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Destigmatising the Placebo Effect

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Alfano's reframing of the operationalization of the placebo effect (PE) in the context of informed consent (IC) has broader implications for clinical practice, particularly with regard to the employment of the concept of authorized libertarian paternalism (Alfano 2015).

Stigmatization of people refers to the development of a value judgment declaring that a person with certain attributes is in some way of lesser status, diminished, or invalid, with resultant negative consequences for such individuals. Concepts may also be stigmatized, particularly those that are easily falsifiable, including, apropos of the subject of PEs, mesmerism, sugar pills, and sham procedures, and hence PEs have historically been regarded with great skepticism, exemplifying something dishonest, misleading, "unscientific," or invalid (Gold and Lichtenberg 2014).

While recent studies have revealed extraordinary insights into the placebo and nocebo effect (PNE), in many ways these insights have had only limited impact upon the practice of medicine or upon (negative) views of the PNE. There may be many reasons why this is so. It may be because of the inherent conservatism of medicine, the need for medicine to distinguish itself from nonconventional practices through its (scientific) method and its capacity to provide an account of mechanism, or the intransigence of firmly held views in any field of practice. Indeed, investigators have "long recognized that individuals tend to maintain rather than change their stereotypes, despite receiving evidence that counters them" (Lyons and Kashima 2003, 989). Enculturation in medicine, in particular, systematically reinforces that certain concepts and actions are "foreign" to valid practice through a process of stereotype maintenance. Conscious, deliberate, or incidental/unwitting utilization of the placebo effect is characterized as deceptive, unethical, unscientific, and unprofessional and hence an action that separates physicians from nonphysicians. However, as distinct from a modern correlate of mesmerism or purely charismatic practice, there is an extensive, well-validated evidence base demonstrating specific psychological and biological processes underpinning PNEs (Hall, Loscalzo, and Kaptchuk 2015). This emergent evidence base is not simply of passing interest but poses significant challenges to traditionally held beliefs about both the role of PNEs in medical practice and about medical practice more generally.

For this reason, we believe that it is essential to reconceptualize PNEs within the framework of routine clinical care and evidence-based medicine. Ignoring placebo effects as a result of definitional negativity will inevitably lead to the “theoretical, empirical, and programmatic difficulties” (Alfano 2015, 4) that have hitherto led physicians to willingly ignore or fail to consider the role of PNEs in their practice. This may impoverish physicians’ understanding of the range of factors that may determine their patients’ adherence to recommended treatment regimens, the adverse effects they experience, and the outcomes they achieve.

The teleological ends of any practitioner–patient interaction or intervention are, as Alfano notes, to provide benefit and reduce harms to the patient (Alfano 2015). Physicians operate to a greater or lesser extent within a biomedical interpretive framework, and their actions are often similarly based. Evidence-based medicine (EBM) encourages physicians to employ population data to inform individual patient treatments. Because of the difficulty in measuring particular outcomes at a population level and generalizing the results of population-derived data to the care of individual patients, physicians bound too closely to EBM may employ an epistemologically stunted viewpoint in relation to the clinical benefits of treating diseases like hypertension, limiting their assessment of benefit to easily quantifiable outcomes such as stroke and death. While it was certainly not the intention of the EBM movement to encourage a reductionist and context-independent approach to patient care, it is also widely acknowledged that much of medicine is practiced in a manner that excludes evidence or otherwise uses poor evidence.

One of the key issues in EBM is the limitation of understanding of what the evidence actually means, particularly to the patient (as discussed by Alfano [2015]). Each health care interaction occurs in a very specific context, and in the setting of EBM and IC, there is natural uncertainty as to how one distills and applies different forms of evidence in that context. Stigmatizing PNEs by ignoring a robust body of literature for their application to clinical care only adds to further uncertainty, particularly when considering shared decision making. A genuine dialogue between a physician and an empowered patient should enable authorization by the patient for the physician to undertake activities that may augment responses/outcomes and also minimize generic deleterious effects (Gold and Litchenberg 2014).

Alfano builds on the notion that unfettered patient autonomy might undermine the ends of treatment, particularly in an increasingly data-rich and complex interpretive climate of medical practice (McGuire, McCulloch, and Evans 2013). Alternatively, understanding patients’ perspectives may assist in directing their autonomy and agency towards beneficence and nonmaleficence. Indeed, noncoercive influencing is based on an appreciation of patients’ conception of their personal flourishing, and offers an explanation of how treatment effects might be augmented via expectation confirmation, classical conditioning, somatic attention, and feedback.

The expectation confirmation mechanism noted by Alfano clearly operates in clinical medicine, particularly in regard to nocebo phenomena, when exhaustive lists of potential adverse effects are typically delivered verbally and supplemented by acontextual consumer medical information. Such a negative context can also be reinforced by any bias induced by the physician’s own beliefs regarding the balance between efficacy and the risks of harm, which may influence the quality and quantity of information given as well as the manner of delivery (particularly the behavioral components of the clinical encounter). Taken together, this can leave the patient free to misinterpret the somatic sensations that he or she might experience simply as a part of everyday life (Petrie et al. 2014). As Fasse and Petrie observe, such priming may mean that the “expectation of treatment side effects is consistently linked with those symptoms being realised” (Faasse and Petrie 2013). This has the potential to undermine not only current treatment, but in the context of learning processes (such as classical conditioning), future therapeutic interactions.

Destigmatizing the PE necessitates an understanding that “placebogenic mechanisms are not alternatives to traditional treatments; they can be used to fine-tune and enhance traditional

treatments” (Alfano 2015, 8). In fact, PEs are inherent in routine medical practice, and destigmatizing the PNE is an appropriate step in further improving therapeutics. Using a well-established EBM approach, we would suggest that the PICO (Patient, Intervention, Comparator, Outcome) strategy both easily and naturally incorporates contemporary understanding of PNEs:

Patient: Knowledge of your patient’s problems at biological, psychological and social levels, particularly appreciating the application of the literature to the specific therapeutic context, without which one lacks a complete appreciation of the different influences on responses to treatment.

Intervention: Consider both the specific intervention itself and how the role of context may shape the overall benefit (or harm) of that intervention. In other words, select what represents the contextually defined best intervention.

Comparator: What are the comparative benefits and harms that are identified in the evidence-based literature that are relevant to the patient in the particular context in which they are evaluated.

Outcome: Determine what outcome(s) the patient desires, and whether these outcomes can realistically be achieved in their situation. This represents an important alignment between the patient’s expectancies and desires, the physician’s beliefs about outcome and the application of various levels of evidence, including at times a potential conflict between outcomes which are deemed meaningful in research trials and those deemed meaningful by patients and their physicians which would contribute to informed decision making (Bromwitch 2015, 4).

Destigmatizing PNEs will provide opportunities to improve clinical outcomes and the ethics of clinical care by enhancing beneficence and nonmaleficence. Research findings over the last decade leave us no option but to accept the biological validity of PNEs and acknowledge that they are integral to routine care. As Alfano alludes to, modern conceptualizations of PNEs are not about the nefarious deceptive administration or omission of treatments, but rather the optimization or management of these mechanisms in practice. This is particularly true in light of evidence demonstrating that placebo effects can be enhanced even when patients are aware that they are receiving treatments that are aimed at augmenting PEs (Kaptchuk et al. 2010). Studies such as these force us not only to destigmatize PNEs but also to radically rethink the psychosocial context in which medical care occurs and the impact that this may have on patient outcomes.

If we are at least aware of the emerging literature on PNEs and can accept that “people’s preferences and values are to some extent indeterminate, unstable, and context sensitive” (Alfano 2015, 11), then it is much easier to see that framing and shaping advice is not deceptive when undertaken with patient consent. Indeed it is difficult to imagine how a patient would find objectionable a preamble to advice giving that indicated that giving them information in a certain way could increase their benefits and reduce their potential for harms from a form of therapy. Indeed, it would be ethically objectionable not to do so. As Alfano and others have noted, whether physicians “like” it or not, PNEs effects are undoubtedly evoked by and operate within physician–patient encounters, and if we are committed to using therapies supported by the best currently available evidence, then we must destigmatize the PE and harness it to optimize patient outcomes.

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