Memo to STARS Group

On the eve of our first gathering I am composing this memo about key items relevant to our project, while I have before me the sources that I draw upon.

Our proposal lumps together the names of Gell-Mann and Hartle, and Roland Omnes and Griffiths so many times as almost to make it appear that these four are all in the same boat, which (boat) thereby gains the authority of having four eminent physicists, all seeming toBlood Products Advisory Committee MeetingDecember 12, 2002Issue Summary: (1 of 3 for the BPAC Bacterial contamination topic) Quality Control (QC) Measures for Aseptic Collection and Processing of Platelets and Platelets PheresisBackground:Although blood collection and processing procedures are intended to produce non-infectious blood components, bacterial contamination still may occur. Surveillance studies have found rates of contamination as high as 0.4% in single donor platelets, although rates at or below 0.2% are more reported. The causes include occult bacteremia in the donor, inadequate or contaminated skin be on-board.

Actually, there are huge differences between Gell-Mann and Hartle, on the one hand,

and Omnes and Griffiths on the other. The biggest difference concerns the Many-Worlds/Minds (Everett) interpretation. Supporters of this interpretation do indeed often mention these four names together, giving the impression that all support it. But Griffiths (in his book, “Consistent Quantum Theory” never mentions Everett or Many-Worlds (at least if the index and my perusal are good indicators). Griffiths obviously cannot distance himself too much from Gell-Mann and Hartle, whose endorsement provides important support of the notion that his idea is important. But he mentions Gell-Mann and Hartle only once in the main text, on page 358, at the end of the penultimate main-text chapter. And that reference is pretty weak. It mentions the (completely true) fact that decoherence-effects make it very difficult to observe quantum interference effects in macroscopic systems, and ASKS:

“If a quasi-classical family can be shown to be consistent, will preparation at the phlebotomy site, coring of a skin plug by the phlebotomy needle, and breaches of the closed system from equipment defects or mishandling. Platelet products are more likely than other labile components to be associated with sepsis due to their storage at room temperature, which is permissive of bacterial growth. For the same reason, bacterial cultures of platelets provide the best indication of the rate of contamination, provided that the sample for culture is obtained on a suitable sample volume and at a suitable time post-collection.A variety of procedures may be used to obtain a valid platelethe histories in it obey, at least approximately, classical equations of motion? Again, this is at sample for bacterial culture. Aseptic techniques are required in order to minimize the risk of false positive cultures due to contamination at the time of sampling or upon inoculation in culture. Additionally, it is prudent to retain a sample that can be used for repeat culture to validate a positive result. Large volume samples removed from a several unit platelet pool or single donor apheresis unit can be cultured any time post-collection. However small volume samples (e.g. 2-5 ml removed from a single whole blood unit) should be obtained only after a 24-48 hour delay post-collection. The delayed sampling o nontrivial question.”

Thus is the tie-in to G-MH. It is via a double question, neither of which had in 1999 been answered, nor has either one yet been answered. What has been encountered are, instead, huge difficulties, which become truly enormous in a non-linear system with easily tapped energy sources such as a human brain. He ends this chapter on “Decoherence and classical physics” with the assertion “In conclusion, even though many details have not been worked out and much work remains to be done, there is no reason at present to doubt that the equations of classical mechanics represent an appropriate limit of a more fundamental quantum description based upon a suitable set of consistent histories.” No reason to doubt? Tf a small volume permits bacterial growth to a level that subsequent assays will reliably detect, thereby overcoming sampling errors at low contamination levels.High-Throughput Sampling Using a Sterile Connecting Device (SCD) Sampling solely for quality control purposes can be accomplished by an aseptic, but open method (e.g. needle aspiration) for units at the time of issue (i.e. for use within four hours) or on outdating units. Conversely, sampling of platelets for the purpose of establishing a criterion for issuance of platelets as "culture negative to date" based on a negative result of bacterial cultures requihat may be rue! But that is hardy an impressive tie-in to Gell-Mann and Hartle, who, in sharp fundamental contrast to Griffiths, say that their interpretation “is an attempt at extention, clarification, and completion of the Everett interpretation.” Gell-Mann and Hartle treat “measurements” as key building blocks, and use essentially von Neumann’s formulas for probabilities of sequences of *measurements*. Griffiths takes as basic, rather “possessed properties” and uses von Neumann’s formula for more than half his book before introducing measurements, which are deemed merely special situations wheres that the integrity of the closed system should be maintained. This is because platelets may continue to be stored for a variable period after sampling and before use. Suitable methods of sampling in this case would include the use of integral satellite containers, or stripping, refilling, and then pinching off duplicate pigtails. Sampling also may be done into collection containers via the use of sterile connecting devices.The FDA Guidance for Industry (Use of Sterile Connecting Devices in Blood Bank Practice, November, 2000) (1) describes an SCD as a functionally closed system for component preparation. Howere possessed properties of object and apparatus become correlated . But why on earth should mere “possessed properties” be organized to exist only at a sequence of times, which is the situation dealt with by the concept of “consistent histories”.

The same question can be asked about measurements, but G-MH tie measurements to IGUSs (Information Gathering and Utilizing Systems) which are supposed to “have interests” and “make observations”, and “employ the fundamental formver, given the room temperature storage of platelet preparations, current regulations do not permit extension of the 4 hour outdate for pooled random donor platelets pending submission of supporting data to ensure that sterility is not compromised by multiple SCD connections. While published US data support the sterility of SCD procedures when combined with visual inspection of the welded joint(2,3), a single European study described a 1.4% product contamination rate when an SCD was used to obtain samples for culture (4). Recent clearance of two semi-automated culture systems for QC of platelet components has geneula”, which “is used to compute probabilities on the basis of present data, make predictions, control future perceptions on the basis of these predictions (i.e., exhibit behaviour), …”

These marvelous systems, which have a close similarity to our consciourated momentum within industry to culture in-date apheresis products followed by either product quarantine for a defined culture interval, or recall of a culture-positive distributed product. In part due to the absence of published data supporting SCD for sampling from in-date products, FDA has previously taken the position that the cleared culture systems should carry special labeling prohibiting their use as pre-release screening tests, due to a) possible risk of increased extrinsic contamination from SCD sampling and b) absence of data for the cleared devices when used for pre-release testing c) concern about offs thinking selves, lie at the core of the G-MH scheme. But they say that the research into them

“we cannot discuss-label use of platelets older than the current 5 day shelf life (5). Similar concerns regarding extrinsic contamination may also exist if SCD procedures are used to collect a culture sample from many (or all) platelet products prior to release for transfusion. The Committee will hear a summary of available data on this issue. Quality Control StrategiesThe goal of quality control testing for bacterial contamination should be to assure that blood collection and processing procedures conform to defined standards. Statistically-based sampling of platelets for culture (or analogous testing) by a validated method will p here.” But these systems are what hold their whole logical scheme together, and tie the logic both to “our knowledge” and to the issues of what determines the times at which the “measurements” occur, and what is measured at those times.

The nature and functioning of the core elements and the answers to the core questions are left unanswered. Only the relatively simple questions are addressed.

Griffiths says (p.122) that the probability rules will depend on “data…that…must be obtained from observation.” So Griffiths, like G-MH must really bring in “observations”, hence presumably **observers**, who have powers.

Thus Griffiths bases his work on the probability formulas of von Neumann, which were about measurements that might be performed, or at least **events that might occur,** and render certain specified properties definite. But what brings about the specific arrangements of possessed properties only at a particular set of times? The whole approach seems to be radically incomplete, without a theory of event generation/creation! That is, of course, is what Whitehead claims/tries to supply!

Omnes is far more explicit about these issues. He explicitly rejects Everett,

[“we feel it impossible to accept” p. 348; “bluntly contrary to Ockham’s rule”p.348:

“we are goinrovide a reliable indication of the rate of contamination for all the labile products. However, the number of samples tested must be very large. (For example, based on Poisson statistics, it would require 0 failures out of 750 samples to be 95% confident that the contamination rate did not exceed 0.4%.) For very large blood collection centers, sampling on this order of magnitude may be possible by culturing platelets only at outdate. Conversely, small centers should consider testing of all units older than 24-48 hours by a process of sterile sampling at the time of issue or outdate. Daily (or, if frozen, weeklyg to look for another answer” p. 348: “remains, to say the least, difficult to accept” p.493; “is not fitted to bring back common sense into quantum physics” p.511:

“Rule 5: Physical reality is unique.” p. 494:in “The Interpretation of QM” Princeton 1994: “Insane idea, you might think, and I would agree.” p.212, in Quantum Philosophy,

Princeton 1999.]

On page 506 of his 1994 book Omnes summarizes his conclusions in Twenty-one

Theses) samples can be pooled to reduce the number of cultures. Individual samples contributing to positive pools should be retested singly to determine the identity of the contaminated units, thereby permitting a prompt investigation of potential correctable causes. Correlations with common causal factors such as operator errors, shift, reagent batch, or procedure should be considered. Retained duplicate samples should be used to confirm or reevaluate the initial bacteriological findings. The following will be presented by FDA for consideration as a minimal quality control program for all platelet products collected. Thesis 6 asserts: “The theory is unable to give and account of the existence

of facts.” In short, his theory is an empty-of-a-connection-to-REALITY at blood centers.As a quality control for aseptic collection and processing of labile components, blood collection centers should determine the rate of bacterial contamination in platelets at least yearly by culturing 1,500 or more units (about 30 units per week or 5% of units released after 24 hours of storage, whichever is larger.) Standard statistical methods should be used to identify significant deviations from a baseline contamination rate not to exceed 0.2%. The chosen method should be based on a predetermined level of confidence to exclude a maximum tolerated rate of contamination, and an action limit shological scheme.

This is a conclusion that he repeatedly affirms.

p.502 “Both theories (Copenhagen and Omnes’s) however fail when asked to provide an explanation of the existence of facts. …a possible ultimate difference between the mathematics of theoretical physics and reality.”

I would dispute this as regards the Copenhagen which accepts empirical/experiential

facts as givens, but it is, as Omnes himselt repeatedly emphasizes, true of his theory, which does not have IGUSs, or could be established.All instances of a positive culture should be investigated promptly to facilitate identification of a correctable cause. Whenever the observed rate of bacterial contamination exceeds the defined action limit, a comprehensive investigation into potential causes of contamination should be undertaken and all collection and processing procedures should be revalidated.Example: A blood center wishes to establish surveillance to detect bacterial contamination rates significantly in excess of 0.2%. The following chart is derived from binomial statistics:CandidateAction LimitConfidence in Power to detecnscious thinking human beings and their thoughts.

His theory has a logically structure, but no *causation* in the real world, which it fails to make contact with.

p.516 “Another feature of facts is still more striking. As long as one only thinks of them (rather than experiencing them) by envisioning their occurrence as so many possible phenomena, the representation takes care of them perfectly well. This representation

however breaks down when one comes to their actuality.”

p.504 “Finally there remains *the* problem, which is the existence of facts.

It was somewhat hiddenbehind wave packet reduction in the older interpretation,

but now that mostb other problems have been solved, or at least clarified, it stands pure and alone.”

In Omnes’s “Quantum Philosophy” Princeton 1999:

“One more revelation must be borne in mind,…the unbridgeable gap between theory and the real world, between thought and existence….Such is the new state of affairs that we must now face. ” p.238. This is an often-emphasized theme o Omnes.

But it is just a feature of his narrow/restrictive view of theory, which does not encompass an *ontological* theory that encompasses as irreducible realities such things as our human thoughts,t actual contamination rate @#(+)/# sampledPositive Result0.4%0.6%0.8%1.0%>3 per 40095.3%22%43%62%76%>5 per 80097.6%22%52%77%90%>7 per 160095.5%46%84%97%99.6%The blood center collects 12 units of platelets per day, five days per week. Cultures of units released after 48 hours, plus outdated units, number 30 units per week that are processed as 6 weekly cultures of five unit pools. An action limit is set to revalidate the collection procedures if the observed contamination rate exceeds 0.42% for yearly samples of 1,560 units. The action limit was established based on an expected contamination rate of 0.2%, a sampl ideas, and feelings, and similar simpler things also in the realm of concepts.

G-MH do include such realities, buried in the IGUSs that they introduce but fail to provide a theory of. But Whitehead explicitly builds his ontology around them.

Onmes casts doubt upon both the power of decoherence to do all that G-MH require it to do, and even upon the need to invoke decoherence at all!

p.503 (1994) “One of their essential ideas is to attribute completely to decoherence the dynamical origin of phenomena ….This point of view ….has a practical drawback,

which is that the theory of decoherence is still far from complete…, This is why the G-MH theory is still partly a program.” : p.504 The logical interpretation described in this book also remains partly incomplete becaue size of 1,560, and a cut-off determined as baseline plus 2-sigma variation. For this scheme, the likelihood of rejecting a conforming process is 4.5% (once every 22 years). The confidence levels (i.e. power) to exclude actual contamination rates of 1%, 0.8% and 0.6% are 99.6%, 97% and 84% respectively.Over a one-year period, 7 positive platelet pools are identified, traceable to 7 individual units. The individual cases were investigated, but no attributable cause was identified. The observed contamination rate of 7/1,560=0.45% exceeds the action level. Confidence that the actual contamination rate exceeds 0.2se of the unsatisfactory state of decoherence theory.”: “What was said about the impossibility of circumventing decoherence is still nearer to a conjecture than a proof.”

All of this is meant to emphasize that the approaches of Gell-Mann and Hartle,

and of Griffiths and Omnes are far from solid and complete, and that their failings

open the door to Whitehead. The needed theory of events and of IGUSs is built upon the Whiteheadian “Actual Occasions”, whose mental poles are conceptual representations

of the physically described structures that constitute their physical poles, and whose mental poles provide in cases where their physical poles are aspects of human brains the elements of our human streams of consciousness. This allows the IGUSs to have both the observer and control aspects that Gell-Mann and Hartle ascribe to them:

“Both singly and collectively we are examples of the general class of complex adaptive systems. When they are considered within quantum mechanics as portions of the universe, making observations, we refer to such complex adaptive adaptive systems as

information gathering and utilizing systems (IGUSes).The general characteristics of complex adaptive systems is the subject of much o% is greater than 95%. An intensive review is conducted, and all collection and processing procedures are revalidated. Questions for the BPAC:Do available data on the sterility of the sterile connecting device procedure support the use of this procedure to collect samples for bacterial detection from in-date platelet products?Does the Committee concur with FDA’s proposed statistical approach to providing quality control for platelet contamination?References:FDA Guidance for Industry (Use of Sterile Connecting Devices in Blood Bank Practice, November, 2000)AuBuchon JP, Pickard C, Herschel L Sterility of plastic tngoing research, which we cannot discuss here. From a quantum-mechanical point of view the foremost characteristic of an IGUS is that in some form of approxdimation, however crude or classical, it employs th fundamental formula, with what amounts to a rudimentary theory of ρ, H, and quantum mechnics.Probabilities of interest to the IGUS include those for correlations between its memory and the external world. (Typically these are assumed perfect, not always a good approximation!) The approximate fundamental formula is used to compute pubing welds in components stored at room temperature Transfusion 1995 35:303-307.AuBuchon et al. Experience with universal bacterial culturing to detect contamination of apheresis platelet units in a hospital transfusion service. Transfusion 2002; 42, 855-861.Mertens G, Muylle L, Goossens H. Possible implication of sterile connecting device in contamination of pooled platelet concentrates. Trans Sci 1997, 18(3),387-392 Wagner SJ, Moroff G, Katz AJ, Friedman LI, Comparison of bacteria growth in single and pooled platelet concentrates after deliberate inoculation and storage. Transfusion 1995; 35; 298-302.robabilities on the basis of present data, make predictions, control future perceptions on the basis of these predictions (i.e., exhibit behavior), acquire further data, make further predictions, and so on.”

This is a tall order! So a natural task for our group is to use the resources provided by Whitehead to fill this order in a way completely concordant with the principles of relativistic quantum field theory.