SYNESIS
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Wakefield Effect

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Abstract

Herein we address problems related to a paper published by Wakefield and collaborators in the medical journal Lancet. *We use methods of Best Available Science (BAS) and Metrics for Evaluation of Scientific Claims (MESC) derived from BAS and Best Available Public Information (BAPI) developed for the assessment of public media to identify fallacies of "Wakefield Syndrome". We also evaluate the mission of* Lancet *as described by its editor, the impact of the claimed Syndrome. We address problems in the Wakefield paper, as related to the mission of* Lancet*, and the impact of these problems, and so doing we propose a "Wakefield Effect" of dissemination of inaccurate scientific information published in scientific media.*

Keywords: MMR vaccination, Best Available Public Information, peer review process, scientific journals as public media

Introduction

During the last several decades, the interaction between the scientific publications and the public media has increased dramatically, in part as a consequence of the introduction of the Internet. Although the interest of public media in scientific issues has existed for a long time, the increases in public funding of scientific research, particularly in biomedical disciplines, has introduced new opportunities for reporting scientific advances in the media. Unfortunately, for a number of reasons, public media have faced difficulties in making a distinction between reasonably reliable scientific information and speculative information. The publication of an article by Wakefield et al. (1998) in *Lancet*, a reputable medical journal demonstrates the problem (1). Wakefield et al. claimed that children developed autism as a consequence of recurring measles, mumps and rubella (MMR) vaccination. Subsequent to the publication of that article, the term "Wakefield Syndrome" was used to describe the alleged relationship between the MMR vaccine and autism.

Our interest in the Wakefield Syndrome resulted from several projects that fundamentally address scientific issues of societal concern, including information disseminated by journalists and other media sources. The first project, initially called Best Available Journalism, led to an expansion to be called Best Available Public Information (BAPI) due to recognition that journalism is no longer the sole process through which the public receives information. This BAPI project attempts to evaluate the existing journalism process, how the Internet has changed information dissemination, and how the public should evaluate the validity of claims. The BAPI project originated with the Best Available Science (BAS) concept and Metrics for Evaluation of Scientific Claims (MESC) derived from it (2).

In this light, the significance of publishing an inaccurate scientific article in a widely distributed and reputable medical journal, the repudiation of Wakefield Syndrome by a large segment of the scientific community, and disregard of information rejecting Wakefield Syndrome by a segment of media deserves particular attention. Conse-

quently in this paper we propose a new term, the Wakefield Effect, which we define as:

> *the consequences of dissemination of flawed or fraudulent scientific information published in scientific media*.

This paper is not intended to comprehensively review the scientific aspects of the MMR vaccine, including its safety. As of this date BAS/MESC and BAPI systems have not been applied to the Wakefield Syndrome, as they were unavailable to investigators who evaluated the scientific aspects of Wakefield work and the media reaction. Instead the information in this paper attempts to address the following:

1. Key scientific issues related to the publication of the paper by Wakefield et al. (1);

2. The role of the media in reporting the Wakefield Syndrome;

3. Shortcomings of the process used by *Lancet*, where the paper was published, and the need for reevaluation of the process;

4. Application of BAS/MESC and BAPI systems to describe Wakefield Effect.

Procedures and Methods

The BAS/MESC has been widely discussed and published, including in this journal (3). Consequently, in this paper we describe only those features that are applicable to the work of Wakefield et al. The fundamental tenants of BAS/MESC consist of Open-Mindedness; Skepticism; Universal Scientific Principles; Reproducibility; and, Transparency. These are used to evaluate scientific information (SI) using three "pillars", consisting of assessment of reliability of SI; the level of maturity of SI; and areas outside the purview of science.

The core of the reliability pillar is peer review. Key elements of peer review are:

1. that the reviewer must be qualified in the work that is being reviewed, without having to undertake extensive study,

2. that the individual must be independent and has no conflict of interest,

3. the review criteria (questions) must be provided to the reviewer, which address scientific aspects of the paper.

The pillar addressing the level of maturity attempts to standardize SI. The highest level of maturity is Proven SI consisting of scientific laws. The next group "Evolving SI" covers a range of SI in terms of their level of maturity. Evolving SI includes Reproducible Evolving SI, Partially Reproducible SI, Association-based, SI, Hypothesized SI, SI-Based judgment, and Speculation. Finally this pillar also includes fallacious information.

The BAPI project attempts to use a system analogous to BAS/MESC for evaluation of public information. Using criteria and principles common in journalism profession information related to a fact or event can be categorized as follows:

- Coverage of a Fact: The decision by a reporter or manager of public news medium to cover some fact or event.

- Description of a Fact: Once a decision is made to cover a fact, it must be described as accurately and succinctly as possible. Ideally, there is no judgment on what to include or exclude in the coverage of the fact or event- all relevant information is provided.

- Interpretation of the fact: The reporter attempts to interpret the fact, in so doing, makes a judgment, but such judgment is limited to those areas within the fact or event so that the recipient audience can understand as completely as possible.

- Commentary: In contrast to previous parts, Commentary consists of not only interpretation of a fact but also placing it in the context of social issues as envisioned by the commentator. Individuals involved in this category are commonly called pundits who use the fact to express personal opinions.

Classification of Public information

Public information can be classified according to four domains.

1. Proven Information: of materials containing undisputedly true information. For example, there is no dispute that sun rises and sets on a regular basis. The text of the US constitution is well-known and is not

subject to dispute, and there was a war between two forces during the first half of the 20th century and allied forces were victorious.

2. Evidence-Based Information: A public information claim that includes reasonable evidence in support. For example, a reporter claims that an accident occurred on a highway and provides pictorial and other evidence supporting the claim. Historical evidence suggests that in certain cases, the reporter misunderstood the event, the information was incomplete, or there were other shortcomings in reporting. Consequently, only after all potential shortcomings are satisfactorily resolved, can this be considered Proven Information. The journalism profession has established a verification process to ensure the reliability of information in this class. Although many newspapers follow this process, others do not. In addition, each newspaper follows its own version of the verification process (see Rudin and Ibbotson 2002; Stovall 2004, 2005 (4-6)).

3. Gray Information: Information resulting from a claim without providing any evidence falls into this class. For obvious reasons, this class must first be raised to Evidence-Based Information before it can be seriously considered, and advanced then to the next class (Proven Information) before it can be considered to be true.

4. Fallacious Information: This class consists of clearly false, misconstrued, or incorrect information. Unfortunately, the volume and quantity of information falling into this class is large, too large to be reasonable (5,6).

Wakefield Syndrome

In this section we attempt to address key scientific issues related to the publication of the "Early Report" published by Wakefield et al. in which "…groups of 12 previously normal children…" were studied who were vaccinated with measles, mumps and rubella (MMR) vaccine (1). The authors claimed that the age of the children vaccinated ranged between 3-10 years; nine children developed autism,three had other behavioral problems. The authors performed a number of tests and found that the vaccinated children had more clinical abnormalities than normal children. One of the key conclusions of Wakefield et al. was: "We did not prove an association between the MMR vaccine and the syndrome described."(1). They also claimed that if there is a causal relationship between MMR vaccine and autism, the occurrence of autism would increase in the future in the UK (as MMR vaccine started to be used extensively in the UK at about 1998) (1). Wakefield et al. quoted Wing (1996) indicating that there was no evidence for or against the prevalence of autism in the UK (7).

The editor of *Lancet* sought comments dealing with the paper by Wakefield et al. and published in the same issue of the journal a commentary by Chen and DeStefano from Center for Disease Control and Prevention (CDC) in Atlanta, GA who suggested that a true reaction to a vaccine requires (8):

1. a specific laboratory finding,

2. a specific clinical finding,

3. epidemiological evidence.

In a cautiously worded statement, Chen and DeStefano suggested that Wakefield et al. did not meet any of these requirements. Subsequent to the publication of the two papers, several letters to editor appeared in *Lancet* in (March of) 1998 including Lee et al.; Black et al.; Beal; O'Brien et al.; Payne and Mason; and Lindley and Milla (9-14). Of interest was the response by Wakefield (1998) who defended the study and claimed a distinction between clinical medicine and public health (15). The same issue included a response by three other authors of the Wakefield et al. paper (Murch et al. 2008) who were somewhat more cautions by stating that "we emphatically endorsed the current vaccination policy until further data are available" (16). Shortly thereafter Peltola et al. (1998) provided the results of a 14-year study in Finland claiming no evidence for association between MMR and autism (17). Similarly, Taylor et al. found no epidemiological relationship between the MMR vaccine and autism (18).

Facing severe criticism, Wakefield and Montgomery (2000), using the information published by Stokes et al. (1971), claimed to have evaluated data during 1975 in the US, and during 1988 in the UK that confirmed the findings of Wakefield et al. (1998) (1,19,20). However, Elliman and Bedford (2001) subsequently evaluated the study by Wakefield and Montgomery and identified numerous shortcomings and errors (21). For example, the study by Stokes et al. (1971) evaluated data in 1971 in the US, and 1972 in the UK and not 1975 and 1988 as

claimed by Wakefield and Montgomery (19). Similarly, Wakefield and Montgomery disregarded a large number of studies that contradicted their claim, notably the study Peltola et al. (17).

A retraction signed by 10 of the original coauthors of Wakefield et al. (1998) indicated that they did not accept the conclusions of the initial paper (1,22). Horton, the editor of *Lancet* shared the concern expressed by Murch et al. and complained that unethical behavior of authors needed to be addressed by the organization where the investigators are employed (22,23). In addition Horton (2004) stated that "It seems obvious now that …publication [Wakefield et al. paper] would not have taken place in the way that it did." (23).

In response to significant criticism of the *Lancet* process Horton published a book (Horton 2004) attempting to address key issues that led to the publication of the Wakefield et al. paper (24). Referring to the statement by Murch et al., Horton claimed that the Wakefield paper was at least partially withdrawn in 2004 (22). He also identified a number of allegations against Wakefield, and suggested that *Lancet* should apply guidelines of the Committee on Publication Ethics (COPE) in accepting future manuscripts. Despite the statement by Horton the withdrawal took place much later (25) and was explained by Horton in 2001 (26).

A report by the Institute of Medicine, an organization within the National Academy of Sciences, National Academy of Engineering, and National Research Council reviewed the safety of the MMR vaccine and concluded that there was no evidence that autism was caused by MMR vaccination (27). However, the report recommended further research. A later report confirmed the previous report and expanded the process by providing guidance and structure for weight of evidence for or against the application of a vaccine (28).

Reaction of the Public Media

It would have been desirable to evaluate the reaction of the public media to the paper by Wakefield et al. between 1998 when the paper was published, and about 2004 when convincing evidence on the false claims of the paper became evident. Unfortunately lack of access to the local newspapers in the UK made it impossible to do so. However, Mason and Donnelly (2000) provided a description of relevant information published in *South Wales Evening Post*, a local newspaper in the UK (29). The newspaper started a campaign "MMR parents' fight for facts" Apparently during the period July to September 1997 the paper published 26 articles (including six front page articles). As expected the vaccination rate among children was reduced. Starting with information published in *Lancet* in 2004 many news organizations published information describing the issues related to the subject. The media, particularly in the UK reported extensively once the paper was withdrawn.

One of the key issues in addressing the reaction of the public media is the identification of the nature of the journal where the paper by Wakefield et al. was published. There are fundamentally three groups of scientific publications. Whereas the first group, journals, publishes almost entirely peer-reviewed scientific articles, the second group, magazines, publishes news and other information of interest to its readers. Traditionally, the information published in a magazine follows the process and tradition of the news media with comparable reliability. The third group, including *Lancet*, is a hybrid that publishes both peer reviewed articles as well as news items much like magazines. This categorization of scientific publications is important as each category has specific audience. Horton (2004) the editor of *Lancet* suggests that "Today the pivot between scientists and the public is the scientific journal." (24). He implicitly and explicitly implies that the journal is published not only for the scientific community but also for the public including journalists. Horton suggests that "Medical journals are ...highly specialized newspapers" (24, p.148). Accordingly, *Lancet* is the medical version of a newspaper that publishes information for, let us say, Hispanic Americans or UK residents of Pakistani origin. Horton implied that the authors of scientific articles have freedom of expression similar to those expressed by journalists in their publications in the public media (24).

In a series of articles, Deer described misrepresentations, falsification of the data, financial conflict of interest, and numerous other misdeeds of the primary author (30,31). In many cases, the journals cannot readily identify these misdeeds as peer review cannot readily identify falsification of data and many other misdeeds of the authors (32). The Deer studies were commissioned by a medical journal but were widely distributed in the public media. Deer raised several questions identifying not only misdeeds of the authors, but also shortcomings of the processing of the manuscript.

Emergence of the Wakefield Effect

Here we will try to address shortcomings of the process used by *Lancet*, the journal in which the Wakefield et al. paper was published. Horton, the Editor of *Lancet* has published information that provides the philosophical foundation of the journal's publication process. In the response to several letters to the Editor criticizing publication of the Wakefield et al. article, Horton (1998) defended the decision to publish the paper (33). He conceded that he decided to publish the paper because "The description of what seems to be a new syndrome and its relation to possible environmental triggers was original and would certainly interest our readers" and "…full disclosure of new data is preferable to well-meaning censorship". He continued by stating that "Rather than dismiss what they have reported, other investigators must urgently seek to confirm or refute their findings." (33).

In his book, Horton wrote the details of investigations dealing with misdeeds of the authors of Wakefield et al. (24). He considered the reputation of journals to be based on several criteria including their longevity, impact, the fame of their editors, and their visibility. Not mentioned is the reproducibility of information they publish, which we believe is by far the most important criterion for a journal.

Horton argued that there are several questions that have not been asked and have not been answered (24). He claimed that there are no answers to what he called urgent questions. These questions are (24):

1. Who represents families impacted by MMR vaccine?

2. What qualifies as reasoning? Would newspapers' accusations or personal attacks qualify as reasoning?

3. Who defines what is uncertain and who decides when uncertainties are resolved?

4. Who decides what admissible defense to diminish uncertainty is?

5. Where is the reasoning to be played out and do we need a process to make a decision?

By asking these questions Horton expressed his views as a journalist rather than as the editor of a scientific journal. The primary responsibility of a scientific journal must be to ensure scientific accuracy of the published material. The editor of a scientific journal must insist that authors address uncertainties in their paper, as was done by Wakefield et al. Furthermore, a properly performed peer review must also identify uncertainties associated with the experimental data or other information included in the manuscript.

Peer Review Process

One of the important issues of the article by Wakefield et al. was the peer review process used by *Lancet*. Horton argued that editors must "…rely upon imperfect process of peer review to assist their decision" (24). However, regardless of imperfections in the peer review process, there is a need to evaluate the peer review process used by *Lancet*.

Review Criteria: In the past, many journals identified reviewers and asked them to evaluate a manuscript without providing them specific questions, known as review criteria. However, experience has shown that without review criteria reviewers often answer general questions and do not address key issues. Consequently virtually all reputable journals provide the reviewers with specific review criteria (34). The editor considers the comments and recommendation by the reviewers and decides to accept the manuscript, reject it, or ask the authors to revise it.

Our attempt to obtain details of the peer review process from *Lancet* was unsuccessful. On April 17, 2011 one of the authors of this paper (35) contacted the Editor of *Lancet* asking for review criteria used to process the article by Wakefield et al. On April 26, 2011 Sabine Kleinert, Senior Executive Editor of *Lancet* suggested that "… the peer review process is confidential." We responded by indicating that "…we do appreciate that the comments by the reviewers are confidential. However, the review criteria are not confidential and are often placed on the website so that the authors can design their submission in a manner that reduces the time and the labor of everyone involved." The response by Kleinert was quick, stating that "… we do not have any generic review criteria."(35). The website of *Lancet* references the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications" for its peer review process. Under section II C Peer Review that document states: "In the interest of transparency each journal should publicly disclose its policies and instructions for authors."

Reviewers:In a blind or double blind review the identity of reviewers is not revealed. Therefore it is not possible to evaluate the qualifications of the chosen reviewers or if they had conflict of interest and if they did how the subject was addressed. Characteristically, many scientific journals require reviewers to declare (potential) conflicts of interest prior to reviewing a particular paper. Similarly we had only indirect information on the number of reviewers. Offit indicated that the paper was submitted to six peer reviewers and four reviewers recommended rejecting it (36). We have no information on the comments by those reviewers who recommended rejection or those who did not.

The Role of the Editor: It is well-known and well-recognized that the Editor of a journal is legally, intellectually, and morally responsible for accepting or rejecting a submitted manuscript. In a journal that publishes broad areas of science, the editor faces significant problems in identifying qualified reviewers and must judge the validity of their comments. Although in most cases, particularly in journals that receive many manuscripts, some of these activities are delegated to Assistant Editors and others, the Editor retains the ultimate responsibility.

By far the most important responsibility of the editor is to work to ensure the scientific acceptability of the paper before it can be published. In particular, the conclusions of a manuscript must be based on the results of the experimental or other parts of the study. Furthermore, certain information generated between the time that a manuscript is submitted and its acceptance is considered to be privileged. At least in one case when an affected company tried to receive reviewers' comments the courts in the US agreed with the journal (37).

Transparency of the Process: One of the key criteria for acceptability of the peer review process is transparency Moghissi et al. describe in detail a court case when a drug company sued a medical journal seeking the comments of the peer reviewers prior to the publication of paper (32). The court decided in favor of the medical journal. Although there may be an inherent conflict confidentially requirements of the peer review process and the highly desirable transparency. This conflict is often resolved by having reasonably detailed manuscript management process that includes how the reviewers are selected, availability of review criteria that are applicable to all submissions, how manuscript specific criteria are selected, and several other relevant issues. In contrast, identity of reviewers, response of the reviewers to the review criteria, and details of interaction between the editor and the authors remain confidential.

The editorial process attempts to ensure that submitted manuscripts meet certain fundamental requirements:

1. The manuscript must be within the area of coverage the journal.

2. The manuscript must have been prepared in a style that is consistent with the format, and related requirements of the journal.

3. Most importantly (in scientific publishing), that the manuscript is scientifically acceptable.

4. (For some journals- notably those dealing with biomedical research) The potential impact and importance of the study.

Horton (2004) extensively discussed problems related to uncertain science and recommended the establishment of a National Agency for Science and Health (NASH) in Britain to assess the validity of various claims (Reference). In 1967 Kantrowitz proposed the establishment of a science court to reconcile scientific disagreements similar to the NASH idea (38). After a considerable discussion the concept was rejected. The primary reason was and continues to be the availability of the scientific consensus process when an independent organization establishes a panel and provides them with specific questions (assessment criteria) asking them to evaluate the existing literature. In addition, given the international nature of scientific endeavor, there is no reason for NASH having any more credibility than any other scientific organization in the UK or elsewhere.

Assessment of the Wakefield Effect

Given the views expressed by Horton, the first issue to be addressed is the role of a scientific journal. The second issue is a comparison between the process used by *Lancet* to accept the paper by Wakefield et al, and the process that is used by most other journals. Finally, the role of the media needs to be addressed. The assessment process will use BAS/MESC and BAPTI systems.

The Mission of Journals

There appears to be a wide gap between the views expressed by the editor of *Lancet* and the prevailing consensus on the role of scientific and medical journals. Based on his repeated statements, Horton considers a journal to be a specialized newspaper (26). Accordingly, *Lancet* is the medical version of a newspaper that publishes information for, let us say, Hispanic Americans or UK residents of Pakistani origin. The philosophical views of the editor of *Lancet* have a profound impact on the processing of manuscripts submitted to that publication. According to the US Constitution and comparable laws of many other nations, freedom of the press is guaranteed, and with minor exceptions, there is no limit on freedom of expression. The BAPI project was initiated to make a distinction between the description of facts and the opinion of journalists and others. Newspapers can and routinely do express opinions ranging from true facts, to biased or factually incorrect information. In contrast, based on the guides published by virtually all US and international professional scientific (including biomedical) societies (38, 39) the acceptance of a submitted manuscript implicitly and explicitly is based on reliability of the claim by the author. It is true that a hybrid (as defined in this paper) that publishes both peer reviewed articles as well as news and other items, the review and dissemination of the latter follows a process similar or identical that that used by newspapers. However, scientific articles published in either journal or hybrid must comply with scientific requirements.

As indicated above, the Editor of *Lancet* considers it to be newspaper covering medical information. Accordingly, if we accept that during the processing of the manuscript the editor assumed that experimental part to be correct, in the BAPI system they would fall in the "Interpretation of the Fact". In contrast the remainder of the information would fall at best in Gary Information or more likely in Fallacious Information.

Processing of the Wakefield Manuscript

Let us first accept the notion that during the processing of the manuscript the editors were unaware of falsification of the information in the paper and unethical behavior of the authors. Furthermore, let us assume that various tests reported by the authors were indeed performed, and the reported results were correct. This point implies that if other investigators would have performed the same tests using the same children, the results would have been the identical to those as reported by Wakefield et al. Accordingly, during the initial processing of the manuscript this part of the study would have qualified as Reproducible Evolving Science.

The authors were unable to identify the cause of the observed effects and conceded that they were not to establish a correlation between the MMR vaccine and autism. In other words, they made an observation and tried to explain it. This is the classical case of Hypothesized SI in the BAS/MESC system. Consequently, it is surprising that it took a long time for the editor of *Lancet* to recognize the problem and describe it in the statement published many years later (24). Another potential shortcoming of the process was the lack of generic review criteria. Virtually every scientific paper requires a structure, consistency with established scientific information relevant to the topic of the manuscript and several other critical criteria. Anecdotal evidence suggests that several reviewers recommended the rejection of the paper. The editor did not provide a reason for accepting it despite the recommended rejection.

Would it not be logical to inform the all authors- including Wakefield et al.- of generic review criteria that are used to evaluate the manuscript? How could the scientific community in general, and the affected scientific discipline, in particular, assess the reliability of the peer review process if there is no indication of the questions that were given to the reviewers to assess a manuscript? In effect, the editor tells the reader: trust me.

Conclusions

The philosophical foundations of processing the paper by Wakefield et al. were flawed. Scientific journals are not newspapers for medical people. It is true that peer review is unlikely to identify falsified data. However, a scientific journal as represented by the editor must recognize potential consequences of a paper and ensure that the claims of the authors are clearly derived from the information provided in the paper. The mission of a scientific journal is to provide its readers with the most accurate scientific information.

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