



# When Do Behavioral Treatments Become Generic?

Unintended Barriers to Dissemination in the  
Treatment Development System

Elizabeth Gifford, Ken Weingardt & Michael Wiesner  
Center for Health Care Evaluation  
VA Palo Alto Health Care System  
Stanford University School of Medicine

# Disclaimer

- The views expressed in this presentation do not represent the view of the US Department of Veterans Affairs or the VHA Office of Mental Health Services.
- We are Psychologists. We are not experts on copyright law.

# Case #1: Print materials

- A large integrated health care system decides to train all of its clinicians to competently deliver an evidence-based psychotherapy.
- The progenitor of the EBP receives usual and customary consulting fees for conducting workshops & supervision, and the system purchases hundreds of copies of the treatment manual.
- Clinicians would like to be able to download popular client handouts for download from their intranet site, but the publisher argues that this would violate their copyright protection.

# Case #2: Training workshops

- A university faculty member obtains a series of NIH grants to develop & evaluate a new EBP. She publishes a number of RCTs in the empirical literature documenting its efficacy.
- The professor establishes a for-profit business to offer clinicians training and certification in the EBP.
- A third party who would like to offer training in the EBP for public sector employees receives a cease and desist order from the company citing copyright protection.

# Case #3: Software application

- A University professor receives an NIH grant to develop a patient-facing web application designed to automate the delivery of an EBP.
- The professor publishes several RCTs in top-tier, peer-reviewed journals demonstrating that patients who complete the program have better long-term outcomes than those who receive treatment as usual.
- A large public healthcare agency would like to make the software application widely available to its patients, but the professor refuses, arguing that he “doesn’t disseminate before he evaluates”.

**Interestingly, this is not the first time this has come up...**

# NIH Public Access Policy

- The NIH Public Access Policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008). The law states:

The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available *no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.*

# NIH Public Access Policy Impact

- **Voluntary policy:**
  - From May 2005 to December 31, 2007,
  - 14,397 research-articles supported by NIH – out of a total 189,000 – were made publicly available through PubMed Central through a voluntary policy.
- **Mandatory policy:**
  - January 1, 2008
  - Well over half of NIH-funded articles are being submitted to PubMed Central, and the percentage is growing every day.
  - 400,000 users are accessing 700,000 articles every day.

# Definition of Public Access

- The author(s) and copyright holder(s) grant(s) to all users a free, irrevocable, worldwide, perpetual right of access to, and a license to copy, use, distribute, transmit and display the work publicly and to make and distribute derivative works, in any digital medium for any responsible purpose, subject to proper attribution of authorship, as well as the right to make small numbers of printed copies for their personal use.

--Bethesda Statement on Open Access Publishing

# The Fair Use Doctrine

- The “fair use” of a copyrighted work, including its reproduction for purposes of comment, teaching, scholarship or research, is not an infringement on copyright.
- The four-factor “fair use” balancing test
  - 1. the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
  - 2. the nature of the copyrighted work;
  - 3. the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
  - 4. the effect of the use upon the potential market for or value of the copyrighted work.

# Degrees of access

- **Traditional**
  - Access requires payment to a private publisher, the publisher typically owns the copyright and exercises close control over use
- **Public access**
  - Access is granted free of charge after a year, but many copyright restrictions remain
  - Addresses price barriers but not permission barriers
- **Open access**
  - Articles are free to access immediately upon publication, many copyright restrictions are lifted but some still remain
  - Creative commons licensing agreements
  - Addresses price barriers and permission barriers
- **Public domain**
  - All information is freely accessible, freely reusable, and unprotected by copyright

**Should treatment research  
products be publicly accessible?**

# Mandatory public access policy premises

- The integration and accessibility of biomedical research will speed discoveries, resulting in the prevention of death and disability
- The integration and accessibility of treatment research products will speed dissemination and implementation, resulting in the reduction of death and disability

# Mandatory public access policy premises

- The public has a right to have full access, without charge, to research findings supported by taxpayer dollars, after a reasonable period of embargo.
- The public has a right to have full access, without charge, to research products supported by taxpayer dollars, after a reasonable period of embargo.

# Challenge to Public Access

- Fair Copyright in Research Act (HR6845 – Now HR 801)
  - Conyers: It isn't fair to others who have contributed to the research (e.g., publishers). NIH policy will remove financial incentives and thereby impede scientific progress
  - Rebuttal: The 12 month embargo insures that incentives are maintained, copyright is not violated, and the public interests are served.

# Does public access slow scientific progress or creativity?

- Intellectual property law protects financial incentives and economic growth
- Importance of revenue as an incentive to produce creative works such as textbooks, monographs, works of fiction or new discoveries (in the case of patents)
- How do we weigh the financial incentives of private parties against the need for access to taxpayer funded treatment research products?
- If researchers were required to relinquish all copyright and patent rights, research product development and distribution would become less profitable. Would this slow the progress and distribution of research?

# Is treatment process copyrighted?

- (a) Copyright protection subsists, in accordance with this title, in *original works of authorship fixed in any tangible medium of expression*, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device.
- (b) In no case does copyright protection for an original work of authorship extend to *any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work.*

# National Center for Biological Information

- More than 2 million people a day are accessing these databases, seeking information to understand disease and advance research.
- The majority of these databases are integrated, allowing, for example, a researcher to instantaneously link from a study on a drug compound to a 3-dimensional view of the compound and then to genetic data on a gene thought to be related to the disease being studied.
- The linkages are copious, and this extensive integration is the great power behind these databases that drives discoveries.

# Do we need a National Center on Dissemination and Implementation?

- Treatment Manuals
- Treatment Components / Interventions
- Fidelity Measures
- Applications [e.g., web based trainings]
- Implementation interventions
- Implementation processes
- Treatment and Implementation Taxonomies