annual accrued deficit of almost 10% annually which has required Congressional action to avoid implementation. As a result of this and other revisions to payment policy, the surgical fee schedule has dropped by almost 50% in nominal dollars since 1987, and may drop further with reforms currently being proposed. However, this sad state of affairs is a symptom of a greater disease that we can directly and positively affect and that is the overall cost of medical care. The physician fee schedule was simply the politically most expedient cost component to address, however this attention has not stemmed the double digit annual inflation rate experienced by American health care over the last decade. Nothing is more expensive in a US hospital than an ink pen in the hand of an ordering physician and we haven't always written wisely. One of the most rapidly rising components of the CMS budget has been imaging, however I have yet to see a CT scan order itself to image a patient. Our patients have clearly benefited from a number of technological advances in medications, surgical intruments and procedures, and enhanced diagnostics. However, it is not clear that these resources are appropriately focused towards provision of high value care (cost/quality) in each and every instance. We are all aware of the data demonstrating significant differences in resource consumption across the nation without evidence of differential outcomes in terms of morbidity and mortality. These concerns over uncontrollable health budget expansion, coupled with the perception of poor quality and value by the major purchaser of health care, the Federal government, has resulted in the

usual government response MORE REGULATION (the typical approach to a black swan by the way- BLAME). Regulatory agencies have forced significant changes on the structure and processes of our training, certification, and maintenance of certification programs, often without consultation of our profession. Competing agencies have produced a burgeoning number of "quality" programs with complex and expensive reporting schema, with little direct evidence of benefit and in some cases adverse outcome. However, we can remain blind and unresponsive to the fact that colorectal surgical procedures account disproportionately for surgical morbidity.[6] The result of all these pressures has been a loss of autonomy for our profession and in many cases a negative impact for our patients. Whining has clearly been an unsuccessful strategy, so lets focus on a more positive approach to these difficult and far reaching challenges by recognizing the real meaning of the Black Swan.

In 1996 the Health Care Financing Administration (HCFA), now named Centers for Medicare and Medicaid Services (CMS), revised the rules for payment for teaching physicians. The subsequent rules required physical presence of the attending physician, except under very specific guidelines. Although the original intent of the administrative change was to address concerns regarding appropriate billing and reimbursement, dramatic changes occurred in most teaching sites. In fact, this was an unrecognized and missed opportunity, a "Black Swan" to fundamentally control the quality and cost reduction initiatives by attending surgeons. This was an opportunity to provide more rigorous and structured oversight to our trainees. However, we failed to recognize the "opportunity" and did not change the process of education to document the positive impact of direct supervision of residents and oversight of a migration to independent

clinical responsibility by the residents. Subsequently in 2003 the swan grew in prominence. This was the year that mandatory implementation of the ACGME duty hour restrictions was implemented. How did this occur when ostensibly far more direct supervision was being provided for residents by attending surgeons? Now is the time to impact this swan in a favorable way to maintain and enhance the delivery of quality colorectal surgical care. The three major stakeholders in colorectal surgery, the American Society of Colon and Rectal Surgeons, the Colorectal Surgery Residency Review Committee, and the American Board of Colon and Rectal Surgery, must collectively redefine the meaning and scope of colorectal surgery. Once defined the components and processes of training can be defined and the process of teaching those skills transformed. The Blue Ribbon Committee of the American Board of Colon and Rectal Surgery, originally led by Dr. Bruce Wolff began the process of defining case volume minimums for training. However, it is not only numbers of procedures that makes a high quality colorectal surgeon but rather the ability to understand the patient with a given illness, so as to provide the "right amount of care, the right way, at the right time. The stakeholders must work together to develop a set of experiences which will produce a fully trained colorectal surgeon with clear competency in the field. My interpretation of competency is a bit different than our colleagues at the ACGME. My level of competency in golf does not approach that of Tiger Woods (ie. I really can't drive the ball 300 yards in the fairway and make 6 foot putts regularly). Transformation of the colorectal training process will require that the general surgical training years be used to prepare our trainees for effective and rapid mastery of the additional skills and knowledge of our specialty, not every specialty. There is cause for concern during this

evolutionary process in surgical training. A recent study by Kairys et al defines the losses in educational experience for general surgical trainees and the need for replacement of those lessons.[3] The authors discovered that although total case volume remained unchanged and junior level surgical case volume decreased by only 2.3% as a result of the work restrictions, chief resident cases dropped by 8.3%, first assistant cases decreased by 79% and teaching assistant cases decreased by 66%. These data suggest potential and worrisome gaps in surgical maturation. The reduction in first assistant opportunities forfeits the opportunity to observe senior surgeons, while benefiting from Socratic learning of the cognitive components of intraoperative decision making without performance stress. The loss of teaching assists, a victim of both the resident supervision rules and the work hour restrictions, removes the optimal graded experience of taking a junior resident through a case with access to experienced backup. There is no greater validation of mastery than the ability to teach and mentor someone.

The other victim of the training paradigm changes has been the loss of continuity of care delivered by the residents who often miss 2 days out of every 7 days. The impact has been a reduced experience with recognizing and managing major changes and therefore may not acquire all the skills required for comprehensive patient care. Despite being better rested and theoretically free to study more efficiently, there has not been a dramatic improvement on the American Board of Surgery In-Training Examination nor the qualifying examinations. Finally, reducing work hours has not lowered mortality rates for most hospitals.[4]

Ultimately, we need to recognize and adapt to the current structure and provide an entirely new, curriculum based process of training that is defined by true competency, i.e

one can actually successfully complete the task independently. This will require much better coordination from medical school through residency, and earlier selection of specialization of skills to optimize the available time and reduce the cost of training. We will need to embrace newer techniques to efficiently transmit the didactic information required for the safe practice of colorectal surgery. Simulation can play a role in skill acquisition, team interaction, and ongoing assessment of the competency of trainees and eventually practicing colorectal surgeons. An often unrecognized opportunity in low cost simulation is role playing for patient management issues which used to be accomplished on work rounds or down times between cases or late in the evening between senior ad junior residents. Training by shear repetition of participation in clinically similar but diverse patient scenarios can no longer be relied upon as the way to effectively train residents. Conversely, as outlined by Malcolm Gladwell in his book Outliers, mastery of any skill requires 10,000 hours, somehow this experience must be replicated.[5]

Specialization today fits with the current and future practice of medicine, as techniques become increasingly driven by technology and the amount of information regarding disease processes and treatments moves into the arena of personalized medicine. An example of how the inability to embrace technology at an appropriate time can be create a sea change, is evidenced by the incredible impact of catheter based cardiac procedures. The impact of stents and the future impact of endovascular valvular heart surgery have significantly impacted the training and practice of cardiovascular surgery. We must always be vigilant to opportunities and by reasoned evaluation, rather than hype or market pressure, appropriately adopt technology where is makes sense for value to our patients. Laparoscopic colectomy has languished in adoption compared to

all other advanced laparoscopic surgical procedures for a variety of reasons, however we might finally be at the tipping point. This surgical approach has demonstrated clear benefits in skilled hands with decreased morbidity, faster recovery, and decreased cost. The tools we have for minimally invasive procedures today dramatically extends our capabilities, however we must remember the adage "right time, right place, right amount" if we desire to be relevant in the transformation of medical care coming soon. Similarly, we should be appropriately skeptical of very expensive and exciting technologies that may have a difficult value proposition beyond sexiness.

The other major "Black Swan" resulted after the Institute of Medicines publication of the "Crossing the Quality Chasm: A New Health System for the 21st Century", in which the now infamous 100,000 preventable deaths concept was initiated. Following on the heals of this report the Congress, through the Deficit Reduction Act of 2005, Section 5001(b), authorized the Secretary of Health and Human Services to develop a plan to implement value-based purchasing (VBP) commencing Fiscal Year (FY) 2009 for Medicare hospital services provided by subsection (d) hospitals paid under the Inpatient Prospective Payment System (IPPS). By statute, the plan must include consideration of: (1) the development and selection of measures of quality and efficiency in inpatient settings; (2) reporting, collection, and validation of quality data; (3) the structure, size, and source of value-based payment adjustments; and (4) disclosure of information on hospital performance. CMS is working with a multitude of organizations including the Hospital Quality Alliance (HQA), the American Hospital Association, the Federation of American Hospitals, the Association of American Medical Colleges, the Agency for Healthcare Research Quality (AHRQ), the National Quality Forum, The Joint Commission, and the American Medical Association, Consumer-Purchaser Disclosure

Project, AFL-CIO, AARP and the U.S. Chamber of Commerce. Just to name a few. The result has been a variety of hospital and physician quality measures. For hospitals the public reporting is mandatory, however for physicians it remains voluntary public reporting. If you are interested, the results are available on *Hospital Compare*, a website/webtool developed to publicly report user-friendly information about the quality of care delivered in the nation's hospitals (www.hospitalcompare.hhs.gov). As surgeons, we are all familiar with the Surgical Care Improvement Project or SCIP measures. The benefits of these efforts have been somewhat illusory to this point as outlined in a recent New York Times editorial by Groopman and Hartzband entitled "Why 'Quality' Care is Dangerous".[6] In the article they highlight a number of "unexpected" outcomes due to unknown unknowns despite the desire to do the right thing. Some pertinent examples include the adverse outcomes with aggressive glucose control as a result of both hypoglycemia and a completely unexpected increase in the risk of ischemic cardiovascular events resulting from endothelial dysfunction. The authors also reference an analysis of Medicare pay-for-performance for hip and knee replacement by orthopedic surgeons at 260 hospitals in 38 states published in the most recent March/April issue of Health Affairs showed that conforming to or deviating from expert quality metrics had no relationship to the actual complications or clinical outcomes of the patients. The ongoing discussion regarding the 12 lymph nodes is another attempt at micromanaging outcome. The data comes to us from studies designed to assess various chemotherapy regimens or administrative datasets. However, more recent single institution data raises questions regarding the validity of the number of lymph nodes assessed as an important surrogate or predictive measure. We are left with the conundrum of whether this is a test of

surgical skill, of diligence at gross pathology, the limitations of the individual patient's anatomy, or no real validity and the result is due to the completeness of adjuvant therapy? These, and many more, are examples of the rush to implement unvalidated process measures based upon either anecdotal information or studies not specifically designed to fully assess the measure being proposed in the fashion now recommended. No one is in favor of poor quality, however it our professional responsibility to seek, refine and ultimately define appropriate care plans. The cost of reporting data elements that at best are neural and at worst can lead to erroneous assumptions about surgeons or institutions must be considered in this predominantly economically driven lust for quality. There is always tension between the means and the ends of a given process and outcome relationship. We can not simply reward the outcome regardless of the process for fear fulfilling the old saw, "it is better to be lucky than good any day". Conversely, rewarding only the effort without concern for the required outcome completes the prior saying, "you cant be lucky every day but you can be good every day".

How best do we respond to these pressures and desires of the health care system to provide better value? The ASCRS through the years has benefited from leadership that has been forward thinking and provided us with the tools to assess ourselves, test hypotheses, teach our members and trainees, and communicate to the greater medical system. Under the leadership of both Dr. Robert Beart and Dr. Victor Fazio our journal, Diseases of the Colon and Rectum, enjoys an increasing readership and impact factor as a leading surgical journal. Dr. Patrick Mazier and Dr. James Guthrie raised the Research Foundation from a coma to be able to be one of the most effective and financially stable philanthropic agencies administered by and for a specialty society. Leaders like Dr.

Frank Opelka and more recently Dr. Guy Orangio (who most recently was elected to a voting seat on the Relative Value Update Committee, a first for our society) have taken on the arduous task of participating in the thankless arena of socioeconomics on our behalf. Finally, Dr. David Beck and Dr. James Fleshman and many other members of this society have produced a textbook by and for our specialty.

So, how do we move forward after correctly assessing the true nature of our "Black Swan". We must first realize and then believe that our response to the fee schedule, resident work hours, quality measures, outcomes analysis, maintenance of certification and all the other challenges of the future must be the same: "We are the best group to develop, assess, educate, and implement all of the components that will deliver high value care to our patients". Convincing our physician colleagues and the remainder of the health care system will be a challenge, however success is rooted in focusing on the true cost and quality components that will fundamentally transform the delivery system. This will require focused research efforts on comparative effectiveness of surgical techniques, competing technologies, medical imaging, and quality of life. We will face great pressures from new devices and new medications, but it is our responsibility to sort out the value for our patients.

This meeting is an attempt to provide this broad approach to these issues for all of our members. Dr. Neal Ellis and Dr. James Merlino worked diligently to structure a well balanced program. The team have introduced the first large scale simulation based laparoscopic training schema to augment the traditional didactic and cadaver based programs. The combination of symposia and scientific sessions will relay information regarding management of many of the issues that distinguish a colorectal surgeon: rectal

cancer; inflammatory bowel disease, perioperative care of the colorectal surgical patient; and complex anorectal surgery. Dr. Martin Luchtefeld will update us on the components of Maintenance of Certification (MOC) that will need to be made relevant and confirmatory of the longitudinal competency of a colorectal surgical specialist. Provision of a focused curriculum created to develop excellent colorectal surgeons capable of image guided, endoscopic, laparoscopic, and open surgical management of colorectal pathology, as well as the ability to deliver high quality proctology should remain our imperative.

In conclusion, it is best to accept the unknown unknowns, our Black Swan, assess their true meaning and successfully adapt by looking forward not backward. Blame and retrospective analysis of how we got here have little role nor benefit. We have the opportunity to construct and transmit meaningful care plans for the treatment of our patients which appropriately apply technology, skill, and caring while carefully balancing the cost. Value is the most successful component of a business model for any company and clearly well within the reach of the ASCRS membership to deliver to our patients. It has been my distinct honor and privilege to work with and for all of you over the last 20 years. I am confident that given our past successes, and our well shepherded and developed resources, we will continue to be the leaders in colorectal surgery for the benefit of our patients.

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