

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.

SUPERIOR COURT
CIVIL ACTION NO. _____

TAMAR MASSOYAN-ARTINIAN, on behalf of
her children, and MADISON SCHILTZ,

Plaintiffs,

v.

MONICA BHAREL, in her official capacity as
Commissioner of the Massachusetts
Department of Public Health and the
MASSACHUSETTS DEPARTMENT OF
PUBLIC HEALTH,

Defendants.

JURY TRIAL DEMANDED

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR
EMERGENCY MOTION FOR PRELIMINARY INJUNCTION**

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Plaintiffs Tamar Massoyan-Artinian, on behalf of her children, and Madison Schiltz (collectively, “**Plaintiffs**”), by and through their attorneys, Siri & Glimstad LLP, respectfully submit this memorandum of law in support of their motion for a preliminary injunction against Monica Bharel in her official capacity as Commissioner of the Massachusetts Department of Public Health and the Massachusetts Department of Public Health (“**Defendants**”).

PRELIMINARY STATEMENT

The Massachusetts Legislature has carefully considered which vaccinations should be mandatory for students attending both K-12 schools in the Commonwealth, and its world-renowned colleges and universities. For K-12 schools, the Legislature created a list of required vaccinations but then granted the Department of Public Health (“**DPH**”) authority to add additional vaccinations to that list through the usual process of adopting regulations. On the other hand, the Legislature required a different set of vaccinations for post-secondary students and did not give the DPH any authority to alter or enlarge that list.

The Legislature pointedly did not include the influenza vaccine in any of its lists. Nevertheless, on August 19, 2020, the DPH took it upon itself to issue a “press release” announcing it now required all children in K-12 schools, and all students attending colleges and universities to receive the influenza vaccine before December 31, 2020 (the “**Flu Shot Mandate**” or the “**Mandate**”). The problem is that the DPH has no authority to create a new vaccination mandate for students attending colleges and universities – only the Legislature can do that. Furthermore, all it did was issue a press release. It never took the steps needed to adopt a new regulation, such as providing prior notice or a public comment period. Thus, the Flu Shot Mandate is not a formal “regulation” and as such is unenforceable.

In addition to its other deficiencies, the DPH enacted the Flu Shot Mandate as a measure to prevent transmission of the flu and thereby decrease the burdens on the Commonwealth’s

healthcare system. However, over the past decade, multiple published surveys of all available medical studies have “found no evidence that vaccines prevent viral transmission” of influenza. This means that mandating the influenza vaccine does not serve to prevent its transmission. Further, independent reviews have repeatedly concluded that there is no reliable evidence that the influenza vaccine reduces the burden on healthcare resources. And since the DPH cannot support that the Flu Shot Mandate will prevent the spread of influenza or reduce the burden on the healthcare system, it has no rational basis or other grounds to vitiate the fundamental constitutional rights to bodily integrity, informed consent, parental choice, and substantive due process by forcing unwilling individuals to receive the influenza vaccine. Nor does it have grounds to so burden the right to an education enshrined in the Massachusetts Constitution.

Plaintiffs are an adult graduate student at Springfield College and a parent of two elementary school students in Waltham Public Schools. Each of these three students has received all the required vaccines to attend school but has not received the influenza vaccine. Nothing in the Commonwealth’s laws requires them to receive the influenza vaccine in order to exercise their constitutional right to an education. Nevertheless, the Flu Shot Mandate wrongfully threatens to prevent Plaintiffs from attending school on January 1, 2021, because they made the informed choice to not receive the influenza vaccine. Plaintiffs now bring this action seeking a declaration that the Flu Shot Mandate is invalid and *ultra vires* along with an injunction preventing its enforcement.

Plaintiffs do not question the need for robust public health tools to cope with the COVID 19 pandemic. However, the Flu Shot Mandate is neither legally adopted nor scientifically supported. If instead proper legislative and regulatory process had been followed, there would have been an opportunity to present to legislators and regulators powerful evidence that the Flu

Shot Mandate infringes on protected constitutional rights for no demonstrable public health benefit.

By granting the instant motion and enjoining the DPH from enforcing the Flu Shot Mandate, this Court will merely be maintaining the status quo. Plaintiffs do not oppose any individual choosing to receive the influenza vaccine. In fact, currently by employing non-coercive means, the DPH has achieved one of the highest levels of child influenza vaccination in the nation. Even with an injunction, the DPH will be free to continue to non-coercively encourage parents and students to receive the influenza vaccine just as it does now. Plaintiffs merely ask that they, and other students like them, be allowed to continue to attend their same schools during the pendency of this action without having to sacrifice their constitutionally protected rights in the process.

FACTS

A. Statutory Framework for Requiring Influenza Vaccine for School

The Massachusetts Legislature determined that in order to attend a K-12 school, absent an exemption, a child shall have been “immunized against diphtheria, pertussis, tetanus, measles, and poliomyelitis and *such other communicable diseases as may be specified from time to time by the department of public health.*” G.L. c. 76, § 15 (emphasis added). As for students attending colleges and universities in the State, the Legislature provided that all college students under thirty years of age, and all students in undergraduate or graduate health science programs need to have “been immunized against measles, mumps, rubella, tetanus and diphtheria,” and all college or university students who live in a dormitory must also be immunized against “meningococcal disease.” G.L. c. 76, §§ 15C, 15D. Thus, the Legislature chose a different set of vaccinations to apply to students in higher education settings as opposed to children in lower schools, and it did not grant the DPH authority to require additional immunizations for higher education students. *Compare* G.L. c. 76, § 15 *with* G.L. c. 76, § 15C.

The Massachusetts Administrative Procedures Act (“MAPA”), G.L. c. 30A, § 1 *et seq.*, provides the statutory scheme for an administrative agency to adopt regulations. Among other requirements, prior to adopting any regulation, MAPA requires an administrative agency, like the DPH, to provide notice to the public and a period of time during which the public has an opportunity to comment on the proposed regulations. G.L. c. 30A, § 3.

B. The Flu Shot Mandate

On August 19, 2020, without adopting a regulation, the DPH issued a press release entitled “*Flu Vaccine Now Required for all Massachusetts School Students Enrolled in Child Care, Pre-School, K-12, and Post-Secondary Institutions.*” (Ex. A.)¹ The press release declared that:

State public health officials today announced that influenza immunization will be required for all children 6 months of age or older who are attending Massachusetts child care, pre-school, kindergarten, K-12, and colleges and universities. ...

All students in K-12 must receive the seasonal influenza vaccine annually by December 31. ...

For older students, the flu vaccine requirement applies to all full-time undergraduate and graduate students under 30 years of age and all full- and part-time health science students. ... The only exception is for college and university students who exclusively attend classes online and never visit campus in person. College students who attend any classes or activities on campus, even once, must be vaccinated by December 31.

(*Id.*) The DPH also issued an FAQ which made clear that this requirement will apply perpetually henceforth. (Ex. B.)

At no point did the DPH adopt any regulation to codify this new purported requirement in this press release, nor were any of the MAPA requirements for adopting a regulation followed –

¹ All exhibits referenced herein refer to exhibits appended to the Declaration of Elizabeth A. Brehm filed herewith.

no prior notice to the public, no public comment period, no business impact statement published, nor anything filed with the secretary of state regarding any proposed regulation.

C. Plaintiffs Will Be Wrongfully Excluded from School or College on January 1, 2021

Plaintiffs and their affected children have received all immunizations required to attend college or school pursuant to G.L. c. 76, § 15 and § 15 C. None of them, however, have received an influenza vaccine. It is on that basis alone that Plaintiffs or their children will be excluded from their public K-12 schools or from their graduate program on January 1, 2021.

Plaintiff Tamar Massoyan-Artinian is the mother of two children, R.A., age 7 and H.A., age 11. (*See* Affidavit of Tamar Massoyan-Artinian, hereinafter “**TMA Aff.**”, at ¶ 1.) Both of the children have received all of the vaccinations required to attend their public schools in Massachusetts as of December 11, 2020. *Id.* Both children have a history of allergies and adverse reactions to medications, including amoxicillin and influenza vaccines. (*Id.* at ¶ 2.)

Plaintiff Massoyan-Artinian’s older child previously experienced intense adverse reactions to the influenza vaccine. (*Id.* at ¶ 3.) This child developed asthma at a young age and the condition worsened over time. (*Id.*) Each year, after receiving the influenza vaccine, the child suffered complications including bronchitis, bacterial pneumonia, respiratory infections, and asthma attacks. Most of these reactions led to Emergency Room visits, and one led to a hospitalization at Boston Children’s Hospital. *Id.* Her younger child had adverse reactions to the influenza vaccine as well, including high fevers, rashes, and asthmatic tendencies such as requiring a nebulizer and steroids to stabilize breathing. (*Id.* at ¶ 4.)

After the last adverse response to the influenza vaccine, Plaintiff Massoyan-Artinian stopped having it administered to both of her children. (*Id.* at ¶ 5.) She inquired about a medical exemption to the influenza vaccine from her pediatrician based on her children’s prior experiences

but was told that the medical practice “decided that it will not provide exemptions for the flu vaccine.” (*Id.* at ¶ 6.)

If the DPH mandate is enforced, it will make Plaintiff Massoyan-Artinian face the Hobson’s Choice to either (i) comply against her judgment as their parent and risking her children’s’ health, or (ii) continue to refuse and have her children excluded from school. (*Id.* at ¶ 7.)

If the children are excluded from school, it will have devastating real-world effects on the family whether they leave or stay in the state. (*Id.* at ¶¶ 8-14.) They have many strong ties to their local cultural and religious communities. (*Id.* at ¶ 9.) Plaintiff Massoyan-Artinian’s husband’s parents live close to them, and they are the reason the family is living where they are. (*Id.*) Leaving their family and community would be devastating. (*Id.*)

On the other hand, if they stay in the state and are excluded from school other irreparable harm will result. (*Id.* at ¶¶ 10-12.) Both Plaintiff Massoyan-Artinian and her husband work. (*Id.* at ¶ 10.) If their children are excluded from school, they will be forced to homeschool the children. (*Id.*) This will come at great expense as one of them would likely have to give up his or her salary to stay home and educate the children. (*Id.*) Neither of the parents is trained as an educator and homeschooling is outside their life plans and abilities. (*Id.*)

Furthermore, if the children are excluded from their school in January, they will be devastated. (*Id.* at ¶ 11.) Like other students, they have already experienced upheaval due to the COVID-19 restrictions, but now as there is light at the end of the tunnel on COVID, they will be told they can never go back with their friends, or their teachers. (*Id.*) The children will suffer emotionally and will experience anxiety if this new dramatic change is foisted upon them, especially after the very challenging and trying year they have already experienced. (*Id.* at ¶ 12.)

Plaintiff Madison Schiltz is a 27-year-old student, teacher, and coach. (*See* Affidavit of Madison Schiltz, hereinafter “**MS Aff.**”, at ¶ 1.) She is fully vaccinated and has received every vaccine recommended to her by her doctors except for the influenza vaccine. (*Id.* at ¶ 2.) She is a master’s graduate student at Springfield College, pursuing a masters in strength and conditioning. (*Id.* at ¶ 3.) She is completing her third semester, has a 3.78 g.p.a. which she has worked hard for, and currently expects to graduate with her master’s degree in May 2021. (*Id.*)

Plaintiff Schiltz grew up getting vaccinated “on schedule.” (*Id.* at ¶ 5.) She understands the risks and benefits involved with her medical choices, including vaccines, and typically feels the benefit outweighs the risks. She has not reached that conclusion with regard to the influenza vaccine. (*Id.*) She has worked very hard to get where she is, and to know she may be unable to complete her education due to something she does not consent to is troubling. (*Id.* at ¶ 6.) Thus, the fact that her education is being threatened by an unlawful mandate has caused her mental and emotional distress. (*Id.*)

When Plaintiff Schiltz first heard about the DPH mandate, she took action. (*Id.* at ¶ 7.) She contacted her student body government, other students, and eventually the President of Springfield College to discuss her concerns and her objection to this mandate. (*Id.*) Plaintiff Schiltz was told that this was a mandate from the DPH and so the school’s hands were tied. (*Id.*)

When Plaintiff Schiltz was accepted at Springfield College, an influenza vaccine was not required. (*Id.* at ¶ 8.) She cannot comply with this mandate and will continue to stand up for what she believes in: informed consent, bodily autonomy, and her constitutional rights to liberty. (*Id.* at ¶ 9.) If she is merely excluded from campus, and forced to complete her degree remotely, that too will cause her numerous harms. *Id.* Specifically, as she is currently a Graduate Assistant she will lose that position and the thousands of dollars in free tuition and monthly stipend that comes with the position. (*Id.* at ¶¶ 4, 11.) Without these, she likely would be unable to afford to complete

her degree. (*Id.* at ¶ 11.) Therefore, if the mandate is enforced, Plaintiff Schiltz will be forced out of her school and will be unable to complete the degree that she has already expended significant time and resources to obtain. (*Id.* at ¶¶ 11-13.)

D. The “Flu” and Influenza Vaccines

The DPH repeatedly refers to influenza vaccines as an approach for dealing with the “flu.” (*See* Expert Affidavit of P. Doshi, T. Jefferson, P. Gotzsche, and C. Heneghan, hereinafter “**Doshi et al. Aff.**” at ¶ 7.) However, most cases of the “flu,” respiratory infections, and illnesses are not caused by influenza virus but rather by other viruses. (*Id.*) Every year, hundreds of thousands of respiratory specimens are tested across the United States and, on average, only 16% are found to be influenza positive. *Id.* Hence, the influenza vaccine, even if it were an effective product, could only address a small fraction of the “flu” cases in Massachusetts. (*Id.*)

The influenza vaccine also changes every year to target new strains of influenza virus. (*Id.* at ¶¶ 7-9.) One implication of this variation is that influenza vaccines are manufactured each year without knowing their efficacy or safety profile. (*Id.* at ¶ 10.) This can only be discovered after the fact. *Id.* Moreover, as discussed in the accompanying expert affidavits by world-renown scientists, there is no credible evidence these products reduce the incidence of hospitalization or mortality. (*Id.* at ¶¶ 14-16.) On the other hand, those same experts detail how influenza vaccines can cause serious injury and death, including various autoimmune and neurological disorders (*Id.* at ¶¶ 17-22) and can have serious unintended consequences including increasing susceptibility to other infections. (*Id.* at ¶¶ 23-26.)

ARGUMENT

I. PLAINTIFFS ARE ENTITLED TO A PRELIMINARY INJUNCTION

Given the December 31, 2020 deadline established by the DPH, Plaintiffs are forced to seek a preliminary injunction to stay enforcement of the Flu Shot Mandate so as to avoid the

irreparable harm of being precluded from attending school. To be awarded an injunction, the Plaintiffs must satisfy the familiar three-part test: “(1) a likelihood of success on the merits; (2) that irreparable harm will result from denial of the injunction; and (3) that, in light of the [moving party's] likelihood of success on the merits, the risk of irreparable harm to the [moving party] outweighs the potential harm to the [nonmoving party] in granting the injunction.” *Loyal Order of Moose, Inc., Yarmouth Lodge #2270 v Bd. of Health of Yarmouth*, 439 Mass. 597, 601 (2003) (quotations omitted). “When a party seeks to enjoin governmental action, a judge is also required to determine that the requested order promotes the public interest, or, alternatively, that the equitable relief will not adversely affect the public.” *Id.* (quotations omitted)

“A preliminary injunction ordinarily is issued to preserve the status quo pending the outcome of litigation.” *Doe v. Superintendent of Sch. of Weston*, 461 Mass. 159, 164 (2011). That is all that Plaintiffs seek here, to preserve their ability to receive an education while the court adjudicates the DPH’s mandate.

II. PLAINTIFFS HAVE A HIGH LIKELIHOOD OF SHOWING THAT THE FLU SHOT MANDATE IS INVALID AND UNENFORCEABLE

Plaintiffs are highly likely to succeed in the instant action because the Flu Shot Mandate is invalid and unenforceable for three separate reasons. First, the DPH lacked authority to apply the Mandate to post-secondary students and did so *ultra vires*. Second, for K-12 students, the DPH failed to comply with the MAPA procedures, making the Mandate unenforceable. Third, the Mandate is unconstitutional.

A. The DPH Lacked Authority To Adopt The Mandate For Post-Secondary Students

1. The Legislature Chose Not To Grant DPH Discretion to Mandate Any New Vaccines for College Students

It is settled law that “an administrative agency has no authority to promulgate rules or regulations that conflict with the statutes or exceed the authority conferred by the statutes by which

the agency was created.” *Massachusetts Mun. Wholesale Elec. Co. v. Energy Facilities Siting Council*, 411 Mass. 183, 194 (1991); *Goldberg v. Board of Health of Granby*, 444 Mass. 627, 633 (2005) (if a court “conclude[s] that the statute is unambiguous, [it] give[s] effect to the Legislature’s intent”).

With regard to requiring immunizations for attending K-12 school, the Legislature provided a list of required vaccinations, but then also permitted “such other communicable diseases as may be specified from time to time by the” DPH. G.L. c. 76, § 15. However, it made a different choice for immunizations required to attend colleges and universities. *Compare* G.L. c. 76, § 15 *with* § 15C. There, the Legislature did not grant the DPH any role in selecting the required vaccinations. Instead, it identified a finite list of required vaccinations. Specifically, the Legislature mandated that post-secondary students need to have “been immunized against measles, mumps, rubella, tetanus and diphtheria,” and “meningococcal disease” if they live in a dormitory. G.L. c. 76, §§ 15C, 15D.

It is axiomatic that a statute should be read in accordance with its plain meaning in light of the whole statutory scheme. *ENGIE Gas & LNG LLC v. Dep’t of Pub. Utils.*, 475 Mass. 191, 199, (2016). Clearly the Legislature knew full well how to grant the DPH authority in Chapter 76 to expand the list of required vaccinations through duly promulgated regulations and did so for K-12 students in Section 15. The fact that Section 15D is silent as to the DPH’s involvement, necessarily means that the Legislature intended to *not* empower the DPH to require additional immunizations to attend colleges and universities. Without such authorization to act, the DPH lacked authority to enact the Flu Shot Mandate for post-secondary students, and Plaintiffs will be able to establish that the Mandate cannot be enforced against such students.

2. The Legislative History Further Makes Plain the DPH's Lack of Authority to Mandate the Flu Shot to College Students

The vaccine requirements for a “child” to attend K-12 “school” in Section 15 was last amended in 1972. (1972 Mass. Acts 77.) When the Legislature, in 1985, wanted to require immunizations for attending college, it promulgated a new Section 15C. (1985 Mass. Acts 98.) At that time, bills were introduced to grant the DPH similar authority under Section 15C as it already enjoyed under Section 15. *See* MA H.B. 6099 (1984) and MA H.B. 222 (1985) (seeking to have Section 15C include in the list of required vaccines “such other communicable diseases as may be specified from time to time by the department of public health.”). But such language did not make it into the final bill. Thus, the Legislature’s choice to withhold authority from the DPH in this latter statute was not an oversight, but rather a deliberate choice.

Furthermore, during the thirty-five years since its enactment, the Legislature has had numerous opportunities to amend Section 15C to again grant the DPH a role in selecting the required vaccines. Numerous bills have been introduced to amend Section 15C to adopt language similar to Section 15, but each bill has failed to pass. For example, MA H.B. 180, introduced January 1, 1992, proposed amending Section 15C to add that the required vaccinations would include “other such communicable diseases, in accordance with regulations of the department of public health.”²

Given the Legislature’s unambiguous choice to withhold authority from the DPH regarding vaccinations for college students, that agency cannot now simply appropriate to itself the authority long denied it. For this reason, the Court must hold that the DPH cannot now be allowed to apply the Flu Shot Mandate to post-secondary students.

² The following bills also attempted to add the above language to Section 15 C: MA H.B. 192 (1993); MA H.B. 204 (1994); MA H.B. 170 (1997); MA H.B. 123 (1999); MA H.B. 133 (2001); MA H.B. 74 (2003).

B. The Flu-Shot Mandate Is Invalid Because The DPH Did Not Comply With MAPA

In order for the Flu Shot Mandate to apply to K-12 students, DPH should have enacted a “regulation” promulgated pursuant to the procedure required by the MAPA. G.L. c. 30A, § 1 *et seq.* However, DPH chose to not enact the Flu Shot Mandate as a regulation. It failed to provide prior notice to the public, an opportunity for the public to comment, and it never entered the Flu Shot Mandate into the Code of Massachusetts Regulations (“**CMR**”), all steps required by the MAPA. The DPH’s failure to follow such procedures means that the Flu Shot Mandate is nothing more than an *ultra vires* fiat with no legal force.

1. DPH Was Required to Follow the MAPA

When the provisions of the agency’s enabling legislation “prescribe a mode and method for the procedure for the promulgation of rules or regulations,” the agency must follow those procedures. *New England Milk Dealers Ass’n v. Department of Food & Agric.*, 33 Mass. App. Ct. 935, 936 (1992). “But where no mode and method of procedure for rulemaking are provided, the provisions of the Massachusetts Administrative Procedure Act are generally applicable.” *Id.*

G.L. c. 76, § 15 is the enabling legislation by which the DPH is authorized to regulate which additional immunizations – beyond those already required by that section – shall be required to attend K-12 school in Massachusetts. Because this enabling legislation does not specify the “mode and method” for adopting a regulation to require an additional immunization for school attendance, the DPH was bound to abide by the procedures contained in the MAPA before adopting the Flu Shot Mandate. *See New England Milk Dealers*, 33 Mass. App. Ct. at 936.

2. The Flu Shot Mandate is a Regulation

The MAPA, broadly defines a “regulation” as “the whole or any part of every rule, regulation, standard or other requirement of *general application and future effect*, including the amendment or repeal thereof, adopted by an agency to implement or interpret the law enforced or

administered by it.” G.L. c. 30A, § 1 (5) (emphasis added); *Carey v. Comm'r of Correction*, 479 Mass. 367, 371 (2018) (“Given the purpose of the APA, we interpret its definition of regulation broadly.”). Just because an agency chooses not to call something a regulation does not mean the requirements of the MAPA do not apply to it, rather a court must determine for itself whether the agency’s action falls within the definition of a regulation. *Carey*, 479 Mass. at 371 (holding that contrary to the commissioner’s contention, enacting a policy regarding visitors to prisons had to conform to the MAPA’s rules).

Even though the DPH only released it as a press release, the Flu Shot Mandate squarely falls within the definition of a “regulation” as defined by the MAPA. *Id.* It is a rule or standard of “general application and future effect,” and thus the DPH was required to comply with the procedures in the MAPA before adopting the Flu Shot Mandate. *See, e.g., Id.; Kneeland Liquor, Inc. v. Alcoholic Beverages Control Comm’n.*, 345 Mass. 228 (1962) (finding that alcohol price schedules that require agency approval set down public policy with legal consequences and thus are regulations under the MAPA); *Allied Theatres of New England, Inc. v. Commissioner of Labor & Indus.*, 338 Mass. 609, 611 (1959) (holding that labor department’s order setting minimum wages was a regulation under the MAPA).

3. Public Comment was a Prerequisite to Adopting the Flu Shot Mandate

The MAPA requires that “[p]rior to the adoption, amendment, or repeal of any regulation ... the agency shall ... afford interested persons an opportunity to present data, views or arguments in regard to the proposed action orally or in writing” and “[i]f the agency finds that oral presentation is unnecessary or impracticable, it may require that presentation be made in writing.” G.L. c. 30A, § 3. These notice and comment procedures are not mere formalities. Indeed, failure to abide by these requirements results in the invalidation of the regulation. *See, e.g., Carey*, 479 Mass. at 371 (holding that notice and hearing procedures under the MAPA are required to be

followed prior to adopting a new policy and deeming the new regulation unenforceable until it was reenacted by following the MAPA's procedures).

Here, the DPH never provided notice that it intended to adopt the Flu Shot Mandate, nor did it provide an opportunity for comment on the mandate prior to its adoption. These procedural lapses, among others, are fatal to the Flu Shot Mandate because, by failing to abide by the MAPA procedures, the Flu Shot Mandate was *never* properly adopted and so it is invalid.

Consequently, the Flu Shot Mandate does not carry the force of law as a "regulation." As explained by the Supreme Judicial Court, rules issued by an administrative agency without following procedures under the MAPA "do not have the same status as regulations adopted pursuant to the [MAPA]. . . . they do not carry the force of law." *Global NAPs, Inc. v. Awiszus*, 457 Mass. 489 (2010); *see also Evans v. Mayer Tree Service, Inc.*, 89 Mass. App. Ct. 137, 149 (2016) (agency protocols not formally promulgated do not carry force of law); *Massachusetts Gen. Hosp. v. Rate Setting Comm'n.*, 371 Mass. 705, 707 (1977) (finding that non-regulation agency guidance does not "have the binding force attributable to full-blown regulation").

Furthermore, the lack of public comment had substantive consequences here because it allowed the DPH to act based on faulty assumptions about the effects of the influenza vaccine, including that it would reduce hospitalization and the transmission of the flu. However, as discussed below, Plaintiffs' experts' reports show that these assumptions are not supported by scientific studies, a fact that could have been brought to the DPH's attention if it allowed the public to comment. (*Infra* § C.1.)

4. DPH Failed to Follow Procedures for Adopting an Emergency Regulation

The DPH's press release announcing the Flu Shot Mandate stated that "[t]he new vaccine requirement is an important step to reduce flu-related illness and the overall impact of respiratory

illness during the COVID-19 pandemic.”³ However, even assuming *arguendo* the DPH was entitled to a waiver from the formal deliberative processes of notice, hearing and public comment required by MAPA, due to the ongoing COVID-19 public health emergency, the DPH failed even to comply with requirements of the MAPA applicable to issuing emergency regulations.

Pursuant to sections 2 and 3 of the MAPA, an administrative agency may dispense with the notice, hearing, and public comment phases in the process of adopting an “emergency regulation” so long as “the agency’s finding and a brief statement of the reasons for its finding [are] incorporated in the emergency regulation as filed with the state secretary under section five” and any emergency regulation “shall not remain in effect for longer than three months.” G.L. c. 30A, §§ 2-3. The DPH did not comply with any of these when adopting the Flu Shot Mandate. It did not include a brief statement of the reasons to support an emergency regulation, did not file any such statement with the secretary of state, nor did it in fact promulgate any regulation, emergency or otherwise, to incorporate into the CMR. Moreover, the DPH provided that the mandate would continue indefinitely, well beyond the three-month time limit provided for an emergency regulation.

For all these reasons, Plaintiffs are highly likely to show that the Flu Shot Mandate cannot be enforced because it was not adopted pursuant to any of the requirements of the MAPA.

C. The Flu Shot Mandate Is Unconstitutional

Even if the DPH had enacted the Flu Shot Mandate pursuant to the rules required by MAPA, and it had the authority to regulate vaccinations for post-secondary students, neither of which it did, the Flu Shot Mandate must still be struck down as unconstitutional under the

³ <https://www.mass.gov/news/flu-vaccine-now-required-for-all-massachusetts-school-students-enrolled-in-child-care-pre>.

Massachusetts and United States Constitutions. When the DPH chose to condition the provision of an education on their injection of an influenza vaccine, the agency invalidated Plaintiffs' informed medical decisions, and impinged upon Plaintiffs' fundamental constitutional rights to bodily integrity, informed consent, parental choice, and the substantive due process rights under the United States Constitution and the Massachusetts Constitution.

1. Plaintiffs' Have Valid Constitutionally Protected Reasons to Refuse the Influenza Vaccine

While not necessary to decide that the Flu Shot Mandate is unconstitutional, Plaintiffs' decisions to not receive the influenza vaccine are entirely reasonable and rational. With virtually all pharmaceutical products, there are risks and benefits. Vaccines are no exception. (*See* Expert Affidavit of P. Aaby and C. Stabell Benn, hereinafter "**Aaby and Benn Aff.**" at ¶ 8; *see also* Doshi et al. Aff. at ¶¶ 17-26.) This is why the cornerstone of medical ethics is informed consent, a principle which is also a long recognized fundamental, civil, and human right. (*Aaby and Benn Aff.* at ¶ 5.) Informed consent requires conveying the risks and benefits of a medical procedure or pharmaceutical product to a patient and obtaining un-coerced consent. *See, e.g., Shine v. Vega*, 429 Mass. 456, 463 (1999) (reiterating the fundamental right to informed consent to "decide whether a particular medical treatment is in [the patient's] best interests"). Nonetheless, in enacting the Flu Shot Mandate, the DPH took away this right to informed consent for the influenza vaccine from all students in the Commonwealth.

It is a well-established fact that influenza vaccines can cause serious injury and death, as well as various harmful unintended consequences. (*Doshi et al. Aff.* ¶¶ 17-26; *Aaby and Benn Aff.* at ¶ 8.) Because of the dangers posed by vaccines, Congress enacted the National Childhood Vaccine Injury Act of 1986 (the "**1986 Act**"), which granted vaccine manufacturers (and any medical personnel that administers a vaccine) blanket immunity from liability for injuries caused

by these products.⁴ Vaccines are the only medical products in the U.S. with such immunity. This immunity creates a moral hazard for those promoting these products because product liability lawyers, one of the other pillars of how the U.S. ensures the safety of its drug supplies, play no role in the safety of vaccines.

Those injured by the influenza vaccine must file a claim against the U.S. government in the Vaccine Injury Compensation Program, administered in the United States Court of Federal Claims. (Doshi et al. Aff. ¶¶ 20-21.) Over \$4 billion has been paid out by this program for vaccine injury claims and influenza vaccines represent over 50% of these claims. (*Id.* at ¶ 21.) Injuries from influenza vaccines for which compensation has been paid include Anaphylaxis (severe allergic reaction), Bell's Palsy, Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), Complex Regional Pain Syndrome (CRPS), Cardiac Arrest, Death, Fibromyalgia, Guillain-Barre Syndrome (GBS), Multiple Sclerosis (MS), and Transverse Myelitis (TM), among many others. (*Id.*)

Moreover, in the last ten years, the Vaccine Adverse Events Reporting System (VAERS), administered by the CDC and FDA, has received reports of the following serious events following receipt of an influenza vaccine: 1,527 deaths; 3,327 permanent disabilities; 12,692 hospitalizations; and 40,040 emergency room and/or medical office visits. (*Id.* at ¶ 20.) A report from researchers at Harvard Medical School, including the Director of Bioinformatics, funded by an agency within the U.S. Department of Health and Human Services, stated that “fewer than 1% of vaccine adverse events are reported” to VAERS. (*Id.*)

The assumptions and advertised views about influenza vaccine products have stifled the ability for most people – even otherwise intelligent and analytical individuals – to rationally and

⁴ See <https://www.law.cornell.edu/uscode/text/42/300aa-1>.

objectively consider these products. This issue is compounded by the fact that many consider it off limits to even request to see the evidence which underpins claims regarding influenza vaccines. In a court, public health officials cannot justify their policies and statements regarding the influenza vaccine without evidence. Plaintiffs, therefore, respectfully ask that all preconceived notions regarding these products be set aside. That only proven statements be considered. And that the Court, if it reaches the constitutional issues in this case, cautiously examine the proof for any claim regarding influenza vaccines made by either party.

2. The DPH Did Not Have A Compelling Interest to Enact the Mandate

Having impinged on these constitutional rights, the DPH has the burden to prove it has a compelling state interest to exclude adults from college and children from K-12 school, and that exclusion is the least restrictive means to achieve the compelling interest.

Courts have recognized that the desire to control the spread of an infection can constitute such a compelling state interest. However, **that compelling interest to control influenza spreading from student-to-student is absent with regard to the influenza vaccine because studies have repeatedly concluded that there is no evidence to support that the influenza vaccine prevents transmission of the influenza virus.** (Doshi et al. Aff. at ¶¶ 11-13.)

As detailed in the accompanying expert report, Cochrane is an independent scientific body that conducts systematic reviews of available scientific studies to assess the current state of knowledge on questions of interest. (*Id.* at ¶ 11.) Its partners and funders include the National Institutes of Health (NIH) and the World Health Organization (WHO). *Id.* The process Cochrane undertakes to conduct a systematic review involves a thorough search and critical assessment of all the published articles on a given clinical topic. *Id.* By reviewing all existing studies, Cochrane's systematic reviews aim to reduce bias when appraising the scientific literature and help

protect against “cherry picking.” *Id.* Systematic reviews are widely regarded as the most trustworthy sources of information, sitting atop the Evidence-Based Medicine Pyramid. *Id.*

In 2010, Cochrane published a systematic review entitled “Vaccines for preventing influenza in healthy adults” which, after a review of the published randomized clinical trials and comparative studies for the influenza vaccine, “found no evidence that vaccines prevent viral transmission” of influenza. (*Id.* at ¶12.) In 2014, Cochrane updated this systematic review with 41 new trials and in 2018 it updated it again with 52 additional trials comprising over 80,000 additional individuals. (*Id.*) These updates did not change the conclusion it reached in 2010 that there is no evidence that influenza vaccines prevent viral transmission of influenza. (*Id.*)

In 2018, Cochrane conducted the same systematic review of all published clinical trials and studies with regard to influenza vaccination and children entitled “Vaccines for preventing influenza in healthy children.” (*Id.* at ¶ 13.) It concluded that “we could find no convincing evidence that vaccines can reduce ... community transmission of influenza.” (*Id.*)

Furthermore, Plaintiffs are submitting with this brief expert affidavits from world-renown experts on the influenza vaccines. Those experts affirm that “at present we could find no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, or community transmission of influenza.” (*Id.* at ¶ 15.)

In addition to preventing transmission in school settings (for which the evidence is lacking, as noted above), the DPH has also asserted that a goal of the Flu Shot Mandate was to “save lives and preserve healthcare resources.”⁵ And in its press conference, Commonwealth officials cited in support of the Flu Shot Mandate statistics for emergency room visits and deaths associated with the “flu.”

⁵ <https://www.mass.gov/news/flu-vaccine-now-required-for-all-massachusetts-school-students-enrolled-in-child-care-pre>.

However, this premise is not supported by the available science. Randomized clinical trials have not demonstrated that administration of influenza vaccines reduces the risk of hospitalization or mortality, a failing clearly set forth in the Cochrane review on this topic. (Doshi et al. Aff. at ¶¶ 14-16.) In 2018, the Cochrane review of influenza vaccines in healthy children reached the conclusion that “at present we could find no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, or community transmission of influenza.” (*Id.* at ¶15.) As for adults, in 2018 Cochrane concluded that “We found low-certainty evidence that hospitalization rates and time off work may be comparable between vaccinated and unvaccinated adults, although the confidence interval around the effect for hospital admission is wide and there was substantial variation in the direction of effect on time off work.” (*Id.*) In other words, there was no compelling evidence of benefit in a reduction in hospital admission or time off work. (*Id.*) Other systematic reviews focusing on randomized controlled trials have reached similar conclusions regarding the lack of a reduction in hospitalization and mortality from influenza vaccines. (*Id.*)

In fact, there are randomized trials which report findings that raise questions about the ability of influenza vaccines to **increase** the risk of non-influenza flu-like symptoms. (*Id.* ¶ 16.) In one such study, conducted by the Centers for Disease Control and Prevention, the authors wrote: “During the 1997-1998 influenza season, vaccine recipients reported significantly more ILI-related [ILI = influenza like illness] sick days, lost workdays, and lost work hours for physician visits than placebo recipients.” (*Id.*)

For these reasons, the DPH cannot assert a compelling interest to impinge upon Plaintiffs’ constitutional rights. All that remains is a naked infringement on these rights, which is unconstitutional.

3. The DPH Had No Rational Basis for the Flu Shot Mandate

The Flu Shot Mandate cannot survive the strict scrutiny analysis that applies where, as here, fundamental rights are infringed. However, even apart from a strict scrutiny analysis, for the same reasons discussed *supra*, the Flu Shot Mandate cannot even survive the more lenient “rational basis” test. Indeed, the DPH’s stated reasons for the Flu Shot Mandate are so inadequate and so scientifically unsound that the Flu Shot Mandate is not even rationally related to a legitimate governmental purpose. It does not, and cannot, meet the policy objectives the DPH has proposed.

The purported purpose of the flu shot mandate is to “reduce flu-related illness and the overall impact of respiratory illness during the COVID-19 pandemic.” (Ex. A.) DPH’s reasoning that the spread of influenza or hospitalization rates might decrease with an increase in influenza vaccine uptake is not founded in fact or science. *See* Section C.2., *supra*.

III. PLAINTIFFS WILL SUFFER IRREPARABLE HARM, WHICH WILL OUTWEIGH ANY DELAY IN ENFORCING THE FLU SHOT MANDATE

An irreparable harm is one that “cannot be vindicated” by an award of damages if the moving party prevails in the case. *Doe vs. Yunits*, No. 001060A, 2000 WL 33162199 (Mass. Super. Oct. 11, 2000) (applying the irreparable harm standard in an educational setting) (Ex. C.) Here the plaintiffs, and numerous other students in the Commonwealth, are all facing the prospect of being denied their right to an education, or at the very least being denied the right to receive that education in their chosen schools. By being excluded from school, plaintiffs are not only missing educational opportunities, but are also “being denied the benefits of attending school with [their] peers, learning in an interactive environment, and developing socially.” *Id.* In such situations, Massachusetts courts have previously had no problem finding that the student missing school will suffer irreparable harm. *Id.* (finding irreparable harm where a student was being forced to be home schooled because “the doctrine of ‘separate but equal’ has no place” in education (internal

quotations omitted)); *see also Doe v. Worcester Pub. Sch.*, 484 Mass. 598, 604 (2020) (affirming the conclusion that that a student who is suspended from school would suffer irreparable harm). Alternatively, if Plaintiffs do not receive an injunction, and are forced to choose to receive the influenza vaccine against their will, that is not an act that can be undone.

With regard to the relative burdens faced by the parties, Plaintiffs are merely asking that the Court preserve the current status quo, as it has stood for years. As the DPH press release noted, the Flu Shot Mandate is a new requirement, one that neither the Legislature nor the DPH had previously seen fit to require. Even though the state is still experiencing the COVID-19 pandemic, as discussed in the accompanying expert affidavits, there is little support for the idea that the Flu Shot Mandate will reduce either transmission or hospitalizations. (Doshi et al. Aff. ¶¶ 11-16.) And many other states and countries have chosen to *not* enact such a mandate in the face of the pandemic. (*E.g.*, Aaby and Benn Aff. at ¶¶ 7.) As such, the evidence is that the effect on the Commonwealth's pandemic response will be minimal if the proposed injunction is granted. Thus, this is "a case where the status quo should be maintained to minimize the harm that final relief cannot redress ... by creating or preserving, ... a state of affairs such that after the full trial, a meaningful decision may be rendered for either party." *Loyal Order of Moose, Inc.*, 439 Mass. at 603.

Lastly, it is unquestionably in the public's interest to prevent a state agency, like the DPH, from acting outside of the authority granted to it by the Legislature, especially whereas here, allowing such actions will irreparably impinge on important constitutional rights. Plaintiffs do not oppose any individual receiving the influenza vaccine, and even with an injunction the DPH will be free to encourage people to receive the influenza vaccine (without forcing them to receive it).

CONCLUSION

Wherefore, Plaintiffs respectfully request the court grant their motion and issue a preliminary injunction prohibiting the DPH from enforcing the Flu Shot Mandate during the pendency of this action.

Dated: December 17, 2020

Respectfully submitted,

SIRI & GLIMSTAD LLP

/s/ Aaron Siri

Aaron Siri (*pro hac vice* motion filed herewith)
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SUPERIOR COURT
CIVIL ACTION NO. _____

TAMAR MASSOYAN-ARTINIAN, on behalf of
her children, and MADISON SCHILTZ,

Plaintiffs,

v.

MONICA BHAREL, in her official capacity as
Commissioner of the Massachusetts
Department of Public Health and the
MASSACHUSETTS DEPARTMENT OF
PUBLIC HEALTH,

Defendants.

JURY TRIAL DEMANDED

DECLARATION OF ELIZABETH A. BREHM, ESQ.

I, Elizabeth A. Brehm, declare as follows:

1. I am an associate with the law firm of Siri & Glimstad LLP, counsel to Plaintiffs in this action. My *pro hac* application for appearance before this court is filed and pending. I make this declaration in support of Plaintiffs' Motion for Preliminary Injunction in the above-referenced action.

2. Exhibit A, attached hereto, is a true and correct copy of an August 19, 2020 Department of Public Health ("DPH") press release titled "*Flu Vaccine Now Required for all Massachusetts School Students Enrolled in Child Care, Pre-School, K-12, and Post-Secondary Institutions*" available at <https://www.mass.gov/news/flu-vaccine-now-required-for-all-massachusetts-school-students-enrolled-in-child-care-pre>.

3. Exhibit B, attached hereto, is a true and correct copy of an FAQ released by DPH titled “New! Influenza Vaccine Requirement for School Attendance: Kindergarten through Grade 12 available at <https://archives.lib.state.ma.us/bitstream/handle/2452/832122/on1187155975.pdf>.

4. Exhibit C, attached hereto, is a true and correct copy of *Doe vs. Yunits*, No. 001060A, 2000 WL 33162199 (Mass. Super. Oct. 11, 2000) which is cited on page 21 of Plaintiffs’ Memorandum of Law in Support of a Preliminary Injunction.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury the foregoing to be true and correct, to the best of my knowledge, information and belief.

Executed this 17th day of December, 2020.



Elizabeth A. Brehm, Esq.

EXHIBIT A



SEARCH

OFFERED BY Department of Public Health

PRESS RELEASE

Flu Vaccine Now Required for all Massachusetts School Students Enrolled in Child Care, Pre-School, K-12, and Post-Secondary Institutions

FOR IMMEDIATE RELEASE:

8/19/2020

Department of Public Health

MEDIA CONTACT

Omar Cabrera, Manager of Ethnic Media and Community Outreach

Phone

(617) 624-5006

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Feedback

BOSTON — State public health officials today announced that influenza immunization will be required for all children 6 months of age or older who are attending Massachusetts child care, pre-school, kindergarten, K-12, and colleges and universities. The new vaccine requirement is an important step to reduce flu-related illness and the overall impact of respiratory illness during the COVID-19 pandemic.

Students will be expected to have received a flu vaccine by December 31, 2020 for

the 2020-2021 influenza season, unless either a medical or religious exemption is provided. Also exempted are K-12 students who are homeschooled and higher education students who are completely off-campus and engaged in remote learning only. This new flu immunization requirement to enter school in January is in addition to existing vaccine requirements for all those attending child care, preschool, K-12, and colleges and universities in Massachusetts. Elementary and secondary students in districts and schools that are using a remote education model are not exempt.

“Every year, thousands of people of all ages are affected by influenza, leading to many hospitalizations and deaths,” said **Dr. Larry Madoff, Medical Director, DPH’s Bureau of Infectious Disease and Laboratory Sciences**. “It is more important now than ever to get a flu vaccine because flu symptoms are very similar to those of COVID-19 and preventing the flu will save lives and preserve healthcare resources.”

All children at least 6 months old who attend child care or preschool must be immunized in accordance with the [ACIP Recommended Immunization Schedule](#).

All students in K-12 must receive the seasonal influenza vaccine annually by December 31. New students entering between January 1 and March 31 must have received a dose of vaccine for the current flu season before entry.

Depending on the child’s age and flu vaccination history, a second dose of flu vaccine in the same season may be recommended. In these cases, the second dose is not required for school entry.

For older students, the flu vaccine requirement applies to all full-time undergraduate and graduate students under 30 years of age and all full- and part-time health science students. The requirement includes individuals from outside the U.S. attending or visiting classes or educational programs in Massachusetts as part of an academic visitation or exchange program. The only exception is for college and university students who exclusively attend classes online and never visit campus in person. College students who attend any classes or activities on campus, even once, must be vaccinated by December 31.

The updated table of immunization requirements for the upcoming school year can be found at www.mass.gov/doc/immunization-requirements-for-school-entry-0/download.

More information can be found [here](#).

###

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EXHIBIT B

New!

Influenza Vaccine Requirement for Childcare Attendance for Children 6 months of age or older

Beginning in the fall of 2020, influenza vaccine will be required for all children attending childcare who are 6 months of age or older. Influenza vaccine is always important to receive to reduce the risk of getting sick with the influenza, reduce the severity of disease if one does get sick (including the risk of hospitalization) due to influenza, as well as preventing the spread of influenza to others. During the COVID-19 pandemic, influenza vaccine will be especially critical to reduce the overall impact of respiratory illness on the population, protect vulnerable populations from severe illness, and decrease the overall burden on the healthcare system.

Which children need to receive influenza vaccine?

All children attending childcare who are 6 months of age or older will be required to receive influenza vaccine for the current influenza season for childcare attendance unless they have a medical or religious exemption.

When do children need to receive influenza vaccine?

Children must receive influenza vaccine for the current flu season by December 31, 2020.

Are there any exemptions to receiving influenza vaccine?

Medical and religious exemptions are allowable in the state of Massachusetts.

What type of influenza vaccine can children receive?

Any age-appropriate licensed influenza vaccine for the current season fulfills the requirement. Influenza vaccine is not recommended or licensed for children less than 6 months of age.

Should children without a documented dose of seasonal influenza vaccine be excluded from childcare on January 1st?

Address questions about enforcement of immunization requirements with your legal counsel. We encourage childcare providers to work with families and healthcare providers to satisfy the requirements for children who are not compliant on January 1st.

What about children who enroll after December 31?

Newly enrolling children between January 1 and March 31 must have a documented dose of influenza vaccine for the current influenza season (along with all other required vaccinations) when they start childcare.

What about children who enroll later in the spring?

Children enrolling after March 31 are not required to have a dose of influenza vaccine for enrollment.

Will my program have to report the number of children who received influenza vaccine in the preschool/childcare immunization survey?

Yes, there will be a survey to report influenza vaccination rates for children in childcare. The timing and details of the survey are still being developed. More information will be available soon.

Will influenza vaccine be required every year?

Influenza vaccine is now a required vaccine for childcare attendance and will be required as of December 31 for all children 6 months of age or older attending childcare each year.

Are 2 doses of influenza vaccine required for some children, according to ACIP guidelines?

Children younger than 9 may need two doses of influenza vaccine depending on the number of influenza vaccines they've received in the past. Children should be vaccinated according to ACIP recommendations but only one dose of influenza vaccine is required for childcare attendance.

New!
**Influenza Vaccine Requirement for School Attendance:
Kindergarten through Grade 12**

Beginning with the 2020-2021 school year, influenza vaccine will be required for all students. Influenza vaccine is always important to receive to reduce the risk of getting sick with influenza, reduce the severity of disease if one does get sick (including the risk of hospitalization) due to influenza, as well as preventing the spread of influenza to others. During the COVID-19 pandemic, influenza vaccine will be especially critical to reduce the overall impact of respiratory illness on the population, protect vulnerable populations from severe illness, and decrease the overall burden on the healthcare system.

Which students need to receive influenza vaccine?

Students in Kindergarten – Grade 12 will be required to receive influenza vaccine for the current influenza season for school attendance unless they have a medical or religious exemption.

When do students need to receive influenza vaccine?

Students must receive influenza vaccine for the current season by December 31, 2020.

Are there any exemptions to receiving influenza vaccine?

Medical and religious exemptions are allowable in the state of Massachusetts.

What type of influenza vaccine can students receive?

Any age-appropriate licensed influenza vaccine for the current season fulfills the requirement. This includes injectable and nasal spray vaccine types.

Should students without a documented dose of seasonal influenza vaccine be excluded from school on January 1st?

Enforcement of school immunization requirements is determined at the local level. We encourage school communities to work with families and healthcare providers to satisfy the requirements for students who are not compliant on January 1st.

What about students who enroll after December 31?

Newly enrolling students between January 1 and March 31 must have a documented dose of influenza vaccine for the current influenza season (along with all other required

vaccinations) when they start school.

What about students who enroll later in the spring?

Students enrolling after March 31 are not required to have a dose of influenza vaccine for the current school year.

Will my school have to report on influenza vaccine in the Kindergarten and Grade 7 school immunization surveys?

Yes—the surveys will be open as usual during the fall to input information on other vaccines. By January 2021, a new section of the survey may be completed to report influenza vaccination rates for students enrolled in Kindergarten and Grade 7. We anticipate both parts of the survey, the traditional school immunization survey and the influenza component, will be due by the end of January 2021.

Will my school have to report the number of students who received influenza vaccine in the Grade 11 school immunization survey?

Yes—the Grade 11 survey will open in early 2021 and will include the influenza question with the survey. More information on the timeline for the Grade 11 survey will be available in the future.

Will my school have to report the number of students who received influenza vaccine for students in all grades?

While the influenza vaccine requirement exists for every grade, you will be asked to complete school immunization surveys for Kindergarten, Grade 7, and Grade 11.

Will influenza vaccine be required every year or just for the 2020-2021 school year?

Influenza vaccine is now a required vaccine for school attendance and will be required as of December 31 for all students in Kindergarten through Grade 12 each school year.

Do younger students require 2 doses according to ACIP guidelines?

Children younger than 9 may need two doses of influenza vaccine depending on the number of influenza vaccines they have received in the past. Children should be vaccinated according to ACIP recommendations but only one dose of influenza vaccine is required for school attendance.

If my school will be providing instruction remotely, will students still need to meet immunization requirements?

The school immunization requirements, including the requirement for seasonal influenza vaccine, apply to all Massachusetts students enrolled in Kindergarten through Grade 12, regardless of whether the district is providing instruction in-person, or using a hybrid or remote learning model.

Do the flu immunization requirements apply to students that are home schooled?

Immunization requirements, including the flu immunization requirement, do not apply to home schooled students unless the student will ever need to access the school building for sports, after school activities or any other reason.

New!
**Influenza Vaccine Requirement for Attendance at
Post-Secondary Institutions**

Beginning with the 2020-2021 school year, influenza vaccine will be required for all full-time undergraduate and graduate students under 30 years of age and all full- and part-time health science students at post-secondary institutions. Influenza vaccine is always important to receive to reduce the risk of getting sick with influenza, reduce the severity of disease if one does get sick (including the risk of hospitalization) due to influenza, as well as preventing the spread of influenza to others. During the COVID-19 pandemic, influenza vaccine will be especially critical to reduce the overall impact of respiratory illness on the population, protect vulnerable populations from severe illness, and decrease the overall burden on the healthcare system.

Which students need to receive influenza vaccine?

Requirements apply to all full-time undergraduate and graduate students under 30 years of age and all full- and part-time health science students. Student may have a medical or religious exemption.

When do students need to receive influenza vaccine?

Students must receive influenza vaccine for the current season by December 31, 2020.

Are there any exemptions to receiving influenza vaccine?

Medical and religious exemptions are allowable in the state of Massachusetts.

What type of influenza vaccine can students receive?

Any age-appropriate licensed influenza vaccine for the current season fulfills the requirement. This includes injectable and nasal spray vaccine types.

Should students without a documented dose of seasonal influenza vaccine be excluded on January 1st?

Enforcement of immunization requirements is determined at the local level. We encourage post-secondary institutions to work with families and healthcare providers to satisfy the requirements for students who are not compliant on January 1st.

What about students who enroll after December 31?

Newly enrolling students between January 1 and March 31 must have a documented dose of influenza vaccine for the current influenza season (along with all other required vaccinations) when they start school.

What about students who enroll later in the spring?

Students enrolling after March 31 are not required to have a dose of influenza vaccine until they enroll in the Fall 2021 semester.

Will my institution have to report on influenza vaccine in the college immunization survey?

Yes—the surveys will be open as usual during the fall to input information on other required vaccines. There will also be a survey to report influenza vaccination rates for students at post-secondary institutions. The timing and details of the survey are still being developed. More information will be available soon.

Will influenza vaccine be required every year or just for the 2020-2021 school year?

Influenza vaccine is now a required vaccine for attendance at a post-secondary institution in Massachusetts and will be required annually as of December 31 for all students who will be on campus for any reason and are subject to immunization requirements.

If my school will be providing instruction remotely, will students still need to meet immunization requirements?

The immunization requirements apply to all students who attend any classes or activities on campus, even once. If all instruction and activities are conducted remotely and the student will never be on campus in person, the requirements would not apply. If the first part of the year will be conducted remotely but later portions may be in person, we recommend collecting immunization records as early as possible to ensure all records are in place prior to students attending classes or activities in person.

EXHIBIT C

Not Reported in N.E.2d, 2000 WL 33162199 (Mass.Super.)
(Cite as: 2000 WL 33162199 (Mass.Super.))

Only the Westlaw citation is currently available.

Superior Court of Massachusetts.
 Pat DOE,^{FN*,FN1}

FN* Editor's Note: A petition for interlocutory relief from the preliminary injunction entered in this opinion was denied by the Appeals Court sub nom *Doe v. Brockton School Committee*, No.2000-J-638 (November 30, 2000) (Jacobs, J.).

FN1. By her next friend, Jane Doe, plaintiff's grandmother and guardian.

v.
 John YUNITS, et al.^{FN2}

FN2. Maurice Hancock, Wayne Carter, George Allen, Mary Gill, Dennis Eaniri, Kevin Nolan, Ronald Dobrowski. School Committee Members; Joseph Bage, Superintendent; Kenneth Cardone, Principal of South Junior High School; Dr. Kenneth Sennett, Senior Director for Pupil Services, in their individual and official capacities; and Brockton Public Schools.

No. 001060A.
 Oct. 11, 2000.

MEMORANDUM OF DECISION AND ORDER
 ON PLAINTIFF'S MOTION FOR PRELIMINARY
 INJUNCTION

GILES.

*1 Plaintiff Pat Doe^{FN3} ("plaintiff"), a fifteen-year-old student, has brought this action by her next friend, Jane Doe, requesting that this court prohibit defendants from excluding the plaintiff from South Junior High School ("South Junior High"), Brockton, Massachusetts, on the basis of the plaintiff's sex, disability, or gender identity and expression. Plaintiff has been diagnosed with gender identity disorder, which means that, although plaintiff was born biologically male, she has a female gender identity.^{FN4} Plaintiff seeks to attend school wearing clothes and fashion accouterments that are consistent with her

gender identity. Defendants have informed plaintiff that she could not enroll in school this academic year if she wore girls' clothes or accessories. After a hearing, and for the reasons stated below, plaintiff's motion for preliminary injunction is *ALLOWED*.

FN3. A pseudonym.

FN4. This court will use female pronouns to refer to plaintiff: a practice which is consistent with the plaintiff's gender identity and which is common among mental health and other professionals who work with transgender clients.

BACKGROUND

Plaintiff began attending South Junior High, a Brockton public school, in September 1998, as a 7th grader. In early 1999, plaintiff first began to express her female gender identity by wearing girls' make-up, shirts, and fashion accessories to school. South Junior High has a dress code which prohibits, among other things, "clothing which could be disruptive or distracting to the educational process or which could affect the safety of students." In early 1999, the principal, Kenneth Cardone ("Cardone"), would often send the plaintiff home to change if she arrived at school wearing girls' apparel. On some occasions, plaintiff would change and return to school; other times, she would remain home, too upset to return. In June 1999, after being referred to a therapist by the South Junior High, plaintiff was diagnosed with gender identity disorder. Plaintiff's treating therapist, Judith Havens ("Havens"), determined that it was medically and clinically necessary for plaintiff to wear clothing consistent with the female gender and that failure to do so could cause harm to plaintiff's mental health.

Plaintiff returned to school in September 1999, as an 8th grader, and was instructed by Cardone to come to his office every day so that he could approve the plaintiff's appearance. Some days the plaintiff would be sent home to change, sometimes returning to school dressed differently and sometimes remaining home. During the 1999-2000 school year, plaintiff stopped attending school, citing the hostile environment created by Cardone. Because of plaintiff's

Not Reported in N.E.2d, 2000 WL 33162199 (Mass.Super.)
(Cite as: 2000 WL 33162199 (Mass.Super.))

many absences during the 1999-2000 school year, plaintiff was required to repeat the 8th grade this year.

Over the course of the 1998-1999 and 1999-2000 school years, plaintiff sometimes arrived at school wearing such items as skirts and dresses, wigs, high-heeled shoes, and padded bras with tight shirts. The school faculty and administration became concerned because the plaintiff was experiencing trouble with some of her classmates. Defendants cite one occasion when the school adjustment counselor had to restrain a male student because he was threatening to punch the plaintiff for allegedly spreading rumors that the two had engaged in oral sex. Defendants also point to an instance when a school official had to break up a confrontation between the plaintiff and a male student to whom plaintiff persistently blew kisses. At another time, plaintiff grabbed the buttock of a male student in the school cafeteria. Plaintiff also has been known to primp, pose, apply make up, and flirt with other students in class. Defendants also advance that the plaintiff sometimes called attention to herself by yelling and dancing in the halls. Plaintiff has been suspended at least three times for using the ladies' restroom after being warned not to.

*2 On Friday, September 1, 2000, Cardone and Dr. Kenneth Sennett ("Sennett"), Senior Director for Pupil Personnel Services, met with the plaintiff relative to repeating the 8th grade. At that meeting, Cardone and Sennett informed the plaintiff that she would not be allowed to attend South Junior High if she were to wear any outfits disruptive to the educational process, specifically padded bras, skirts or dresses, or wigs. On September 21, 2000, plaintiff's grandmother tried to enroll plaintiff in school and was told by Cardone and Sennett that plaintiff would not be permitted to enroll if she wore any girls' clothing or accessories. Defendants allege that they have not barred the plaintiff from school but have merely provided limits on the type of dress the plaintiff may wear. Defendants claim it is the plaintiff's own choice not to attend school because of the guidelines they have placed on her attire. Plaintiff is not currently attending school, but the school has provided a home tutor for her to allow her to keep pace with her classmates.

On September 26, 2000, the plaintiff filed a complaint in this court claiming a denial of her right

to freedom of expression in the public schools in violation of G.L.c. 71, § 82; a denial of her right to personal dress and appearance in violation of G.L. c. 76, § 83; a denial of her right to attend school in violation of G.L. c. 76, § 5; a denial of her right to be free from sex discrimination guaranteed by Articles I and XIV of the Declaration of Rights of the Massachusetts Constitution; a denial of her right to be free from disability discrimination guaranteed by Article CXIV of the said Declaration of Rights; a denial of her due process rights as guaranteed by G.L. c. 71, § 37 and G.L. c. 76, § 17; a denial of her liberty interest in her appearance as guaranteed by the Massachusetts Declaration of Rights, Art. I and X; and a violation of her right to free expression as guaranteed by the said Declaration of Rights, Art. I and X.

DISCUSSION

I. Introduction

In evaluating a request for a preliminary injunction, the court must examine "in combination the moving party's claim of injury and chance of success on the merits." *Packing Industries Group, Inc. v. Cheney*, 380 Mass. 609, 617 (1980). "If the judge is convinced that failure to issue the injunction would subject the moving party to a substantial risk of irreparable harm, the judge must then balance this risk against any similar risk of irreparable harm which granting the injunction would create for the opposing party ... Only where the balance between these risks cuts in favor of the moving party may a preliminary injunction properly issue." *GTE Products Corp. v. Stewart*, 414 Mass. 721, 722-23 (1993), quoting *Packaging Industries Group, Inc. v. Cheney*, *supra* (footnote omitted). In addition, where the injunction is sought against a public entity, as it is here, the court must consider the risk of injury to the public interest which would flow from the grant of the injunction. *Brookline v. Goldstein*, 388 Mass. 443, 447 (1983); *Biotti v. Board of Selectmen of Manchester*, 25 Mass.App.Ct. 637, 639 (1988).

II. The Likelihood of Plaintiff's Success on the Merits

*3 Plaintiff's complaint asserts eight causes of action based on the Massachusetts Declaration of Rights and the General Laws. They are individually addressed below to evaluate the likelihood of success on the merits.

A. Freedom of Expression, Massachusetts Declaration of Rights, Art. II and X

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The Massachusetts Declaration of Rights, Article XVI (as amended by Article 77) provides, “[t]he right of free speech shall not be abridged.” The analysis of this article is guided by federal free speech analysis. See *Hosford v. School Committee of Sandwich*, 421 Mass. 708, 712 n. 5 (1996); *Opinion of the Justices to the House of Representatives*, 387 Mass. 1201, 1202 (1982); *Colo. v. Treasurer and Receiver General*, 378 Mass. 550, 558 (1979). According to federal analysis, this court must first determine whether the plaintiff’s symbolic acts constitute expressive speech which is protected, in this case, by Article VXI of the Massachusetts Declaration of Rights. See *Texas v. Johnson*, *supra*, citing *Spence v. Washington*, *supra*. If the speech is expressive, the court must next determine if the defendants’ conduct was impermissible because it was meant to suppress that speech. See *Texas v. Johnson*, 491 U.S. 397, 403 (1989), citing *United States v. O’Brien*, 391 U.S. 367, 377 (1968); see also *Spence v. Washington*, 418 U.S. 405, 414 n. 8 (1974). If the defendants’ conduct is not related to the suppression of speech, furthers an important or substantial governmental interest, and is within the constitutional powers of the government, and if the incidental restriction on speech is no greater than necessary, the government’s conduct is permissible. See *United States v. O’Brien*, *supra*. In addition, because this case involves public school students, suppression of speech that “materially and substantially interferes with the work of the school” is permissible. See *Tinker v. Des Moines Community School Dist.*, 393 U.S. 503, 739 (1969).

1. The Plaintiff’s Conduct is Expressive Speech Which is Understood by Those Perceiving It

Symbolic acts constitute expression if the actor’s intent to convey a particularized message is likely to be understood by those perceiving the message. See *Spence v. Washington*, 418 U.S. 405, 410-11 (1974) (finding that an upside-down flag with a peace symbol attached was protected speech because it was a purposeful message people could understand); see also *Chalifoux v. New Caney Independent School Dist.*, 976 F.Sup. 659 (S.D.Tex.1997) (students wearing rosary beads as a sign of their religious belief was likely to be understood by others and therefore protected).

Plaintiff in this case is likely to establish that, by dressing in clothing and accessories traditionally associated with the female gender, she is expressing her

identification with that gender. In addition, plaintiff’s ability to express herself and her gender identity through dress is important to her health and well-being, as attested to by her treating therapist. Therefore, plaintiff’s expression is not merely a personal preference but a necessary symbol of her very identity. Contrast *Olesen v. Board of Education of School District No. 228*, 676 F.Sup. 820 (N.D.Ill.1987) (school’s anti-gang policy of prohibiting males from wearing earrings, passed for safety reasons, was upheld because plaintiff’s desire to wear an earring as an expression of his individuality and attractiveness to girls was a message not within the scope of the First Amendment).

*4 This court must next determine if the plaintiff’s message was understood by those perceiving it, i.e., the school faculty and plaintiff’s fellow students. See *Bivens v. Albuquerque Public Schools*, 899 F.Sup. 556 (D.N.M.1995) (student failed to provide evidence that his wearing of sagging pants to express his identity as a black youth was understood by others and, therefore, such attire was not speech). In the case at bar, defendants contend that junior high school students are too young to understand plaintiff’s expression of her female gender identity through dress and that “not every defiant act by a high school student is constitutionally protected speech.” *Id.* at 558. However, unlike *Bivens*, here there is strong evidence that plaintiff’s message is well understood by faculty and students. The school’s vehement response and some students’ hostile reactions are proof of the fact that the plaintiff’s message clearly has been received. Moreover, plaintiff is likely to establish, through testimony, that her fellow students are well aware of the fact that she is a biological male more comfortable wearing traditionally “female”-type clothing because of her identification with that gender.

2. The Defendants’ Conduct Was a Suppression of the Plaintiff’s Speech

Plaintiff also will probably prevail on the merits of the second prong of the *Texas v. Johnson* test, that is, the defendants’ conduct was meant to suppress plaintiff’s speech. Defendants in this case have prohibited the plaintiff from wearing items of clothing that are traditionally labeled girls’ clothing, such as dresses and skirts, padded bras, and wigs. This constitutes direct suppression of speech because biological females who wear items such as tight skirts to

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school are unlikely to be disciplined by school officials, as admitted by defendants' counsel at oral argument. See *Texas v. Johnson*, 491 U.S. 397, 408-16 (1989). Therefore, the test set out in *United States v. O'Brien*, which permits restrictions on speech where the government motivation is not directly related to the content of the speech, cannot apply here. Further, defendants' argument that the school's policy is a content-neutral regulation of speech is without merit because, as has been discussed, the school is prohibiting the plaintiff from wearing clothes a biological female would be allowed to wear. Therefore, the plaintiff has a likelihood of fulfilling the *Texas v. Johnson* test that her speech conveyed a particularized message understood by others and that the defendants' conduct was meant to suppress that speech.

3. Plaintiff's Conduct is not Disruptive

This court also must consider if the plaintiff's speech "materially and substantially interferes with the work of the school." *Tinker v. Des Moines Community School Dist.*, *supra*. Defendants argue that they are merely preventing disruptive conduct on the part of the plaintiff by restricting her attire at school. Their argument is unpersuasive. Given the state of the record thus far, the plaintiff has demonstrated a likelihood of proving that defendants, rather than attempting to restrict plaintiff's wearing of distracting items of clothing, are seeking to ban her from donning apparel that can be labeled "girls' clothes" and to encourage more conventional, male-oriented attire. Defendants argue that any other student who came to school dressed in distracting clothing would be disciplined as the plaintiff was. However, defendants overlook the fact that, if a female student came to school in a frilly dress or blouse, make-up, or padded bra, she would go, and presumably has gone, unnoticed by school officials. Defendants do not find plaintiff's clothing distracting *per se*, but, essentially, distracting simply because plaintiff is a biological male.

*5 In addition to the expression of her female gender identity through dress, however, plaintiff has engaged in behavior in class and towards other students that can be seen as detrimental to the learning process. This deportment, however, is separate from plaintiff's dress. Defendants vaguely cite instances when the principal became aware of threats by students to beat up the "boy who dressed like a girl" to support the notion that plaintiff's dress alone is dis-

ruptive. To rule in defendants' favor in this regard, however, would grant those contentious students a "heckler's veto." See *Fricke v. Lynch*, 491 F.Supp. 381, 387 (D .R.I.1980). The majority of defendants' evidence of plaintiff's disruption is based on plaintiff's actions as distinct from her mode of dress. Some of these acts may be a further expression of gender identity, such as applying make-up in class; but many are instances of misconduct for which any student would be punished. Regardless of plaintiff's gender identity, any student should be punished for engaging in harassing behavior towards classmates. Plaintiff is not immune from such punishment but, by the same token, should not be punished on the basis of dress alone.

Plaintiff has framed this issue narrowly as a question of whether or not it is appropriate for defendants to restrict the manner in which she can dress. Defendants, on the other hand, appear unable to distinguish between instances of conduct connected to plaintiff's expression of her female gender identity, such as the wearing of a wig or padded bra, and separate from it, such as grabbing a male student's buttocks or blowing kisses to a male student. The line between expression and flagrant behavior can blur, thereby rendering this case difficult for the court. It seems, however, that expression of gender identity through dress can be divorced from conduct in school that warrants punishment, regardless of the gender or gender identity of the offender. Therefore, a school should not be allowed to bar or discipline a student because of gender-identified dress but should be permitted to ban clothing that would be inappropriate if worn by any student, such as a theatrical costume, and to punish conduct that would be deemed offensive if committed by any student, such as harassing, threatening, or obscene behavior. See *Bethel v. Fraser*, 478 U.S. 675 (1986).

B. G.L. c. 71, § 82

Defendants argue that G.L. c. 71, § 82 is inapplicable because the statute only applies to secondary school; and South Junior High has been designated a primary school. Therefore, plaintiff will probably fail in this claim if defendants can substantiate their assertion. Nevertheless, the Supreme Court's constitutional analysis in *Tinker*, which was codified by G.L. c. 71, § 82, see *Pyle v. School Committee of South Hadley*, 423 Mass. 283, 286 (1996), remains applicable in this case and implicates the same principles. As

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discussed, plaintiff has demonstrated a likelihood of success on the merits in her common law freedom of expression claim.

C. Liberty Interest in Appearance Massachusetts Declaration of Rights Article I and X

*6 Plaintiff is also likely to prevail in this claim. A liberty interest under the First Amendment has been recognized to protect a male student's right to wear his hair as he wishes. See *Richards v. Thurston*, 424 F.2d 1281 (1st Cir.1970), cited with approval *Bd. of Selectmen of Framingham v. Civil Service Commission*, 366 Mass. 547, 556 (1974). The question in liberty interest cases is whether the government's interest in restricting liberty is strong enough to overcome that liberty interest. Given that plaintiff has a likelihood of success in proving that her attire is not distracting, as discussed above, she is likely to prove that defendants' interests do not overcome the recognized liberty interest in appearance.

D. Sex Discrimination G.L. c. 76, § 5 and Article I and XIV of the Massachusetts Declaration of Rights

G.L. c. 76, § 5 states that "Every person shall have the right to attend the public schools of the town where he actually resides ... No person shall be excluded from or discriminated against in admission to a public school of any town, or in obtaining the advantages, privileges and course of study of such public school on account of race, color, sex, religion, national origin or sexual orientation." G.L. c. 76, § 5 (2000). Federal cases have recognized the impropriety of discriminating against a person for failure to conform with the norms of their biological gender. See *Price Waterhouse v. Hopkins*, 490 U.S. 228, 250 (1989) (sex stereotyping occurred when members of an accounting firm denied female associate promotion because she failed to walk, talk, and dress femininely); *Rosa v. Park West Bank*, 214 F.3d 213 (1st Cir. 2000) (claim of sex discrimination may be sustained when cross-dressing man was denied a loan application until he went home to change clothes). This court finds plaintiff's reliance on such cases persuasive and the cases cited by defendants distinguishable, as discussed below.

Plaintiff contends that defendants' action constitute sex discrimination because defendants prevented plaintiff from attending school in clothing associated with the female gender solely because plaintiff is male. Defendants counter that, since a female student

would be disciplined for wearing distracting items of men's clothing, such as a fake beard, the dress code is gender-neutral. Defendants' argument does not frame the issue properly. Since plaintiff identifies with the female gender, the right question is whether a female student would be disciplined for wearing items of clothes plaintiff chooses to wear. If the answer to that question is no, plaintiff is being discriminated against on the basis of her sex, which is biologically male.^{FN5} Therefore, defendants' reliance on cases holding that discrimination on the basis of sexual orientation, transsexualism, and transvestism are not controlling in this case because plaintiff is being discriminated against because of her gender. See *Ulane v. Eastern Airlines*, 742 F.2d 1081 (7th Cir.1984).^{FN6} Furthermore, such cases have been criticized and distinguished under both Title VII and the First and Fourteenth Amendments. See *Quinn v. Nassau County Police Dept.*, 53 F.Supp.2d 347 (E.D.N.Y.1999); *Blozis v. Mike Raisor Ford, Inc.*, 896 F.Supp. 805 (N.D.Ind.1995); *Schwenk v. Hartford*, 204 F.3d 1187 (9th Cir.2000).

FN5. This case is distinguishable from *Harper v. Edgewood Bd. of Education*, 655 F.Supp. 1353 (S.D. Ohio 1987). In *Harper*, the court granted summary judgment in favor of the defendants, who prevented two students dressed in clothing of the opposite gender from attending the prom against a claim that the plaintiffs' First Amendment rights were violated. The court found the school's action permissible because it fostered community values and maintained discipline. Plaintiff in this case, however, is not merely engaging in rebellious acts to demonstrate a willingness to violate community norms; plaintiff is expressing her personal identity, which cannot be suppressed by the school merely because it departs from community standards.

FN6. *LaFleur v. Bird-Johnson Co.*, 1994 W.L. 878831 (Mass.Super. Nov. 3, 1994) [3 Mass.L.Rptr. 196], is also distinguishable. *LaFleur* was decided after *Price Waterhouse v. Hopkins* but recognized the Supreme Judicial Court's holding in *Macaulay v. MCAD*, 379 Mass. 279 (1979), that transsexual discrimination is not within the scope of this state's sexual discrimination law.

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However, the case at hand differs from *LaFleur*, where the plaintiff claimed she was discriminated against in the employment context because she was a transvestite, because the instant plaintiff is likely to establish that defendants have discriminated against her on the basis of sex by applying the dress code against her in a manner in which it would not be applied to female students.

*7 In support of their argument, defendants cite cases in which gender-specific school dress codes have been upheld in the face of challenges based on gender discrimination and equal protection because the codes serve important governmental interests, such as fostering conformity with community standards. See *Jones v. W.T. Henning Elementary School*, 721 So.2d 530 (La.App.3rd Cir.1998); *Hines v. Caston School Corp.*, 651 N.E.2d 330, 335 (Ind.App.1995); *Harper v. Edgewood Board of Education*, 655 F.Supp. 1353 (S.D. Ohio 1987). Such cases are not binding on this court. This court cannot allow the stifling of plaintiff's selfhood merely because it causes some members of the community discomfort. "Our constitution ... neither knows nor tolerates classes among citizens." *Plessy v. Ferguson*, 163 U.S. 537, 539 (1896) (dissenting opinion of Harlan, J.). Thus, plaintiff in this case is likely to establish that the dress code of South Junior High, even though it is gender-neutral, is being applied to her in a gender discriminatory manner.

E. Disability Discrimination Article CXIV of the Massachusetts Declaration of Rights

Plaintiff does not have a likelihood of success in proving that the defendants' conduct constituted disability discrimination. Analysis of federal discrimination law is instructive in construing state disability discrimination law. See *Cox v. New England Tel. & Tel. Co.*, 414 Mass. 375 (1993). The federal Americans with Disabilities Act expressly excludes "transvestism, transsexualism ... [and] gender identity disorders not resulting from physical impairments ..." 42 U.S.C. 12211(b) (2000). While noting that the courts of this state can, and often do, provide more protection than its federal counterpart, there is no authority to support the notion that Gender Identity Disorder is a protected disability under the Massachusetts Declaration of Rights of laws of this state.

F. Due Process G.L. c. 76, § 17

Plaintiff does not have a likelihood of success on the merits of this claim because, as defendants correctly point out, the plaintiff has not been expelled from school. Therefore, no process was due the plaintiff.

G. G.L. c. 71, § 83

Defendants again are correct in asserting that this section, which protects a student's right to personal dress, is a local option statute which applies only to jurisdictions that have chosen to adopt it. G.L. c. 71, § 86. Therefore, the plaintiff has not demonstrated a likelihood of success on the merits of this claim.

II. Irreparable Harm

The party seeking an injunction bears the burden of establishing irreparable harm, i.e., that it may suffer a loss of rights that cannot be vindicated should it prevail after a full hearing on the merits. *GTE Products Corp. v. Stewart*, *supra* at 726. Plaintiff in this case has met the burden of establishing irreparable harm. The plaintiff is currently being home schooled because the defendants will not allow her to attend school in girls' attire. Therefore, plaintiff is being denied the benefits of attending school with her peers, learning in an interactive environment, and developing socially. See *McLaughlin v. Boston School Committee*, 938 F.Supp. 1001, 1011-12 (D.Mass.1994). Such harm is further exacerbated by the fact that the plaintiff has been the subject of much controversy over the past two years and now is noticeably absent from school. Defendants argue that any harm to the plaintiff is self-induced because plaintiff has chosen not to attend school under the conditions the defendants have put on her attire. This contention is without merit. Defendants are essentially prohibiting the plaintiff from expressing her gender identity and, thus, her quintessence, at school. Their actions have forced plaintiff to submit to home schooling. However, "in the field of public education the doctrine of 'separate but equal' has no place." *Brown v. Board of Education of Topeka*, 347 U.S. 483, 495 (1954).

III. The Balance of the Equities

*8 The balance of the equities tips in favor of plaintiff in his case. The plaintiff attended South Junior High School for two academic years; and the school and its students, with the exception of new students entering this year, are accustomed to inter-

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acting with plaintiff and, thus, are capable of doing so again. Because the school is empowered to discipline plaintiff for conduct for which any other student would be disciplined, the harm to the school in readmitting plaintiff is minimal. On the other hand, if plaintiff is barred from school, the potential harm to plaintiff's sense of self-worth and social development is irreparable. Defendants cite cases that stand for the proposition that a school's interest in disciplining students by barring them from school outweigh the harm to the student. See *Katchak v. Glasgow Independent School District*, 690 F.Sup. 580, 583 (W.D.Ky.1988). In this case, however, the school is not disciplining the plaintiff for certain conduct. The school is barring her from school on account of the expression of her very identity. Defendants maintain that plaintiff is free to enroll in school as long as she complies with the stated dress code. This is not entirely true because the defendants have placed specific restrictions on plaintiff's dress that may not be placed on other female students. This court does take note of the fact that defendants made efforts to accommodate the plaintiff's desire to dress in girl's clothes for over a year. However, their proscription of the items of clothing that can be worn by plaintiff is likely to be impermissible. Therefore, the harm to plaintiff by the actions of the defendants outweigh the harm to the defendants in granting this injunction.

IV. The Harm to the Public Interest

Defendants have not made a showing that the granting of this injunction will harm the public interest. Although defendants contend that plaintiff's dress is disruptive to the learning process, the workings of the school will not be disrupted if they are permitted to discipline plaintiff according to normal procedures for truly disruptive attire and inappropriate behavior. Furthermore, this court trusts that exposing children to diversity at an early age serves the important social goals of increasing their ability to tolerate such differences and teaching them respect for everyone's unique personal experience in that "Brave New World" out there.

ORDER

For all the foregoing reasons, plaintiff's motion for preliminary injunction is *ALLOWED*; and it is hereby *ORDERED THAT*:

1. Defendants are preliminarily enjoined from preventing plaintiff from wearing any clothing or

accessories that any other male or female student could wear to school without being disciplined.

2. Defendants are further preliminarily enjoined from disciplining plaintiff for any reason for which other students would not be disciplined.

3. If defendants do seek to discipline plaintiff in conformance with this order, they must do so according to the school's standing policies and procedures.

Mass.Super.,2000.

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END OF DOCUMENT

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.

SUPERIOR COURT
CIVIL ACTION NO. _____

TAMAR MASSOYAN-ARTINIAN, on behalf of
her children, and MADISON SCHILTZ,

Plaintiffs,

v.

MONICA BHAREL, in her official capacity as
Commissioner of the Massachusetts
Department of Public Health and the
MASSACHUSETTS DEPARTMENT OF
PUBLIC HEALTH,

Defendants.

**EXPERT AFFIDAVIT OF P. DOSHI, T. JEFFERSON, P. GOTZSCHE, AND C.
HENEGHAN**

We, Peter Doshi, Thomas Jefferson, Peter Götzsche, and Carl Heneghan, state as follows:

1. We submit this affidavit in support of Plaintiffs’ Motion for a preliminary injunction. We have personal knowledge of the facts set forth herein and, if called to testify, each of us could competently testify as to the following:

EXPERIENCE & CREDENTIALS

2. I, Peter Doshi, hold a PhD, and I am an Associate Professor with Tenure in the Pharmaceutical Health Services Research Department at the University of Maryland School of Pharmacy.¹ I teach a required course in the PharmD curriculum, “Medical Evidence,” which trains

¹ <https://faculty.rx.umaryland.edu/pdoshi/>.

students in skills necessary to critically appraise the scientific literature. I research the drug and vaccine approval process, how the risks and benefits of medical products are communicated, and how to improve the credibility and accuracy of evidence synthesis and biomedical publications. At the University of Maryland, I lead the RIAT Support Center which aims to accelerate the correction of the scientific record of clinical trials by making clinical trial publications more accurate and more complete, addressing the problems of publication bias and reporting bias. I have received national recognition for my work on clinical trial data transparency.² I am also an associate editor of *The BMJ* (formerly, the British Medical Journal), which is roughly equivalent to the *Journal of the American Medical Association* in the United States.³ (Attached as Exhibit A is a copy of my CV.) I have studied influenza policy since around 2004. I have many peer reviewed publications on the topic (see Exhibit A), and my PhD dissertation⁴ is on the topic of CDC and WHO influenza control policies (primarily vaccines). In 2013, I published a peer-reviewed article entitled “Influenza Vaccines: Time for a Rethink” by invitation of the editor-in-chief of *JAMA Internal Medicine*, a professor of medicine at U.C. San Francisco, based on being considered an “expert in the field.”

3. I, Thomas Jefferson, hold an MD degree and am a Fellow of Faculty of Public Health in the United Kingdom and a Member of Royal College of General Practitioners. I am a Senior Clinical Tutor at the University of Oxford. My specialty is analyzing evidence-based medicine and bias in drug and vaccines testing. I am the lead author of Cochrane reviews on influenza vaccines, and have published widely on the topic of influenza vaccines, other vaccines, and public health. (Attached as Exhibit B is a copy of my CV.) I started my health care career as

² <https://www.nytimes.com/2013/06/30/business/breaking-the-seal-on-drug-research.html>.

³ <https://www.bmj.com/about-bmj/editorial-staff/peter-doshi>.

⁴ <http://dspace.mit.edu/handle/1721.1/69811>.

a general practitioner (1980–1985 and 1999-2001), trained in public health in 1986 and obtained a MSc and Fellowship of Faculty of Public Health, as well as a diploma in Health Economics. I have been a contributor to The Cochrane Collaboration for over 20 years and am an author and editor for the Cochrane Acute Respiratory Infections (ARI) Group and a member of other Cochrane Groups. I have experience in synthesizing data from both large pharmaceutical and RWE data sets, both within formal studies and raw data. I have worked in vaccines, antivirals, infectious disease agents, neurodegenerative diseases, diabetic drugs, and different devices in classes IIb and III in a variety of designs (such as trials, economic evaluations, meta-analyses and epidemiological studies) and the use of regulatory evidence in Cochrane reviews. My work is cited in the James Lind Library. I am a member of the Italian MoH NITAG (national independent technical advisory group) on vaccines and a founder of the Brighton Collaboration, an international network of researchers developing standardized reporting of potential vaccines' harms.

4. I, Peter Gøtzsche, am a medical doctor and Doctor of Medical Science. I have been involved in medical research and the evaluation of medical research for 45 years. In 1993, I co-founded the Cochrane Collaboration which is a collaborative effort by patients, scientists, and researchers around the world to evaluate medical research to assist patients, health professionals, and policy makers to make better decisions. During the twenty-five years I worked with the Cochrane Collaboration, for which I was the Director of the Nordic Cochrane Centre, the group has published about 10,000 systematic reviews or protocols for upcoming reviews on the benefits and harms of interventions used in healthcare. In 2010, I became Professor of Clinical Research Design and Analysis at the University of Copenhagen. In 2018, I founded the Institute for Scientific Freedom where I continue with the same kind of work that I performed at the Cochrane Collaboration. (A copy of my CV with a list of books, book chapters and publications are attached

as Exhibit C.) I am the author of seven books since 2007, the first of which is *Rational Diagnosis and Treatment: Evidence-based Clinical Decision-making (4th ed.)*. One of my most recent books, published in 2020, and the one which is most relevant to the issues in this case, is titled *Vaccines: Truths, Lies and Controversy*. The book was published by People's Press in Denmark; will be published by Skyhorse in New York in 2021; and will appear in many languages. The book has a chapter on the influenza vaccines, and specifically reviews the evidence of its benefits and harms.

5. I, Carl Heneghan, am a registered medical doctor in the United Kingdom and am on the specialist register as a general practitioner since 2005. I hold a DPhil and I am Professor of Evidence Based Medicine at the University of Oxford. I have 25 years' experience as a clinical epidemiologist with expertise in evidence-based medicine, research methods, and evidence synthesis. I have over 400 peer-reviewed publications (current H index 70); published 95 systematic reviews and am currently Editor in Chief of BMJ Evidence-Based Medicine, contact editor in the Cochrane Acute Respiratory Infection group, and Editor of the Catalogue of Bias. My work includes investigating drugs and devices, advising governments on regulatory evidence, assessing health claims, and research on common presenting conditions in primary care, including work on acute respiratory infections. I am a clinical advisor to two UK All Parliamentary Party Groups on Surgical Mesh and Hormone Pregnancy Tests, an adviser to the WHO clinical trials registry platform and a founder of the AllTrials campaign; three times I have been voted one of the top 100 NHS clinical leaders by the Health Service Journal. In 2018, I was awarded National Institute for Health Research Senior Investigator status (Senior Investigators are among the most prominent and prestigious researchers funded by the NIHR and the most outstanding leaders of patient and people-based research within the NIHR research community). In 2019, I received a lifetime achievement award from Oxford's Medical Science Division for my sustained

commitment to education and teaching. I am Director of the Centre for Evidence-Based Medicine (CEBM), which builds capacity through teaching and training activities. I teach undergraduates, postgraduates, and teachers of EBM, and I am Director of Programs in Evidence-Based Health Care. (Attached as Exhibit D is a copy of my CV.)

6. We have not received any compensation, either directly or in-kind, for this affidavit.

THE “FLU”

7. The Massachusetts Department of Public Health repeatedly refers to influenza vaccines as an approach for dealing with the “flu.” However, most cases of the “flu,” respiratory infections and illnesses, are not caused by influenza virus but rather by other viruses.⁵ Every year, hundreds of thousands of respiratory specimens are tested across the United States and, on average, only 16% are found to be influenza positive.⁶ Other viruses, *e.g.*, adenoviruses, respiratory syncytial virus, rhinoviruses, and coronaviruses, cause a clinically indistinguishable disease all known colloquially as “flu.” Hence, the influenza vaccine, even if it were a 100% effective product, could only address a small fraction of the “flu” cases in Massachusetts as it does not and cannot address the other viruses.

THE INFLUENZA VACCINE

8. There is no single “influenza vaccine.” There are a wide range of distinct products, produced by different manufacturers, each with different ingredients, manufacturing facilities, and safety and efficacy profiles that regulators need to evaluate prior to initial approval and licensing each year.

⁵ See <https://onlinelibrary.wiley.com/doi/epdf/10.1111/irv.12789>; see also <https://academic.oup.com/ajcp/article/147/1/43/2697603>.

⁶ Doshi P. Influenza: marketing vaccine by marketing disease. *BMJ* 2013;346:f3037 <https://www.bmj.com/content/346/bmj.f3037>.

9. Not only is each influenza vaccine a unique product, the process for culturing the influenza virus and creating the vaccines results in variations from year to year, batch to batch, and potentially even from dose to dose. This is because, unlike drugs that are made from a consistent small molecule, these products are biologics produced using biological material. Each brand of influenza vaccine also changes each year to target strains of influenza virus expected to be in circulation in the coming season. The influenza vaccine is therefore not a single, unchanging product over time, but rather differs from year to year, product to product, and batch to batch.

10. One implication of this is that, once a given product is licensed, new formulations of that product (annually produced) are allowed on the market each year without knowing their efficacy or safety profile. Performance in a given season can only be discovered after the fact (*i.e.*, after the season has ended).

NO EVIDENCE THAT INFLUENZA VACCINES PREVENT TRANSMISSION OF INFLUENZA

11. The Cochrane Collaboration, considered an independent scientific body, conducts systematic reviews of all the best available scientific studies to assess the current state of the science on questions of interest. Its partners and funders include the U.S. National Institutes of Health (NIH), the World Health Organization (WHO), national health agencies, and leading medical universities from around the globe.⁷ The process of conducting a systematic review involves a systematic, thorough search, and critical assessment of all relevant articles on a given clinical topic. Systematic reviews are a methodology for reducing bias when appraising the scientific literature and help protect against “cherry picking.” Systematic reviews are widely

⁷ <https://www.cochrane.org/about-us/our-funders-and-partners>.

regarded as the most trustworthy sources of information, sitting atop the Evidence-Based Medicine pyramid.⁸

12. In 2010, Cochrane published a systematic review entitled “Vaccines for preventing influenza in healthy adults” which, after a review of the published randomized clinical trials and comparative studies for the influenza vaccine, “found no evidence that vaccines prevent viral transmission” of influenza.⁹ In 2014, Cochrane updated this systematic review with 41 new trials and in 2018 it updated it again with 52 additional trials comprising over 80,000 additional individuals.¹⁰ These updates did not change the conclusion reached in 2010 that **there is no evidence that influenza vaccines prevent viral transmission of influenza.**

13. In 2018, Cochrane conducted the same systematic review of all published clinical trials and studies with regard to children entitled “Vaccines for preventing influenza in healthy children.”¹¹ It concluded that “**we could find no convincing evidence that vaccines can reduce ... community transmission of influenza.**”¹²

NO RELIABLE EVIDENCE THAT INFLUENZA VACCINES PREVENT HOSPITALIZATIONS AND DEATH

14. Randomized clinical trials have not demonstrated that administration of influenza vaccines reduces the risk of hospitalization or mortality, something demonstrated clearly by the Cochrane review on this topic.¹³ These trials were conducted prospectively and were randomized, hence reducing the potential bias. There have been a number of observational studies (studies that

⁸ <https://guides.lib.uci.edu/ebm/pyramid>.

⁹ <https://pubmed.ncbi.nlm.nih.gov/20614424/>.

¹⁰ <https://pubmed.ncbi.nlm.nih.gov/24623315/>; <https://pubmed.ncbi.nlm.nih.gov/29388196/>.

¹¹ <https://pubmed.ncbi.nlm.nih.gov/29388195/>.

¹² <https://pubmed.ncbi.nlm.nih.gov/29388195/> (emphasis added).

¹³ <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004876.pub4/full>.

looked retrospectively at historical data, generally from medical claims databases) that were not randomized, and hence highly susceptible to bias, which indicated influenza vaccines lowered the rate of hospitalization. These observational studies are unreliable and inconsistent with the well-controlled clinical trials which have not demonstrated any such reduction. Many of them have reported a dramatic and totally implausible efficacy of influenza vaccines (one famous one¹⁴ reported influenza vaccines reduced all deaths by half – not just influenza-associated deaths, but all deaths). Such results have long been criticized as plainly implausible,¹⁵ and a variety of studies have been conducted to understand how these analyses could arrive at such unbelievable results.¹⁶

15. In 2018, the Cochrane review of influenza vaccines in healthy children reached the conclusion that “at present we could find no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, or community transmission of influenza.”¹⁷ As for adults, in 2018 Cochrane concluded that “We found low-certainty evidence that hospitalisation rates and time off work may be comparable between vaccinated and unvaccinated adults, although the confidence interval around the effect for hospital admission is wide and there was substantial variation in the direction of effect on time off work.”¹⁸ In other words, there was no compelling evidence of demonstrating benefit in a reduction in hospital admission or time off work, and Cochrane recommended that a sufficiently large, “publicly funded, high-quality, placebo-controlled trial run over several seasons should be undertaken.”¹⁹ Other systematic

¹⁴ <https://www.nejm.org/doi/full/10.1056/NEJMoa070844>.

¹⁵ <https://pubmed.ncbi.nlm.nih.gov/18163274/>.

¹⁶ <https://pubmed.ncbi.nlm.nih.gov/16368725/> ; <https://pubmed.ncbi.nlm.nih.gov/16368724/> ; <https://pubmed.ncbi.nlm.nih.gov/18556629/>.

¹⁷ <https://pubmed.ncbi.nlm.nih.gov/29388195/>.

¹⁸ <https://pubmed.ncbi.nlm.nih.gov/29388196/>.

¹⁹ <https://pubmed.ncbi.nlm.nih.gov/29388196/>.

reviews focusing on randomized controlled trials have reached similar conclusions regarding the lack of a reduction in hospitalization and mortality from influenza vaccines. For example, a non-Cochrane systematic review published in *The Lancet Infectious Diseases* concluded that the “[e]vidence for protection in adults aged 65 years or older is lacking.”²⁰

16. In addition to the lack of credible evidence demonstrating any ability to prevent hospitalization and death, there are randomized trials which report findings that raise questions about the ability of influenza vaccines to **increase** risk of non-influenza flu-like symptoms; in one such study, conducted by the Centers for Disease Control and Prevention, the authors write: “During the 1997-1998 influenza season, vaccine recipients reported significantly more ILI-related [ILI = influenza like illness] sick days, lost workdays, and lost work hours for physician visits than placebo recipients.”²¹ The fact that the vaccine group in a randomized trial fared worse than the placebo group underscores the unpredictability of effects.

INFLUENZA VACCINES CAN CAUSE SERIOUS HARM

17. While influenza vaccines are often portrayed as risk free, no medical intervention is risk free, and serious adverse events linked to influenza vaccine have occurred. In general, the evidence base on harms from influenza vaccines can be characterized as largely inadequate, leaving great uncertainty about the benefit/harms profile, particularly in children.

18. Part of the reason for this lack of certainty is that harms from influenza vaccines are not adequately studied. For example, while Cochrane explained that “influenza vaccines were associated with serious harms such as narcolepsy and febrile convulsions,” it surprisingly found:

...only one safety study of inactivated vaccine in children under 2 years, carried out nearly 30 years ago in 35 children (ab Wright 1976a). The lack of safety data for inactive vaccines in younger

²⁰ <https://pubmed.ncbi.nlm.nih.gov/22032844/>.

²¹ <https://pubmed.ncbi.nlm.nih.gov/11015795/>.

children is particularly surprising given that the inactive vaccine is now recommended for healthy children six months and older in the USA and Canada (AAPCID 2004; Harper 2004; Orr 2004).²²

The Cochrane report also highlights a number of other issues. For many studies, adverse events are not adequately described or reported. Many important adverse events in part lack a more robust evidence base for lack of standardized ways of measuring adverse events, a point raised in other safety reviews.²³ For some influenza vaccines, manufacturers refused to provide all data regarding harms. Adverse events also tend to be actively monitored for only a short period of time, relying on passive data collection methods for detecting adverse events after a brief initial period.

19. Also consider events that occurred during the last pandemic a decade ago, with two “swine flu” H1N1 vaccines in 2009-10, vaccines for which heightened surveillance was put in place. That influenza season would witness the following, as one of us wrote about in *JAMA Internal Medicine*: “Australia suspended its universal vaccination program for children younger than 5 years because of a surge in febrile convulsions following vaccination (1 in 110 children).²⁴

20. In terms of the potential for injury from the influenza vaccine, it is worth noting that in the last ten years, the Vaccine Adverse Events Reporting System (VAERS), administered by the CDC and FDA, has received reports of the following serious events following receipt of an influenza vaccine: 1,527 deaths; 3,327 permanent disabilities; 12,692 hospitalizations; and 40,040 emergency room and/or medical office visits.²⁵ A report from researchers at Harvard Medical School, including the Director of Bioinformatics, funded by the Agency for Health Research and

²² <https://pubmed.ncbi.nlm.nih.gov/29388195/>.

²³ <https://pubmed.ncbi.nlm.nih.gov/26822822/>.

²⁴ Stokes B. Ministerial review into the public health response into the adverse events to the seasonal influenza vaccine. Department of Health, Government of Western Australia; July 2010. https://ww2.health.wa.gov.au/-/media/Files/Corporate/Reports-and-publications/PDF/Stokes_Report.pdf. Accessed December 7, 2020.

²⁵ <https://wonder.cdc.gov/vaers.html> (Query date Nov 25, 2020; covers July 1, 1990 to present.)

Quality, an agency within the United States Department of Health and Human Services, stated that “fewer than 1% of vaccine adverse events are reported” to VAERS.²⁶

21. Influenza vaccines represent 50% (3,852) of the 7,705 compensated claims (10/01/1988 through 09/01/2020),²⁷ for which damages have been paid out by the Vaccine Injury Compensation Program, administered in the United States Court of Federal Claims.²⁸ The injuries for which this compensation has been paid for claims of injury from the influenza vaccine include: Acute Disseminated Encephalomyelitis (ADEM), Anaphylaxis (severe allergic reaction), Axonal Polyneuropathy, Bell’s Palsy, Cellulitis, Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), Clinically Isolated Syndrome (CIS), Complex Regional Pain Syndrome (CRPS), Cardiac Arrest, Death, Fibromyalgia, Guillain-Barre Syndrome (GBS), Insomnia, Multiple Sclerosis (MS), Motor Neuropathy, Optic Neuritis, Parsonage-Turner Syndrome (brachial neuritis), Postural orthostatic tachycardia syndrome (POTS), Sensory Polyneuropathy, Shoulder Injury Related to Vaccine Administration (SIRVA), Small Fiber Neuropathy, Stevens Johnson Syndrome (SJS), Subcutaneous Abscess, Transverse Myelitis (TM), Vasovagal Syncope.²⁹

22. We are not drawing conclusions regarding the causal role of the vaccine in the VAERS reports or federal court compensation cases, nor do we know the frequency of each type of adverse event in the population as such conclusions cannot be made without further study. Instead, we highlight them to indicate the scale of such reports and the need for more rigorous study of influenza vaccine safety.

²⁶ <https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>.

²⁷ <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/data-statistics-report.pdf>.

²⁸ <https://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters>.

²⁹ <https://www.uscfc.uscourts.gov/aggregator/sources/7>.

UNINTENDED CONSEQUENCES AND NON-SPECIFIC EFFECTS

23. In addition to potential injuries, the influenza vaccine can have other unintended consequences: so-called “off-target” or “nonspecific effects.” This section outlines a few of these nonspecific effects.

24. An important nonspecific effect of influenza vaccine is that it may increase susceptibility to other influenza like illnesses. For example, a study from researchers at the University of Hong Kong, Queen Mary Hospital, and Centre for Influenza Research compared children receiving the influenza vaccine with those receiving a saline injection in a prospective randomized double-blind study.³⁰ Both groups had a statistically similar rate of influenza, but the group receiving the influenza vaccine had a statistically significant 4.4 times increased risk of non-influenza infections. Thus, the influenza vaccine appears to have increased these children’s susceptibility to other respiratory viral infections.

25. Rigorous observational studies also suggest that influenza vaccination may increase the risk of non-influenza respiratory viruses or novel influenza viruses, not covered in that year’s vaccine.³¹

26. There is also evidence for cohort, or year of birth, effects in influenza mortality, which have in particular been noticed during pandemics.³² The difference in survival rates depends on the experience individuals have in surviving influenza infection, which generates robust and long-lived immune memory. These individuals, upon encountering an influenza viral strain in old age for which they previously developed immunity, enjoy immunological memory to

³⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/>.

³¹ <https://pubmed.ncbi.nlm.nih.gov/29525279/>; <https://pubmed.ncbi.nlm.nih.gov/20386731/>.

³² <https://pubmed.ncbi.nlm.nih.gov/23717567/>; <https://pubmed.ncbi.nlm.nih.gov/31502229/>; <https://pubmed.ncbi.nlm.nih.gov/9652423/>.

these strains. In contrast, it is well established that influenza vaccines do not provide long-lived immunity conferred by natural infection and, moreover, influenza vaccines' very modest efficacy is even poorer for the elderly. The combination of these considerations can make a reasonable case that, given what we currently know about the disease and influenza vaccines, arguably the most effective strategy for an individual is to experience some influenza infection as a healthy adult, when the risk of complications is very low, thus generating a better immunity portfolio against influenza in old age, a time when the risk of complications is much higher.

CONCLUSION

27. While the harms from influenza vaccines are typically understated or not properly studied, the benefits of influenza vaccines are exaggerated, often contrary to the scientific findings, or simply asserted without evidence. It is unfortunate that public health officials justify their policies and statements regarding the influenza vaccine through selective citations of the evidence base rather than conclusions reached after systematic and thorough review of the reliable evidence.³³

28. For the avoidance of doubt, we are not against any individual receiving the influenza vaccine and in this affidavit we have not provided any opinion regarding other vaccines.

29. Rather, it is our collective scientific view that before a product is recommended to a patient, let alone mandated to a patient, there should be clear evidence to support the recommendation. There should be rigorous placebo-controlled, randomized trials that have

³³ As an additional example, the CDC technical document on influenza vaccines expressly states that "Influenza vaccination **might reduce** the frequency of secondary complications and risk for influenza-related hospitalization and death," which reflects the unproven nature of whether influenza vaccines can reduce hospitalization and death. <https://www.cdc.gov/mmwr/volumes/65/rr/rr6505a1.htm> (emphasis added). Nonetheless, the CDC's website pages designed for public and state health department consumption does not include this qualifier but rather inaccurately presents the evidence as clear cut and definitive. <https://www.cdc.gov/flu/about/burden-averted/2019-2020.htm> This is another example of the gap between the science and the policy.

demonstrated that influenza vaccines prevent transmission and reduce hospitalizations, ICU admissions, or mortality. Ideally, there should be at least two such trials, publicly funded, and run over multiple influenza seasons with multiple different influenza vaccines. Unfortunately, the reality is that, despite influenza vaccines being recommended since 1960, not a single placebo-controlled randomized trial was ever set up to study whether the vaccine carries any of these potential benefits. The proven benefits should also be large enough that it can be confidently judged that influenza vaccines will bring public health benefits in excess of any harms. The history of influenza vaccines does not support this premise.³⁴


SIGNED UNDER THE PAINS AND PENALTIES OF PERJURY,



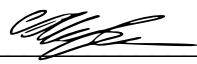
Peter Doshi



Peter Gøtzsche



Thomas Jefferson



Carl Heneghan

This 17 th day of December, 2020.

³⁴ It is also troubling to mandate a product whose safety and efficacy remain untested due to its reformulation every year and hence is effectively a new product every year, in addition to variations between products and lots of each influenza vaccine product.

EXHIBIT A

Curriculum Vitae of Peter Doshi, PhD

1) Biographical Information

A. Undergraduate Education

Brown University 1999 – 2002
Providence, Rhode Island
Bachelor of Arts
Anthropology

B. Graduate Education

Harvard University 2003 – 2006
Cambridge, Massachusetts
Master of Arts
Regional Studies—East Asia

Massachusetts Institute of Technology 2006 – 2011
Cambridge, Massachusetts
Doctor of Philosophy
History, Anthropology, and Science, Technology and Society

C. Postdoctoral Training

Johns Hopkins University School of Medicine 2011 – 2013
Baltimore, Maryland
Postdoctoral fellowship in Comparative Effectiveness Research
Divisions of General Pediatrics and General Internal Medicine

D. Employment Experience

University of Maryland School of Pharmacy
Assistant Professor of Pharmaceutical Health Services Research 2014 – 2019
Associate Professor of Pharmaceutical Health Services Research 2019 – present

BMJ 2013 – present
Associate Editor

Johns Hopkins University November 2012
Krieger School of Arts and Sciences
Part-time lecturer

2) Scholarly Activity

A. Publications in Refereed/Peer Reviewed Journals (Note: **Name of the faculty member in bold** and the corresponding author underlined. Students, residents, fellows, or post-docs supervised by the faculty member are indicated with an asterisk*)

1. **Doshi P**, Spence O*, Kuzucan A*, Powers JH 3rd. Communication of Nonefficacy Benefits of New Drugs Approved on the Basis of Noninferiority Trials Alone: Cohort Study of FDA and Sponsor Communication, 2011-2017. JAMA Intern Med. 2019;179(5):719–721. doi:10.1001/jamainternmed.2018.7040
2. Desai B*, Hong K*, Powers JH 3rd, **Doshi P**. Reporting of Drug Benefit in FDA-Approved Prescription Drug Labeling [published online ahead of print, 2019 Oct 28]. J Gen Intern Med. 2019;10.1007/s11606-019-05460-2. doi:10.1007/s11606-019-05460-2
3. Spence O*, Hong K*, Onwuchekwa Uba R*, **Doshi P**. Availability of study protocols for randomized trials published in high-impact medical journals: A cross-sectional analysis [published online ahead of print, 2019 Aug 26]. Clin Trials. 2019;1740774519868310. doi:10.1177/1740774519868310
4. **Doshi P**, Sieluk J*, Hung A*. The possible harms of statins: What do product labels, patient package inserts, and pharmacy leaflets tell us?. J Am Pharm Assoc (2003). 2019;59(2):195–201. doi:10.1016/j.japh.2018.12.003
5. Jefferson T, **Doshi P**, Boutron I, Golder S, Heneghan C, Hodgkinson A, Jones M, Lefebvre C, Stewart LA. When to include clinical study reports and regulatory documents in systematic reviews. BMJ Evid Based Med. 2018 Dec;23(6):210-217. doi: 10.1136/bmjebm-2018-110963. Epub 2018 Oct 11. PubMed PMID: 30309870.
6. Jørgensen L, **Doshi P**, Gøtzsche P, Jefferson T. Challenges of independent assessment of potential harms of HPV vaccines. BMJ. 2018 Sep 24;362:k3694. doi: 10.1136/bmj.k3694. PubMed PMID: 30249615.
7. **Doshi P**. Pandemrix vaccine: why was the public not told of early warning signs? BMJ. 2018 Sep 20;k3948. doi: 10.1136/bmj.k3948.
8. Jørgensen L, **Doshi P**, Gøtzsche P, Jefferson T. Challenges of independent assessment of potential harms of HPV vaccines. BMJ. 2018 Sep 24;k3694. doi: 10.1136/bmj.k3694.
9. Hodgkinson A, Dietz KC, Lefebvre C, Golder S, Jones M, **Doshi P**, et al. The use of clinical study reports to enhance the quality of systematic reviews: a survey of systematic review authors. Systematic Reviews. 2018 Dec [cited 2018 Oct 2];7(1). doi: 10.1186/s13643-018-0766-x
10. Spence O*, Onwuchekwa Uba R*, Shin S*, **Doshi P**. Patient consent to publication and data sharing in industry and NIH-funded clinical trials. Trials 2018

May 3;19(1):269. doi: 10.1186/s13063-018-2651-2.

0 citations (Scopus), 55 social media mentions (PlumX Metrics), 4 readers on Mendeley (PlumX Metrics)

11. **Doshi P**, Hur P*, Jones M, Albarmawi H*, Jefferson T, Morgan DJ, et al. Informed consent to study purpose in randomized clinical trials of antibiotics, 1991 through 2011. *JAMA Intern Med* 2017;177(10):1452-1459.
4 citations (Scopus), 53 blog and social media mentions (Altmetric), 13 news outlet mentions (Altmetric), 9 readers on Mendeley (PlumX metrics), 7 full text views in EBSCO databases (PlumX Metrics), 342 PDF downloads from journal website
12. **Mayo-Wilson E**, Li T, Fusco N, Bertizzolo L, Canner JK, Cowley T, **Doshi P**, Ehmsen J, Gresham G, Guo N, Haythornthwaite JA, Heyward J, Hong H, Pham D, Payne JL, Rosman L, Stuart EA, Suarez-Cuervo C, Tolbert E, Twose C, Vedula S, Dickersin K. Cherry-picking by trialists and meta-analysts can drive conclusions about intervention efficacy. *J Clin Epidemiol* 2017 Nov;91:95-110.
3 citations (Scopus), 62 blog and social media mentions (PlumX Metrics), 11 readers on Mendeley (PlumX Metrics)
13. **Doshi P**. The unofficial vaccine educators: are CDC funded non-profits sufficiently independent? *BMJ* 2017 Nov 7;359:j5104.
0 citations (Scopus), 273 social media mentions (Altmetric), 4 readers on Mendeley (Altmetric), 1734 full text views on journal website, 205 PDF downloads from journal website
14. Sieluk J*, Palasik B*, dosReis S, **Doshi P**. ADHD medications and cardiovascular adverse events in children and adolescents: cross-national comparison of risk communication in drug labeling. *Pharmacoepidemiol Drug Saf* 2017 Mar;26(3):274-284.
0 citations (Scopus), 6 social media mentions (Altmetric), 3 readers on Mendeley (Altmetric)
15. **Spelsberg A**, Prugger C, **Doshi P**, Ostrowski K, Witte T, Husgen D, et al. Contribution of industry funded post-marketing studies to drug safety: survey of notifications submitted to regulatory agencies. *BMJ* 2017 Feb 7;356:j337.
3 citations (Scopus), 263 blog and social media mentions (Altmetric), 7 news outlet mentions (Altmetric), 21 readers on Mendeley (Altmetric), 18,941 full text views on journal website, 1927 PDF downloads from journal website, 9 user-generated Bitly links to article with a total of 200 link clicks (PlumX Metrics)
16. **Doshi P**, Jefferson T. Open data 5 years on: A case series of 12 freedom of information requests for regulatory data to the European Medicines Agency. *Trials* 2016;17(1).
9 citations (Scopus), 59 blog and social media mentions (Altmetric), 15 readers on Mendeley (PlumX Metrics), 10 full text views in EBSCO databases (PlumX Metrics), 8 user-generated Bitly links to article with a total of 99 link clicks (PlumX Metrics)

17. **Doshi P.** Is this trial misreported? Truth seeking in the burgeoning age of trial transparency. *BMJ* 2016 Oct 24;355:i5543.
2 citations (Scopus), 59 blog and social media mentions (Altmetric), 10 readers on Mendeley (Altmetric), 1761 full text views on journal website, 239 PDF downloads from journal website
18. **Heneghan CJ, Onakpoya I, Jones MA, Doshi P, Del Mar CB, Hama R, Thompson MJ, Spencer EA, Mahtani KR, Nunan D, Howick J, Jefferson T.** Neuraminidase inhibitors for influenza: a systematic review and meta-analysis of regulatory and mortality data. *Health Technol Assess* 2016 May;20(42):1-242.
10 citations (Scopus), 84 blog and social media mentions (Altmetric), 1 news outlet mention (PlumX Metrics) 1 policy document mention (Altmetric), 46 readers on Mendeley (Altmetric), 1 Wikipedia reference (PlumX Metrics)
19. **Doshi P.** Data too important to share: do those who control the data control the message? *BMJ* 2016 Mar 2;352:i1027.
13 citations (Scopus), 93 blog and social media mentions (Altmetric), 4 news outlet mentions (Altmetric), 20 readers on Mendeley (Altmetric), 9127 full text views on journal website, 1086 PDF downloads from journal website, 3 user-generated Bitly links to article with a total of 5 link clicks (PlumX Metrics)
20. **Persaud N, Doshi P.** North American regulatory agencies can and should make clinical trial data publicly available. *CMAJ* 2016 Feb 2;188(2):96-97.
5 citations (Scopus), 21 blog and social media mentions (Altmetric), 1 reader on Mendeley (Altmetric), 1 full text view in EBSCO databases (PlumX Metrics)
21. **Hung A*, Sieluk J*, Doshi P.** The Untapped Potential of Pharmacy Leaflets for Informing Patients About Drug Benefits and Risks. *JAMA Intern Med* 2016 Jan;176(1):11-12.
1 citation (Scopus), 87 blog and social media mentions (Altmetric), 9 readers on Mendeley (Altmetric), 1 full text view in EBSCO databases (PlumX Metrics), 517 PDF downloads from journal website
22. **Doshi P.** Defining antibiotic effectiveness and resistance: how a private party may soon rule judgments over susceptibility testing. *BMJ* 2016 Jan 6;352:h6849.
0 citations (Scopus), 19 social media mentions (Altmetric), 3 readers on Mendeley (Altmetric), 733 full text views on journal website, 168 PDF downloads from journal website
23. **Mayo-Wilson E, Hutfless S, Li T, Gresham G, Fusco N, Ehmsen J, Heyward J, Vedula S, Lock D, Haythornthwaite J, Payne JL, Cowley T, Tolbert E, Rosman L, Twose C, Stuart EA, Hong H, Doshi P, Suarez-Cuervo C, Singh S, Dickersin K.** Integrating multiple data sources (MUDS) for meta-analysis to improve patient-centered outcomes research: A protocol for a systematic review. *Syst Rev* 2015;4(1).
2 citations (Scopus), 13 social media mentions (Altmetric), 22 readers on Mendeley (Altmetric)

24. Mayo-Wilson E, Doshi P, Dickersin K. Are manufacturers sharing data as promised? *BMJ* 2015 Sep 25;351:h4169.
6 citations (Scopus), 57 blog and social media mentions (Altmetric), 4 readers on Mendeley (Altmetric), 974 full text views on journal website, 211 PDF downloads from journal website
25. Doshi P. Speeding new antibiotics to market: a fake fix? *BMJ* 2015 Mar 25;350:h1453.
14 citations (Scopus), 150 blog and social media mentions (Altmetric), 2 news outlet mentions (Altmetric), 25 readers on Mendeley (Altmetric), 6165 full text views on journal website, 811 PDF downloads from journal website, 2 full text views in EBSCO databases (PlumX Metrics), 6 user-generated Bitly links to article with a total of 286 link clicks (PlumX Metrics)
26. Jefferson T, Jones MA, Doshi P, Del Mar CB, Hama R, Thompson MJ, et al. Neuraminidase inhibitors for preventing and treating influenza in adults and children. *Cochrane Database Syst Rev* 2014;2014(4).
128 citations (Scopus), 398 blog and social media mentions (Altmetric), 37 news outlet mentions (Altmetric), 188 readers on Mendeley (Altmetric), 1 policy document reference (Altmetric), 5 Wikipedia references (Altmetric), 4 YouTube video mentions (Altmetric), 9 user-generated Bitly links to article with a total of 32 link clicks (PlumX Metrics)
27. Jefferson T, Jones MA, Doshi P, Del Mar CB, Hama R, Thompson MJ, et al. Risk of bias in industry-funded oseltamivir trials: comparison of core reports versus full clinical study reports. *BMJ Open* 2014 Sep 30;4(9):e005253-2014-005253.
8 citations (Scopus), 88 blog and social media mentions (Altmetric), 1 news outlet mention (Altmetric), 23 readers on Mendeley (Altmetric), 1 policy document reference (Altmetric), 4490 full text views on journal website, 567 PDF downloads from journal website, 9 user-generated Bitly links to article with a total of 18 link clicks (PlumX Metrics)
28. Jefferson T, Doshi P. Multisystem failure: the story of anti-influenza drugs. *BMJ* 2014 Apr 10;348:g2263.
31 citations (Scopus), 26 blog and social media mentions (Altmetric), 33 readers on Mendeley (Altmetric), 1 Wikipedia reference (PlumX Metrics) 5952 full text views on journal website, 1344 PDF downloads from journal website, 5 user-generated Bitly links to article with a total of 3 link clicks (PlumX Metrics)
29. Jefferson T, Jones M, Doshi P, Spencer EA, Onakpoya I, Heneghan CJ. Oseltamivir for influenza in adults and children: systematic review of clinical study reports and summary of regulatory comments. *BMJ* 2014 Apr 9;348:g2545.
106 citations (Scopus), 776 blog and social media mentions (Altmetric), 32 news outlet mentions (Altmetric), 156 readers on Mendeley (Altmetric), 2 Wikipedia references (PlumX Metrics), 105,987 full text views on journal website, 18,869 PDF downloads from journal website, 1 full text view in EBSCO databases

- (PlumX Metrics), 26 user-generated Bitly links to article with a total of 139 link clicks (PlumX Metrics)*
30. **Doshi P**, Dickersin K, Healy D, Vedula SS, Jefferson T. Restoring invisible and abandoned trials: A call for people to publish the findings. *BMJ* 2013;346(7913). *78 citations (Scopus), 336 blog and social media mentions (Altmetric), 47 news outlet mentions (Altmetric), 1 Wikipedia reference (PlumX Metrics), 89 readers on Mendeley (Altmetric), 56,338 full text views on journal website, 5169 PDF downloads from journal website, 19 user-generated Bitly links to article with a total of 134 link clicks (PlumX Metrics)*
 31. **Doshi P**. Influenza vaccines: time for a rethink. *JAMA Intern Med* 2013 Jun 10;173(11):1014-1016. *10 citations (Scopus), 95 social media mentions (Altmetric), 1 news outlet mention (PlumX Metrics), 19 readers on Mendeley (Altmetric), 1 full text view in EBSCO databases (PlumX Metrics), 972 PDF downloads from journal website, 4 user-generated Bitly links to article with a total of 2 link clicks (PlumX Metrics)*
 32. **Doshi P**, Jefferson T. The first 2 years of the European Medicines Agency's policy on access to documents: secret no longer. *JAMA Intern Med* 2013 Mar 11;173(5):380-382. *19 citations (Scopus), 3 blog mentions (Altmetric), 10 readers on Mendeley (Altmetric), 4 full text views in EBSCO databases, 1079 PDF downloads from journal website, 2 user-generated Bitly links to article with a total of 1 link click (PlumX Metrics)*
 33. **Doshi P**, Jefferson T. Clinical study reports of randomised controlled trials: an exploratory review of previously confidential industry reports. *BMJ Open* 2013 Feb 26;3(2):10.1136/bmjopen-2012-002496. Print 2013. *38 citations (Scopus), 57 blog and social media mentions (Altmetric), 1 policy document reference (Altmetric), 18 readers on Mendeley (Altmetric), 10,343 full text views on journal website, 1558 PDF downloads from journal website*
 34. **Doshi P**, Jefferson T, Del Mar C. The imperative to share clinical study reports: recommendations from the Tamiflu experience. *PLoS Med* 2012;9(4):e1001201. *95 citations (Scopus), 117 blog and social media mentions (journal website), 141 readers on Mendeley (Mendeley.com), 1 Wikipedia reference (PlumX Metrics), 62,915 full text views on journal website, 5459 PDF downloads from journal website and PubMed Central, 1 user-generated Bitly link to article with a total of 3 link clicks (PlumX Metrics)*
 35. **Jefferson T**, Jones MA, **Doshi P**, Del Mar CB, Heneghan CJ, Hama R, et al. Neuraminidase inhibitors for preventing and treating influenza in healthy adults and children. *Cochrane Database Syst Rev* 2012 Jan 18;1:CD008965. *89 citations (Scopus), 66 blog and social media mentions (Altmetric), 7 news outlet mentions (Altmetric), 99 readers on Mendeley (Altmetric), 3 Wikipedia references (PlumX Metrics), 1 YouTube video mentions (Altmetric)*

36. **Doshi P**, Jones M, Jefferson T. Rethinking credible evidence synthesis. *BMJ* 2012 Jan 17;344:d7898.
39 citations (Scopus), 26 blog and social media mentions (Altmetric), 58 readers on Mendeley (Altmetric), 1 policy document reference (Altmetric), 11,133 full text views on journal website, 1832 PDF downloads from journal website
37. **Doshi P**. The elusive definition of pandemic influenza. *Bull World Health Organ* 2011 Jul 1;89(7):532-538.
40 citations (Scopus), 41 readers on Mendeley (PlumX Metrics), 515 full text views in EBSCO databases (PlumX Metrics)
38. Jefferson T, **Doshi P**, Thompson M, Heneghan C, Cochrane Acute Respiratory Infections Group. Ensuring safe and effective drugs: who can do what it takes? *BMJ* 2011 Jan 11;342:c7258.
37 citations (Scopus), 12 blog and social media mentions (Altmetric), 2 news outlet mentions (Altmetric), 38 readers on Mendeley (Altmetric), 7022 full text views on journal website, 11 PDF downloads from journal website, 3 user-generated Bitly links to article with a total of 109 link clicks (PlumX Metrics)
39. Jefferson T, Jones M, **Doshi P**, Del Mar C, Dooley L, Foxlee R. Neuraminidase inhibitors for preventing and treating influenza in healthy adults. *Cochrane Database Syst Rev* 2010 Feb 17;(2):CD001265. doi(2):CD001265.
60 citations (Scopus), 2 blog and social media mentions (Altmetric), 14 readers on Mendeley (Altmetric)
40. **Doshi P**. Neuraminidase inhibitors--the story behind the Cochrane review. *BMJ* 2009 Dec 8;339:b5164.
58 citations (Scopus), 47 blog and social media mentions (Altmetric), 4 news outlet mentions (Altmetric), 52 readers on Mendeley (Altmetric), 14,332 full text views on journal website, 7 PDF downloads from journal website
41. Jefferson T, Jones M, **Doshi P**, Del Mar C. Neuraminidase inhibitors for preventing and treating influenza in healthy adults: systematic review and meta-analysis. *BMJ* 2009 Dec 8;339:b5106.
209 citations (Scopus), 45 blog and social media mentions (Altmetric), 5 news outlet mentions (Altmetric), 2 Wikipedia references (Altmetric), 101 readers on Mendeley (Altmetric), 79,183 full text views on journal website, 13,916 PDF downloads from journal website, 7 full text views in EBSCO databases (PlumX Metrics), 2 user-generated Bitly links to article with a total of 1 link click (PlumX Metrics)
42. **Doshi P**. Calibrated response to emerging infections. *BMJ* 2009 Sep 3;339:b3471.
63 citations (Scopus), 2 blog mentions (Altmetric), 1 Wikipedia reference (PlumX Metrics), 8 readers on Mendeley (Altmetric), 9667 full text views on journal website, 30 PDF downloads from journal website
43. **Doshi P**. Trends in recorded influenza mortality: United States, 1900-2004. *Am J*

Public Health 2008 May;98(5):939-945.

48 citations (Scopus), 11 social media mentions (Altmetric), 3 news outlet mentions (Altmetric), 37 readers on Mendeley (Altmetric), 3466 full text views in EBSCO databases (PlumX Metrics)

B. Presentations at Scientific or Professional Meetings

(Note: **Name of the faculty member in bold**. Students, residents, fellows, or post-docs supervised by the faculty member are indicated with an asterisk*)

1. **Doshi P.** The BMJ Investigative Journalism Conference. "Standards for drug approval: too stringent, too lax, or just right?" Berlin, Germany. November 18, 2019
Presentation; International; Podium
2. **Doshi P.** Friends of the National Library of Medicine conference. "Better clinical trials for new product development" Bethesda, MD. June 14, 2017
Invited presentation; National; Podium
3. **Doshi P.** "The gain to be realized by research transparency." 2016 Consumers United for Evidence-based Health Care annual meeting July 29, 2016, Washington DC
Invited presentation; National; Podium
4. **Doshi P**, Sieluk J*, Hung A*. "The Possible Harms of Statins: What do Product Labels and Pharmacy Leaflets Tell Us?" AACP Annual Meeting, Anaheim, CA. July 2016;
Invited presentation; National; Poster
5. **Doshi P.** Johns Hopkins School of Public Health. "The Hopkins mandatory flu vaccination policy, the search for truth, and freedom of speech in an academic institution" Baltimore, MD. June 10, 2016
Invited presentation; Local; Podium
6. **Doshi P.** "Adaptive Licensing & Access to Data" webcast presentation to European Public Health Alliance, Brussels, Belgium. April 18, 2016
Invited presentation; International; Webcast
7. **Doshi P.** "Speeding new antibiotics to market: a fake fix?", National Physicians Alliance annual meeting. Washington, DC.; October 17, 2015
Invited presentation; National; Podium
8. **Doshi P.** "How CUE can engage lay journalists", 2015 Consumers United for Evidence-based Health Care annual meeting, July 24, 2015. Washington, DC
Invited presentation; National; Podium
9. **Doshi P.** "Good and Bad Reanalysis", Society for Clinical Trials. May 19, 2015. Washington, DC
Invited presentation; National; Podium

10. **Doshi P.** “How Open Data Can Reduce Reporting Biases and Help Patients Choose Wisely,” Global Health & Innovation Conference. March 29, 2015, New Haven, CT
Invited presentation; National; Podium
11. **Doshi P.** “Who wants my data and what are they going to do with it?”, Consumers United for Evidence-based Healthcare (CUE) annual meeting, Washington D.C., July 25, 2014
Invited presentation; Non-reviewed; National; Podium
12. **Doshi P.** “Searching for evidence under the waterline”, Health Technology Assessment International (HTAi) annual meeting, Washington, DC, June 18, 2014
Invited presentation; International; Podium
13. **Doshi P.** “‘Open’ access to clinical trials: rhetoric and fine print”, Society for Clinical Trials annual meeting, Philadelphia, May 19, 2014
Invited presentation; National; Podium
14. **Doshi P.** “Thoughts on misleading analyses”, Presentation at Institute of Medicine consensus study meeting, February 4, 2014
Invited presentation; National; Podium
15. **Doshi P.** “Restoring Invisible and Abandoned Trials: the RIAT concept”, presentation at CBI conference on Clinical Data Disclosure and Transparency, January 30, 2014
Invited presentation; National; Podium
16. **Doshi P.** “Restoring Invisible and Abandoned Trials: the RIAT concept”, presentation at “The state of contemporary biomedical literature” conference sponsored by age.na.s, Rome, Italy, December 12, 2013
Invited presentation; International; Podium
17. **Doshi P.** “Restoring Invisible and Abandoned Trials: the RIAT concept”, presentation at oPen conference, Naples, Italy, December 13, 2013
Invited presentation; International; Podium
18. **Doshi P.** “Credible evaluation of trials: what kind of data do we need?”, Presentation at Institute of Medicine workshop on sharing clinical research data, October 5, 2012
Invited presentation; National; Podium
19. **Doshi P, Bass E.** “Do media understand that systematic reviews are not just another ‘new study’?” 18th Annual National Research Services Award (NRSA) Conference; June 23, 2012
Presentation; National; Poster

C. Special Lectures (Invited)

1. "Working with regulatory data – a non-regulatory, non-industry perspective" Presentation to closed FDA-Health Canada meeting, Silver Spring, November 13, 2018; Invited lecture.
2. "Better evidence for better health" Presentation to WHO Uppsala Monitoring Centre 40th Anniversary, Uppsala, Sweden; May 17, 2018; Invited lecture
3. "The RIAT Initiative for Tackling Bias in Biomedical Literature" Presentation to National Library of Medicine ClinicalTrials.gov team, March 5, 2018; Invited lecture.
4. "Interim guidance on how to decide whether to include clinical study reports and other regulatory documents into Cochrane reviews" Presentation to Cochrane Scientific Committee, by web, February 28, 2018; Invited lecture
5. "Ensuring Accuracy in Clinical Trial Publications: Weighing Options" Continuing medical education lecture, Food and Drug Administration. Silver Spring, MD. October 25, 2017; Invited lecture
6. Office of Research Integrity conference "Quest for Research Excellence". Washington, DC. August 9, 2017; Panel Participation
7. "Why we need clinical trial data, and how FDA can help reduce abuse of the medical literature" Food and Drug Administration, Silver Spring, MD. June 6, 2017; Invited lecture
8. "Ensuring accuracy in clinical trial publications: weighing options" online webcast through University of Maryland M-CERSI program. April 20, 2017; Invited lecture
9. "Ensuring accuracy in clinical trial publications: weighing options" Food and Drug Administration, Silver Spring, MD. March 14, 2017; Invited lecture
10. "Finding "Big Data" (OK, big detail) under the waterline" Johns Hopkins University, Baltimore, MD. January 27, 2017; Invited lecture
11. "How We Fooled Ourselves into Thinking the Revolution on Data Transparency Was Won," Johns Hopkins Center for Clinical Trials seminar series January 6, 2016; Invited lecture
12. "The NYAG's contribution to evidence-based medicine," New York State Attorney General's Office. New York, NY; November 9, 2015; Invited lecture
13. "Breaking the Seal on Drug Company Research", presentation at Des Moines University "Leadership series" seminar, Des Moines, Iowa; September 18, 2014; Invited lecture
14. Dean's Convocation panel on "Big Data." University of Maryland School of Law; September 22, 2014; Panel participation

D. Other Publications and Related Activities

1. Publications not peer reviewed

1. Lexchin J, Herder M, **Doshi P**. Canada finally opens up data on new drugs and devices. *BMJ*. 2019;365:l1825. Published 2019 Apr 17. doi:10.1136/bmj.l1825
2. **Doshi P**. EMA scales back transparency initiatives because of workload. *BMJ* 2018;362:k3513. doi: 10.1136/bmj.k3513.
3. **Doshi P**, Shamseer L*, Jones M, Jefferson T. Restoring biomedical literature with RIAT. *BMJ* 2018 Apr 26;361:k1742. doi: 10.1136/bmj.k1742.
0 citations (Scopus), 60 social media mentions (Altmetric), 1 reader on Mendeley (Altmetric), 118 PDF downloads from journal website
4. **Doshi P**. EMA recommendation on hydroxyethyl starch solutions obscured controversy. *BMJ* 2018 Mar 20;360:k1287. doi: 10.1136/bmj.k1287.
1 citation (Scopus), 22 blog and social media mentions (Altmetric), 1 reader on Mendeley (Altmetric), 161 PDF downloads from journal website
5. **Doshi P**. CDC tightens controls on scientists' communication with news media. *BMJ* 2018 Feb 14;360:k675.
0 citations (Scopus), 5 social media mentions (Altmetric), 3 news outlet mentions (Altmetric), 4 readers on Mendeley (Altmetric), 403 full text views on journal website, 63 PDF downloads from journal website
6. **Doshi P**. FDA to begin releasing clinical study reports in pilot programme. *BMJ* 2018 Jan 23;360:k294.
0 citations (Scopus), 47 blog and social media mentions (Altmetric), 294 full text views on journal website, 61 PDF downloads from journal website
7. **Doshi P**. "Independent" reanalysis of landmark starch solutions trial was published by original authors. *BMJ* 2017 Jul 21;358:j3552.
0 citations (Scopus), 96 blog and social media mentions (Altmetric), 2 news outlet mentions (Altmetric), 2 readers on Mendeley (Altmetric), 2536 full text views on journal website, 274 PDF downloads from journal website
8. **Doshi P**. The problem with US website for collecting adverse events after vaccination is resolved. *BMJ* 2017 Sep 8;358:j4164.
0 citations (Scopus), 133 social media mentions (Altmetric), 131 full text views on journal website, 46 PDF downloads from journal website
9. **Doshi P**. US government website for collecting adverse events after vaccination is inaccessible to most users. *BMJ* 2017;357.
0 citations (Scopus), 325 social media mentions and interactions (PlumX Metrics), 2 news outlet mentions (PlumX Metrics), 550 full text views on journal website, 67 PDF downloads from journal website
10. **Doshi P**, Godlee F. The wider role of regulatory scientists. *BMJ* 2017 Apr

27;357;j1991.

4 citations (Scopus), 45 blog and social media mentions (Altmetric), 3 readers on Mendeley (Altmetric), 1224 full text views on journal website, 216 PDF downloads from journal website

11. **Doshi P.** FDA unease about faster drug approval. *BMJ* 2017;357.
2 citations (Scopus), 124 blog and social media mentions (Altmetric), 1 news outlet mention (Altmetric), 3 readers on Mendeley (Altmetric), 908 full text views on journal website, 169 PDF downloads from journal website
12. **Doshi P.** Medical response to Trump requires truth seeking and respect for patients. *BMJ* 2017 Feb 7;356:j661.
0 citations (Scopus), 188 blog and social media mentions (Altmetric), 2 news outlet mentions (Altmetric), 3 readers on Mendeley (Altmetric), 8710 full text views on journal website, 147 PDF downloads from journal website
13. **Doshi P.** Update: New England journal of medicine publishes correction to 2012 chest trial of hydroxyethyl starch versus colloids. *BMJ* 2016;352.
3 citations (Scopus), 4 social media mentions (Altmetric), 2 readers on Mendeley (Altmetric), 653 full text views on journal website, 233 PDF downloads from journal website
14. **Zito JM, Doshi P.** For-profit Uses of Real-World Data: What Would Frances Kelsey Do? *Med Care* 2016 Dec;54(12):1045-1047.
3 citations (Scopus), 1 social media mention (Altmetric), 2 readers on Mendeley (Altmetric)
15. **Doshi P.** FDA drug summaries: a simplification too far? *BMJ* 2015 Jun 12;350:h3135.
0 citations (Scopus), 14 social media mentions (Altmetric), 1 news outlet mention (Altmetric), 4 readers on Mendeley (Altmetric), 665 full text views on journal website, 181 PDF downloads from journal website, 3 user-generated Bitly links to article with a total of 4 link clicks (PlumX Metrics)
16. **Doshi P.** Convicting Zika. *BMJ* 2016 Apr 7;353:i1847.
4 citations (Scopus), 79 social media mentions (Altmetric), 52 readers on Mendeley (Altmetric), 17,401 full text views on journal website, 1085 PDF downloads from journal website, 4 user-generated Bitly links to article with a total of 39 link clicks (PlumX Metrics)
17. **Doshi P,** Jefferson T. The evidence base for new drugs: New legislation in germany provides another piece of a complex puzzle. *BMJ* 2015;350.
0 citations (Scopus), 61 blog and social media mentions (Altmetric), 1 news outlet mention (Altmetric), 1 reader on Mendeley (Altmetric), 1 Wikipedia reference (PlumX Metrics), 1118 full text views on journal website, 474 PDF downloads from journal website, 3 user-generated Bitly links to article with a total of 1 link click (PlumX Metrics)
18. **Doshi P,** Stahl-Timmins W, Merino JG, Simpkins C. Visualising childhood

vaccination schedules across G8 countries. *BMJ* 2015;351.
2 citations (Scopus), 17 social media mentions (Altmetric), 6 readers on Mendeley (Altmetric), 1331 full text views on journal website, 272 PDF downloads from journal website, 1 user-generated Bitly link to article with a total of 1 link click (PlumX Metrics)

19. Jones M, Jefferson T, **Doshi P**, Del Mar C, Heneghan C, Onakpoya I. Commentary on Cochrane review of neuraminidase inhibitors for preventing and treating influenza in healthy adults and children. *Clin Microbiol Infect* 2015;21(3):217-221.
5 citations (Scopus), 2 social media mentions (PlumX Metrics)
20. **Doshi P**. No correction, no retraction, no apology, no comment: paroxetine trial reanalysis raises questions about institutional responsibility. *BMJ* 2015 Sep 16;351:h4629.
16 citations (Scopus), 535 blog and social media mentions (Altmetric), 52 news outlet mentions (Altmetric), 46 readers on Mendeley (Altmetric), 21,165 full text views on journal website, 2473 PDF downloads from journal website, 18 user-generated Bitly links to article with a total of 266 link clicks (PlumX Metrics)
21. **Doshi P**. 21st century cures: is US medicines bill a colossal mistake? *BMJ* 2015 Jul 23;351:h4013.
3 citations (Scopus), 66 blog and social media mentions (Altmetric), 1 news outlet mention (Altmetric), 6 readers on Mendeley (Altmetric), 1563 full text views on journal website, 127 PDF downloads from journal website, 1 user-generated Bitly link to article with a total of 2 link clicks (PlumX Metrics)
22. **Doshi P**. No vote in US Congress on proposal to create new pathway for approving antibiotics. *BMJ* 2015 Mar 31;350:h1767.
0 citations (Scopus), 3 social media mentions (Altmetric), 1 news outlet mention (Altmetric), 152 full text views on journal website, 60 PDF downloads from journal website
23. **Doshi P**, Zito J, DosReis S. Digging for data on harms in duloxetine trials: It's time for policy makers to get serious about drug related harms. *BMJ* 2014;348.
2 citations (Scopus), 6 blog and social media mentions (Altmetric), 16 readers on Mendeley (Altmetric), 1092 full text views on journal website, 363 PDF downloads from journal website
24. Jefferson T, Jones MA, **Doshi P**, Del Mar CB, Hama R, Thompson M, et al. Neuraminidase inhibitors for preventing and treating influenza in healthy adults and children. *Sao Paulo Med J* 2014;132(4):256-257.
2 citations (Scopus), 2 readers on Mendeley (PlumX Metrics)
25. **Doshi P**. US incentive scheme for neglected diseases: a good idea gone wrong? *BMJ* 2014 Jul 21;349:g4665.
4 citations (Scopus), 2 blog and social media mentions (Altmetric), 1 policy document reference (Altmetric), 19 readers on Mendeley (PlumX Metrics), 3158

- full text views on journal website, 350 PDF downloads from journal website, 6 user-generated Bitly links to article with a total of 2 link clicks (PlumX Metrics)*
26. **Doshi P.** EMA policy on transparency is "strikingly" similar to deal struck with drug company, say experts. *BMJ* 2014 Jun 12;348:g3852.
1 citation (Scopus), 16 blog and social media mentions (Altmetric), 3 readers on Mendeley (PlumX Metrics), 606 full text views on journal website, 98 PDF downloads from journal website, 2 user-generated Bitly links to article with a total of 13 link clicks (PlumX Metrics)
 27. **Jefferson T, Doshi P.** Multisystem failure: the story of antinfluenza drugs. *Recent Prog Med* 2014 May;105(5):187-190.
2 citations (Scopus), 11 social media mentions and interactions (PlumX Metrics)
 28. **Doshi P.** From promises to policies: is big pharma delivering on transparency? *BMJ* 2014 Feb 26;348:g1615.
6 citations (Scopus), 60 blog and social media mentions (Altmetric), 1 reader on Mendeley (PlumX Metrics), 1510 full text views on journal website, 345 PDF downloads from journal website, 6 user-generated Bitly links to article with a total of 17 link clicks (PlumX Metrics)
 29. **Doshi P, Groves T, Loder E.** Clinical trial data: get them while you can. *BMJ: British Medical Journal* 2014 01/11;348(7940):8-8.
4 citations (Scopus), 19 social media mentions (Altmetric), 4 readers on Mendeley (PlumX Metrics), 1270 full text views on journal website, 262 PDF downloads from journal website
 30. **Doshi P, Vedula SS, Li T.** Yoda and truth seeking in medicine: Making sense of the curious case of rhBMP-2. *BMJ* 2013;347(7915).
2 citations (Scopus), 12 blog and social media mentions (Altmetric), 4 readers on Mendeley (Altmetric), 967 full text views on journal website, 246 PDF downloads from journal website
 31. **Doshi P, Goodman SN, Ioannidis JP.** Raw data from clinical trials: within reach? *Trends Pharmacol Sci* 2013 Dec;34(12):645-647.
29 citations (Scopus), 1 social media mention (PlumX Metrics), 34 readers on Mendeley (Mendeley.com)
 32. **Doshi P.** Transparency interrupted: the curtailment of the European Medicines Agency's Policy on access to documents. *JAMA Intern Med* 2013 Nov 25;173(21):2009-2011.
7 citations (Scopus), 10 blog and social media mentions (Altmetric), 10 readers on Mendeley (PlumX Metrics), 655 PDF downloads from journal website, 3 user-generated Bitly links to article with a total of 89 link clicks (PlumX Metrics)
 33. **Doshi P.** Putting GlaxoSmithKline to the test over paroxetine. *BMJ* 2013 Nov 12;347:f6754.
6 citations (Scopus), 67 blog and social media mentions (Altmetric), 23 readers on Mendeley (Altmetric), 1 Wikipedia reference (PlumX Metrics), 3012 full text views

on journal website, 466 PDF downloads from journal website, 1 full text view in EBSCO databases (PlumX Metrics), 2 user-generated Bitly links to article with a total of 11 link clicks (PlumX Metrics)

34. **Doshi P.** Influenza: marketing vaccine by marketing disease. *BMJ* 2013 May 16;346:f3037.
17 citations (Scopus), 952 social media mentions (Altmetric), 9 news outlet mentions (PlumX Metrics), 72 readers on Mendeley (Altmetric), 36,002 full text views on journal website, 4488 PDF downloads from journal website, 29 user-generated Bitly links to article with a total of 1535 link clicks (PlumX Metrics)
35. **Doshi P,** Jefferson T. Drug Data Shouldn't Be Secret. *New York Times* 2012 04/11;161(55738):1.
0 citations (Scopus)
36. **Doshi P, Akabayashi A.** Japanese Childhood Vaccination Policy. *Camb Q Healthc Ethics* 2010 Jul;19(3):283-289.
5 citations (Scopus), 2 social media mentions (Altmetric), 5 readers on Mendeley (Altmetric), 22 full text views on journal website, 51 PDF downloads from journal website
37. Jefferson T, Jones M, **Doshi P, Del Mar C.** Possible harms of oseltamivir--a call for urgent action. *Lancet* 2009 Oct 17;374(9698):1312-1313.
30 citations (Scopus), 26 readers on Mendeley (Mendeley.com)
38. **Doshi P.** Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research? *IEEE Technology & Society Magazine* Spring 2006;25(1):10-11.
0 citations (Scopus), 491 full text views on journal website
39. **Doshi P.** Selling 'pandemic flu' through a language of fear. *Christian Science Monitor* 2006 03/21;98(79):9.
0 citations (Scopus)
40. **Doshi P.** Viral Marketing. *Harper's Magazine* 2006 03;312(1870):54.
0 citations (Scopus)
41. **Doshi P.** Are US flu death figures more PR than science? *BMJ* 2005;331(7529):1412.
13 citations (Scopus), 63 blog and social media mentions (Altmetric), 3 news outlet mentions (Altmetric), 11 readers on Mendeley (Altmetric), 1 YouTube video mention (Altmetric), 12,755 full text views on journal website, 1345 PDF downloads from journal website

2. Letters to the editor in refereed journals

1. **Doshi P,** Spence O*, Powers JH. Noninferiority Trials. *N Engl J Med* 2018 Jan 18;378(3):304. 0 citations (Scopus)

2. Jones M, Del Mar C, **Doshi P**. Findings of an Observational Study of Neuraminidase Inhibitors Highly Sensitive to Decision to Exclude 1652 Treated Patients. *Clin Infect Dis* 2017 Sep 15;65(6):1050. 1 citation (Scopus), 2 readers on Mendeley (PlumX Metrics), 104 PDF downloads from journal website
3. Kuzucan A*, **Doshi P**, Zito JM. Pharmacists can help to end direct-to-consumer advertising. *Am J Health Syst Pharm* 2017 May 15;74(10):640-642. 0 citations (Scopus), 58 social media mentions and interactions (PlumX Metrics), 1 reader on Mendeley (Altmetric), 81 full text views in EBSCO databases (PlumX Metrics)
4. **Doshi P**, Jefferson T. Neuraminidase Inhibitors and Influenza Infection. *JAMA Intern Med* 2016 Mar;176(3):415-416. 0 citations (Scopus), 237 PDF downloads from journal website, 22 readers on Mendeley (PlumX metrics)
5. **Doshi P**, Heneghan C, Jefferson T. Oseltamivir for influenza. *Lancet* 2015 Sep 19;386(9999):1134-1135. 0 citations (Scopus), 1 social media mention (PlumX Metrics)
6. Collignon P, **Doshi P**, Del Mar C, Jefferson T. Safety and efficacy of inactivated influenza vaccines in children. *Clin Infect Dis* 2015 Feb 1;60(3):489. 1 citation (Scopus), 2 social media mentions (Altmetric), 10 readers on Mendeley (PlumX Metrics), 2 Wikipedia references (PlumX Metrics), 61 PDF downloads from journal website
7. Del Mar C, **Doshi P**, Hama R, Jones M, Jefferson T, Heneghan C, et al. Neuraminidase inhibitors for influenza complications. *Lancet* 2014;384(9950):1260-1261. 0 citations (Scopus), 1 social media mention (PlumX Metrics), 20 readers on Mendeley (Mendeley.com)
8. **Doshi P**, Jefferson T. Clinical trials: Tamiflu reviewers respond to critics. *Nature* 2014 May 15;509(7500):288. 1 citation (Scopus), 2 social media mentions (Altmetric), 10 readers on Mendeley (Altmetric), 107 full text views in EBSCO databases (PlumX Metrics), 1 user-generated Bitly link to article with a total of 2 link clicks (PlumX Metrics)
9. **Doshi P**, Jefferson T. Authors' reply to Dunning. *BMJ* 2014 Apr 30;348:g3018. 0 citations (Scopus), 1 reader on Mendeley (PlumX Metrics), 295 full text views on journal website, 87 PDF downloads from journal website
10. **Doshi P**. The importance of influenza vaccination-reply. *JAMA Intern Med* 2014 Apr;174(4):645-646. 0 citations (Scopus), 208 PDF downloads from journal website
11. **Doshi P**, Abi-Jaoude E, Lexchin J, Jefferson T, Thomas RE. Influenza vaccination of health care workers. *CMAJ* 2013;185(2):150. 2 citations (Scopus), 3 readers on Mendeley (Mendeley.com)
12. **Doshi P**. EFPIA-PhRMA's principles for clinical trial data sharing have been misunderstood. *BMJ* 2013;347(7922). 2 citations (Scopus), 5 social media mentions (Altmetric), 1 news outlet mention (Altmetric), 2 readers on Mendeley

(Altmetric), 832 full text views on journal website, 170 PDF downloads from journal website

13. **Doshi P.** The 2009 influenza pandemic. *Lancet Infect Dis* 2013;13(3):193. 1 citation (Scopus), 2 readers on Mendeley (Mendeley.com)
14. **Jones M**, Hama R, Jefferson T, **Doshi P.** Neuropsychiatric adverse events and oseltamivir for prophylaxis. *Drug Saf* 2012 Dec 1;35(12):1187-8; author reply 1188-90. 8 citations (Scopus), 2 readers on Mendeley (PlumX Metrics), 47 full text views in EBSCO databases, 122 PDF downloads from journal website
15. **Heneghan C**, Jefferson T, **Doshi P.** Antivirals for treatment of influenza. *Ann Intern Med* 2012 Sep 4;157(5):385-6; author reply 386-7. 0 citations (Scopus)
16. Cochrane Neuraminidase Inhibitors Review Team. Does oseltamivir really reduce complications of influenza? *Clin Infect Dis* 2011 Dec;53(12):1302-3; author reply 1303-4. 0 citations (Scopus), 33 PDF downloads from journal website
17. **Doshi P**, Jefferson T. WHO and pandemic flu. Another question for GSK. *BMJ* 2010 Jun 29;340:c3455. 2 citations (Scopus), 1 social media mention (PlumX Metrics), 4 readers on Mendeley (PlumX Metrics), 1168 full text views on journal website, 4 PDF downloads from journal website
18. **Jefferson T**, **Doshi P.** WHO and pandemic flu. Time for change, WHO. *BMJ* 2010 Jun 29;340:c3461. 5 citations (Scopus), 1 social media mention (PlumX Metrics), 2 readers on Mendeley (PlumX Metrics), 1343 full text views on journal website, 7 PDF downloads from journal website
19. **Collignon P**, **Doshi P**, Jefferson T. Ramifications of adverse events in children in Australia. *BMJ* 2010 Jun 9;340:c2994. 7 citations (Scopus), 132 social media mentions (Altmetric), 6 readers on Mendeley (PlumX Metrics), 2885 full text views on journal website, 11 PDF downloads from journal website
20. **Doshi P.** Pandemic influenza: severity must be taken into account. *J Infect Dis* 2010 May 1;201(9):1444-1445. 4 citations (Scopus), 5 readers on Mendeley (PlumX Metrics), 19 full text views in EBSCO databases (PlumX Metrics), 13 PDF downloads from journal website
21. **Doshi P.** Doshi responds. *Am J Public Health* 2008;98(11):1928-1930. 0 citations (Scopus), 5 social media mentions (Altmetric)
22. **Doshi P.** Reason for optimism. *BMJ* 2008;336(7637):172. 0 citations (Scopus), 4 readers on Mendeley (PlumX Metrics), 457 full text views on journal website, 95 PDF downloads from journal website
23. **Doshi P.** Popular and scientific attitudes regarding pandemic influenza. *Emerg Infect Dis* 2008 Sep;14(9):1501-2; author reply 1502. 1 citation (Scopus), 4 readers on Mendeley (PlumX Metrics), 176 full text views in EBSCO database (PlumX Metrics)

24. **Doshi P.** Estimation of death rates from pandemic influenza. *Lancet* 2007 Mar 3;369(9563):739; author reply 739-40. 1 citation (Scopus), 12 readers on Mendeley (Mendeley.com)
25. **Doshi P.** Influenza vaccination: policy versus evidence: Policy is in the lead. *Br Med J* 2006;333(7576):1020-1021. 2 citations (Scopus), 5 readers on Mendeley (PlumX Metrics), 982 full text views on journal website, 298 PDF downloads from journal website

3. Referee for professional or scientific journal

1. AHRQ Effective Health Care Program
2. American Journal of Respiratory and Critical Care Medicine
3. American Journal of Public Health
4. Annals of Internal Medicine
5. BMC Medical Research Methodology
6. BMC Public Health
7. BMJ
8. Canadian Medical Association Journal (CMAJ)
9. CNS Drugs
10. Drug and Therapeutics Bulletin
11. European Journal of Pediatrics
12. European Journal of Public Health
13. Expert Review of Vaccines
14. Health Affairs
15. Health Policy
16. Health Technology Assessment (Italian government)
17. Healthcare Policy
18. Influenza and Other Respiratory Viruses
19. JAMA Internal Medicine
20. Journal of Biomedical Research
21. Journal of Clinical Epidemiology
22. Journal of Medical Ethics
23. New England Journal of Medicine
24. PLOS Medicine
25. PLOS ONE
26. Trials
27. World Medical and Health Policy

4. Editorial positions on professional or scientific journals

Associate Editor
The BMJ (www.bmj.com)

2013 – ongoing

Guest editorial board member 2017 – 2018
Scientific Data (www.nature.com/sdata/)

E. Honors and Awards

New Investigator Award 2015
American Association of Colleges of Pharmacy

The Wired Smart List 2013 (UK) 2013
<http://www.wired.co.uk/magazine/archive/2013/12/features/the-smart-list-2013>

Nathan Wolfe/CNN Prize 2013
Johns Hopkins Bloomberg School of Public Health

Siegel Teaching Prize 2011
Massachusetts Institute of Technology

MIT-Japan Program intern 2009
Massachusetts Institute of Technology

Presidential Fellowship 2006 – 2007
Massachusetts Institute of Technology

Noma-Reischauer Prize in Japanese Studies 2006
Graduate Student Essay Prize for “The Lost Lessons of SMON [subacute myelo-optico neuropathy]”
Kodansha Ltd., Publishers and the Reischauer Institute, Harvard University

Joseph Fletcher Memorial Prize for excellence in an A.M. thesis 2006
Harvard University

Summer Foreign Language Assistance Scholarship (FLAS) for Japanese 2004
Harvard University

Best Socio-Cultural Anthropologist 2002
Brown University

Perry Gatson Scholarship Award for Outstanding Achievement in Anthropology 2002
Brown University

3) Service

A. Scientific, Professional and Scholarly Organizations

The BMJ **2013 – indefinite**
The BMJ (formerly the *British Medical Journal*) is an international peer reviewed medical journal. I serve as an associate editor, a paid position, in which capacity I write articles, commission articles, handle manuscripts, and contribute to journal decision making.
International organization; Staff position

Health Canada **2017 – ongoing**
Selected to be on “roster of experts” for Health Canada’s Health Products and Food Branch (HPFB) activated related to the implementation of public release of clinical information
International organization; Volunteer position

European Medicines Agency **Jan - Apr 2013**
Participated in two advisory groups (rules of engagement & good analysis practice) regarding EMA’s draft Policy 0070, Publication of Clinical Trial Data
International organization; Volunteer position

Committee on Publication Ethics **2015 – ongoing**
International organization; Member; 3 years

American College of Cardiology **2013**
Writing committee member on Data Transparency Health Policy Statement
National organization; Volunteer position

AACP **2014 – 2016**
National organization; Member; 2 years

Rho Chi **2017 – ongoing**
Inducted in 2017
National organization; Member; 1 years

Cochrane **2018 – ongoing**
International organization; Member; 5 years

B. Additional professional service

Reagan-Udall Foundation for the FDA **2016 – ongoing**
Unpaid member of IMEDS Steering Committee

EXHIBIT B

CURRICULUM VITAE Thomas Oliver JEFFERSON
(1 August 2020)

Brief biographies appear in the series "Lifeline" on [The Lancet 2003](#); 361:188. (11 January)
and in the Feature [Pioneers of Transparency](#) BMJ 2014;350:g7717

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Two most cited papers:

[Guidelines for authors and peer reviewers of economic submissions to the BMJ](#)

MF Drummond, TO Jefferson. BMJ 313 (7052), 275-283 (1720 citations)

[Vaccines for preventing influenza in healthy adults](#)

V Demicheli, T Jefferson, E Ferroni, A Rivetti, C Di Pietrantonj. Cochrane database of systematic reviews (1558 citations)

Key words: Evidence synthesis, Epidemiology, Health Economics, Regulatory data, Market access

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MEDALS & DECORATIONS

UNPROFOR Medal (1992)
OFFICER (BROTHER) Order of St John of Jerusalem (1994).
NATO Medal (Former Yugoslavia Clasp) 1996

RELEVANT ACADEMIC & PROFESSIONAL QUALIFICATIONS

Degree in Medicine and Surgery, Pisa University (1979).
Diploma of the Royal College of Obstetrician & Gynaecologists UK (DRCOG, 1982).
Certificate of Vocational Training in General Practice UK (1984).
Membership of the Royal College of General Practitioners UK (MRCGP 1985).
Membership of the Chartered Institute of Linguists UK (1985).
Diploma in Tropical Medicine & Hygiene UK (London School of Hygiene & Tropical Medicine 1987).
MSc Community Medicine UK (London School of Hygiene & Tropical Medicine 1988).
Membership of the Faculty of Public Health Medicine UK (MFPHM 1990).
Accreditation in Public Health Medicine UK (1990).
Accreditation in General Practice UK (1990).
Titolo di Scuola di Guerra (1991)
Certificate in Health Economics, University of Aberdeen UK (1996).
Fellowship of the Faculty of Public Health Medicine UK (FFPHM 1999).

RECENT and PRESENT ACTIVITIES

Until November 2019 I provided scientific supervision for the Agenas (Agenzia per i Servizi Sanitari Regionali) HTA programme for non-pharmaceuticals. Agenas is an agency of the Italian MoH. Part of my work entailed supervising a group of 10 researchers and taking responsibility for designing, devising and carrying out HTA and Horizon Scanning assessments. I was scientific lead for the European EUNeHTA Joint Action 2 (Workpackage 4 – devices and diagnostics) project (2012-2015, see below). The EUNeHTA Collaboration is a network of European public agencies producing structured HTA information for national use. In 2021 the Collaboration should become a permanent network funded by the

Commission. I was also scientific coordinator for Workpackage 4 which assessed non pharmaceutical interventions, such as in vitro tests. This involved coordinating some 70 researchers from 28 agencies from 23 countries (from Estonia to Bulgaria, to Greece and Sweden). The project started in 2012 and was completed in 2015. I carried out the same role for the previous EUNeHTA project (Joint Action 1 or JA1 with the European Commission). Until November 2019 I was a member of two different workpackages and a reviewer for two projects in these workpackages as part of the EUNeHTA JA3.

I co-developed a methodology for synthesising evidence of effectiveness, efficiency, safety and resource utilisation using regulatory information and data from different sources, both regulatory and open source. This activity was initially funded by NIHR UK until mid-2015, then the Cochrane Methods Innovations Fund (MIF), NIHR again and since 2016 the Cochrane Nordic Centre. The MIF project was a collaboration to draft advice of when and how to include regulatory material in Cochrane reviews. I am developing this work further by streamlining the use of regulatory data and its incorporation into user friendly, timely reviews.

As part of a team in the Nordic Cochrane Centre we carried out a [systematic review of HPV vaccines](#) based on regulatory documents. The evidence set for the review was assembled by us from a variety of sources into an Index of the human papillomavirus (HPV) vaccine industry clinical study programmes and non-industry funded studies, shortly to be published. At present we are developing the same reviews further with the complete regulatory dataset released by Health Canada after a court case.

Since 2015 I am a Fellow of the Centre for Evidence Based Medicine of the **University of Oxford**, in the UK. I am now Senior Clinical Tutor on the Complex Reviews Module of the MSc in Evidence Based Health course.

I am visiting Professor Visiting Professor Institute of Health & Society at the Faculty of Medicine of Newcastle University (2019-2021).

With the 3 other Cochrane colleagues I am a co-investigator in a John and Laura Arnold Foundation grant for development of a RIAT support centre (2017-2020).

RIAT stands for Restoring Invisible and Abandoned Trials. In short, RIAT is a mechanism that enables researchers to address two long-standing problems in the medical literature: non-publication of trials and misreporting. Our concept was first outlined here: <http://www.bmj.com/content/346/bmj.f2865>

The RIAT Support Center will help accelerate the correction of the scientific record of clinical trials by making it more accurate and more complete.

Finally, with the help of the Cochrane Central Editorial Unit we stabilised of our three long-standing influenza vaccine reviews. These were released in January 2018.

My activity line of regulatory data started with updating of Cochrane review A159 (Neuraminidase Inhibitors for influenza). A159 is currently based exclusively on regulatory information (essentially clinical study reports - CSRs from EMA and comments by FDA and PMDA - about 150K pages in all).

The story is told in:

David Payne. Tamiflu: the battle for secret drug data. *BMJ* 2012;345:e7303 doi: 10.1136/bmj.e7303 (Published 29 October 2012).
<http://www.bmj.com/content/345/bmj.e7303>

<http://www.nytimes.com/2013/06/30/business/breaking-the-seal-on-drug-research.html?pagewanted=1&r=3&smid=tw-share>

<http://www.newsweek.com/2014/11/21/medical-science-has-data-problem-284066.html>
[The pioneers of transparency](#). *BMJ* 2015;350:g7717 (Published 02 Jan 2015)

I was a member of EMA's Clinical Trials Advisory Group 2 (CTAG2).

I am on the editorial board of [BMJ Evidence Based Medicine](#) (BMJ EBM).

I am an unpaid collaborator to the project *Beyond Transparency in Pharmaceutical Research and Regulation* led by Dalhousie University and funded by the Canadian Institutes of Health Research (2018-2022).

I currently teach on the Complex Reviews module of the MSc in Evidence Based Health Care at Oxford University and currently supervising to MSc students. This involves reviews of regulatory data, economic studies, diagnostic studies, qualitative studies and IPI meta-analyses.

I am a member of the WHO Infection Prevention and Control Research and Development Expert Group for COVID-19.

PAST CONSULTANCIES AND OTHER ACTIVITIES

In the past I have carried out research for the **Ministry of Defence UK** (suite of Cochrane reviews on viral and arthropod borne fevers prevention), **NICE** (HTA of zanamivir for influenza), **Roche** (the economics of antivirals neuraminidase inhibitors), **EU** (systematic review of evidence of safety of MMR vaccines and of the economics of pneumococcal vaccines), **WHO** (systematic review of evidence of safety of Hepatitis B vaccines), **Glaxo SmithKline** (systematic review of evidence of safety and effectiveness of DPT vaccines), **Sanofi- Synhtelabo** (Development of Pleconaril), **Istituto Superiore di Sanita'** and **ASSR** (now Agenas), (coordinator of the national clinical guidelines project) (see below), **Netherlands Health Council** (safety of Hepatitis B vaccine update review), **IMS Health**

(Antidiabetic drugs) the **Piemonte Region** of Northern Italy (suite of Cochrane reviews on influenza vaccines), **Agenzia di Sanita' Pubblica Lazio** - Public Health Agency of Lazio Region (guidelines implementation trial project and coordination of a two cluster randomised trials of guidelines implementation, on behalf of the UK's Technology Assessment Programme I updated two reviews on the effects of editorial peer review. I have been involved in a 5 year update and rewrite of his Cochrane review on Neuraminidase Inhibitors exclusively based on regulatory information. (HTA – 10/80/01 Update and amalgamation of two Cochrane Reviews: neuraminidase inhibitors for preventing and treating influenza in healthy adults and children—<http://www.nets.nihr.ac.uk/projects/hta/108001>).

I am a member of the editorial base of the Cochrane Acute Respiratory Infections Group. Reviewer, Cochrane Infectious Diseases, Acute Respiratory Infections, Hepato-biliary, Airways and Colorectal Cancer Groups.

Director, Health Reviews Ltd, my own company.

Member, editorial, board of *Recenti Progressi in Medicina* and *BMC Health Services Research*.

Peer reviewer for BMJ, Lancet, JAMA, JAMA Internal Medicine, CMAJ, New England Journal of Medicine, Vaccine and Canadian Coordinating Office for Health Technology Assessment (CCOHTA) Emerging Technology bulletins.

I am an Academic Editor, PLOS ONE (2013-17) and have been a contributor to Last's Dictionary of Epidemiology (4th edition).

I do anonymous market access consultancy interviews for various pharmaceutical companies.

Between 1996 and 2009 I was the Co-ordinator of the Cochrane Vaccines Field and 1999 and 2012 I was honorary Research Fellow at the UK Cochrane Centre.

In 2011-13, I acted as an expert witness in a litigation case related to the antiviral oseltamivir, in two litigation cases on potential vaccine-related damage and in a labour case on influenza vaccines in healthcare workers in Canada. In 2016-17 I was a member of an independent data monitoring committee for a **Sanofi Pasteur** clinical trial on an influenza vaccine and a member of three advisory boards for **Boehringer Ingelheim** (on bronchodilator drug), Takeda (cardiovascular drug) and Bayer (blood replacement).

As part of my [HTA activity](#) I have interviewed, collaborated and interacted with scores of clinicians in both primary and hospital care both in Italy and the rest of Europe. Over the past thirty years, I have worked in most therapeutic and prevention areas. Also as part of my Italian HTA and scientific activity I have interacted with patient organisations and have considerable knowledge of the regional Italian structure and its workings thanks to my role as consultant to Agenas.

The HTA report output is accessible at: <https://www.agenas.gov.it/aree-tematiche/hta-health-technology-assessment/attivita-hta/report-hta>

The Horizon scanning output is accessible at: <https://www.agenas.gov.it/aree-tematiche/hta-health-technology-assessment/hs-horizon-scanning/report-hs>

Since 2017 I am a member of the Italian MoH National Immunisation Technical Advisory Group (NITAG).

GENERAL PERSONAL & PROFESSIONAL BACKGROUND

I was born on 31 March 1954 in Viareggio (near Pisa), Italy. I was educated in Italy and went to UK in 1980 to do my hospital jobs prior to joining the Army. My professional career has spanned two specialties, General Practice (1980-1985) and Public Health (since 1986). I served in the British Army between 1981 and 1999.

My Army service took place in three continents and two conflicts (South Atlantic and Yugoslavia). I held the rank of Lieutenant Colonel. I am married with five children.

GENERAL PRACTICE CAREER

SHO Medicine, Arbroath Infirmary (1980 - 1981).

SHO Casualty, Croydon (1981).

Post Graduate Medical Officers' Course held Royal Military Academy, Sandhurst and the Royal Army Medical College, London (1981).

SHO O&G, British Military Hospital Hong Kong (1982).

Trainee GP and Regimental Medical Officer in several Gurkha units in Hong Kong and Nepal (1982 - 1984).

GP principal at Royal Military Academy Sandhurst, Armoured Regiment in Germany and Gurkha Battalion in UK and South Atlantic (1984 -1986).

Staff officer (various roles, 1987-1999)

Partner (part-time), North Lane Practice, Aldershot, Hampshire (1999-2001).

PUBLIC HEALTH CAREER

Registrar at the Department of Preventive Medicine at the Royal Army Medical College London (1987-1990).

Honorary Lecturer to the Department of Public Health at King's College Hospital, London (Professors Jim McEwen Norman Noah, 1989 - 1996).

Honorary Senior Lecturer to the Department of Public Health at King's College Hospital, London (1997 - current).

Detachment to the London School of Hygiene and Tropical Medicine on the Diploma in Tropical Medicine and Hygiene Course first and then on Master of Science in Community Medicine (1987- 1988).

Senior Registrar at the RAMC Training Centre near Aldershot (1988 - 1990). Student on the Higher Command and Staff Course at the Italian Army Staff College, Rome (1990 - 1991).

Second in Command of a Medical Battalion in Germany consisting of 250 personnel (1991 - 1992).

Assistant Force Medical Officer, United Nations Protection Force in Yugoslavia (UNPROFOR). I set up all medical facilities for the initial deployment in March 1992 and Director of Public Health for UNPROFOR. I was stationed in Sarajevo (Bosnia- Hercegovina), Belgrade (Serbia) and Zagreb (Croatia) for the duration of six months. Deputy Commander Medical (Preventive Medicine) British Army of the Rhine. I was responsible for all Preventive Medicine services for a population of 120.000 souls (1992-93).

Senior Technical Officer on the Health Services Market Test for British Forces Germany (1993-94). Responsible for developing the Statement of Requirement in preparation for the issuing of the Invitation To Tender and the developing of the purchasing function. Staff Officer, Ministry of Defence, Army Medical Directorate (1994-99). Responsible for health surveillance and health policy formulation for the British Army. My department carried out morbidity surveillance for the British Army and for the NATO SFOR mission in the Former Republic of Yugoslavia (FRY).

In February 1994 I was appointed Visiting Professor in Health Services Research at the University of Pavia, Northern Italy.

In June 1997 I was appointed Edmund Parkes Professor of Preventive Medicine at the Royal Defence Medical College. The chair is recognised by the Faculty of Public Health Medicine of the Royal College of Physicians of the United Kingdom. Additional responsibilities included the strategic management of the Army's 90-strong Environmental Health cadre. This lapsed when I left the Army.

Principal in family medicine, Aldershot, UK, 1999-2001.

British Medical Association HC Roscoe Fellow for the study of the prevention and treatment of the common cold (2000-2002).

Adviser the Lazio Region Public Health Agency (IT) and the Istituto Superiore di Sanità (on the development of evidence-based clinical guidelines) 2001-2005

PRIZES

1982 Army Syntex Award for research into obstetric performance in different ethnic groups (see publication 5).

1984 University of Surrey Research Prize for work on haematological indices of pregnant Gurkha women (see publication 6).

1990 Parkes Memorial Prize for work on the selection and training of Army recruits (see publications 17 e 22).

2009 BMJ prize for best use of BMJ archival material (publication 232)

Past grants:

MOD(UK) - systematic reviews of interventions to prevent influenza in healthy adults

Roche UK Ltd - cost of illness study of the burden of influenza.

BMA Roscoe Fellowship - systematic review of the effects of antivirals for the common cold.

UK HTA programme - systematic review of the effects of zanamavir.

EU - systematic review of safety of MMR vaccines.

EU - systematic review of the economics of pneumococcal vaccines.

WHO - systematic review of evidence of safety of Hepatitis B vaccines.

WHO - systematic review of evidence of safety of aluminium in DTP vaccines.

Glaxo SmithKline Ltd - systematic review of evidence of safety and effectiveness of DPT vaccines.

NHS R&D programme - systematic review of the effects of peer review. An update was commissioned in May 2004.

Regione Piemonte, Italy – systematic reviews of the effects of influenza vaccines in children and elderly and quality studies and their publication on high impact factor journals.

Netherlands Health Council (safety of Hepatitis B vaccine update review)

DH (UK)/NIHR Cochrane review update incentive scheme (several awards)

Lazio Public Health Agency – systematic review of the epidemiology of *S.Pneumoniae*

DH (UK) National coordinating Centre for Methodology

WHO - Physical interventions to interrupt or reduce the spread of respiratory viruses: systematic review .

UK NIHR – Developing, updating and rewriting the Cochrane review on Neuraminidase Inhibitors exclusively based on regulatory information.

Cochrane - Methods Innovation Fund (MIF) 2014-17 to develop a methodology for summing up evidence of effectiveness, efficiency and safety using regulatory information and data from different sources, both regulatory and open source.

Arnold Foundation – RIAT centre

RECREATIONAL ACTIVITIES

Weight training, skiing.

MEMBERSHIP OF OTHER ORGANISATIONS (past and present)

Health Economics Study Group (HESG)

International Association of Health Economists (listed in the world directory of Health Economists).

Cochrane Airways Collaborative Review Group

LOCKNET (JAMA/BMJ peer-review network).

World Association of Medical Editors (WAME)

Health Technology Assessment International (international society for HTA)

PUBLICATIONS & REPORTS

1. CAROLI G, JEFFERSON T O. Wedding Party with S.Haifa. Annali Sclavo. 1978; 20: 959-962.
2. CAROLI G, JEFFERSON T O. Finding of E.Coli Phage in Urinary Tract Infections. Annali Sclavo. 1980; 22: 857-860.
3. JEFFERSON T O. Personal View. BMJ. 1982; 284: 1328.
4. JEFFERSON T O, COHEN C. Familial Siringomyelia with Mental Impairment. J R Army Med Corps. 1982; 128: 41-42.
5. JEFFERSON T O, REIDY A J. Incidence of Instrumental Deliveries in Primigravidae of 3 Different Ethnic Groups. J R Army Med Corps. 1983; 129: 46-47.
6. REIDY A J, JEFFERSON T O, KENNEDY P M D. Some Haematological Data on Pregnant Gurkha Women. J R Army Med Corps. 1984; 130: 20-21.

7. JEFFERSON T O. Physical Fitness and Smoking Patterns in a Gurkha Battalion. J R. Army Med Corps. 1986; 132: 168-172.
8. JEFFERSON T O, RASOR P A. Non Simulated Casualty Workload in 2 Field Hospital During Exercise "Bold Gannett". Giornale di Medicina Militare. 1985; 135: 265-268.
9. JEFFERSON T O, TAYLOR V M. Perinatal mortality in infants of two different ethnic groups. Family Practice 1985; 2:175-176.
10. JEFFERSON T O. (Anonymous) Mea culpa. Update. 1985; 31: 932.
11. JEFFERSON T O. Patterns of smoking in 2 infantry battalions. British Army Review. 1986; 82: 84.
12. JEFFERSON T O. A Camera in general practice (Ota's Naevus). Update. 1987; 35: 237.
13. KENNEDY P M D, JEFFERSON T O, REIDY A J. Growth in Gurkha Infants. Family Practice. 1986; 3: 54.
14. JEFFERSON T O. Buon Natale (Letter to the Editor). J Royal Coll Gen Pract. 1986: 291.
15. OLLIER W, FENSTENSTEIN, JEFFERSON T O. HLA Antigens in Nepalese. Proceedings of the 3rd Asian Oceania Histocompatibility Conference, Sapporo 1986.
16. JEFFERSON T O. The Prevention of AIDS: Some Principles for the Inception and Assessment of a Health Education Campaign. Rivista Italiana d'Igiene 1988; 48: 3-11.
17. JEFFERSON T O. An Investigation of Medical Discharges from the British Army 1979-1986. J R Army Med Corps. 1989; 135: 115-123.
18. JEFFERSON T O, BRAND H, LEVRE` E, CAROLI G. The Personal Prevention of Malaria. Rivista Italiana d'Igiene 1989; 430: 443-450.
19. JEFFERSON T O, CAROLI G, MOLINARI G, PEIRONE A P. Public Health and Community Medicine in England. Rivista Italiana d'Igiene 1989; 49: 226-238.
20. BASNET I, HADYAPANIOTOU C, JEFFERSON T O, MILLS A. Abortion Services in Wandsworth (MSc Field Service Attachment). London School of Hygiene & Tropical Medicine, 1988.
21. TAYLOR L E, JEFFERSON T O, CAROLI G . Water Supply Engineering and Public Health in the United Kingdom. Rivista Italiana d'Igiene 1990; 50: 81-93.

22. JEFFERSON T O. An Investigation into Regular Recruit Wastage from the British Army, 1988. J R Army Med Corps 1990; 136: 138-145.
23. TAYLOR L E, JEFFERSON T O, CAROLI G. The Water Supply of London. Rivista Italiana d'Igiene. 1990; 3-4: 169-177.
24. DEMICHELI V, JEFFERSON T O, AMPOLA M, CAROLI G, PEIRONE A P. Il Lay Belief System. Nota 1: Lo Studio del Comportamento Sanitario. Rivista Italiana d'Igiene 1990; 3-4: 134-150.
25. JEFFERSON T O, DEMICHELI V, CAROLI G. Nesso tra Casi di Leucemia Infantile e Centrale Nucleare di Sellafield (U K): un Puzzle Epidemiologico. Rivista Italiana d'Igiene 1990 3-4: 178-191.
26. DEMICHELI V, JEFFERSON T O. Le Conseguenze Economiche della Salmonellosi. Antibioticoterapia per la pratica. 1991; 2: 73-81.
27. JEFFERSON T O. First Aid Training. An Appraisal. The Soldier's Longest Journey. J R Army Med Corps. 1991; 137: 27-30.
28. JEFFERSON T O. Procedures for the collection and bottling of mineral waters - Guidelines for handlers. Rivista Italiana d'Igiene 1990; 5-6: 496-8.
29. BISOGNI L, JEFFERSON T O, DEMICHELI V, LOMOLINO G, PACELLI G. Studio della prevalenza delle infezioni ospedaliere in un ospedale generale di zona. Rivista Italian di Antibioticoterapia per la pratica 1991; 4: 159-63.
30. DEMICHELI V, LOMOLINO G, JEFFERSON T O. Audit nei servizi di Igiene Pubblica: l'opinione dei cittadini sugli interventi per inconvenienti igienici. Atti del IV Congresso Nazionale della Societa` Italiana di VRQ, Pavia 22-25 Settembre 1991, pagina 66. Editrice Periodici 1991.
31. DEMICHELI V, LOMOLINO G, JEFFERSON T O. La qualita` delle iniziative di formazione: l'aggiornamento del personale sul problema delle infezioni ospedaliere. Atti del IV Congresso Nazionale della Societa` Italiana di VRQ, Pavia 22-25 Settembre 1991, pagina 81. Editrice Periodici 1991.
32. DEMICHELI V, LOMOLINO G, JEFFERSON T O. L'apporto della Economia Sanitaria alla qualita` delle decisioni. La determinazione del costo della sofferenza. Atti del IV Congresso Nazionale della Societa` Italiana di VRQ, Pavia 22-25 Settembre 1991, pagina 106. Editrice Periodici 1991.
33. DEMICHELI V, LOMOLINO G, JEFFERSON T O. Affermazioni di consenso e verifica della qualita`. Atti del IV Congresso Nazionale della Societa` Italiana di VRQ, Pavia 22-25 Settembre 1991, pagina 107. Editrice Periodici 1991.

34. DEMICHELI V, JEFFERSON T O. Cost-benefit analysis of the introduction of mass vaccination against Hepatitis B in Italy. *Journal of Public Health Medicine* 1992; 4: 367-375. (Paper presented to the third European Health Services Research Meeting - University College London, 13 - 14 December 1991).
35. DEMICHELI V, JEFFERSON T O. Manuale di Programmazione e organizzazione Sanitaria. Quaderni di Epidemiologia 17. La Goliardica Pavese, Pavia 1992.
36. DEMICHELI V, JEFFERSON T O. Criteri di valutazione del nesso causale e loro applicazione alla questione delle relazioni fra le radiazioni ionizzanti e la leucemia infantile. *Tecnica Sanitaria* 1993 (in press).
37. JEFFERSON T O, DEMICHELI V, LOMOLINO G. Problemi di Valutazione epidemiologica nelle piccole catastrofi ambientali. Il caso di Camelford in Cornovaglia. *Tecnica Sanitaria* 1993 (in press).
38. JEFFERSON T O. Public Health Aspects of the war in Yugoslavia. *Public Health* 1993; 107: 75-8.
39. JEFFERSON T O, DEMICHELI V, WRIGHT D A. An economic evaluation of the introduction of vaccination against Hepatitis A in a peace-keeping operation. The case of the United Nations Protection Force in Yugoslavia (UNPROFOR). *International Journal of Technology Assessment in Health Care* 1994; 10:490-97. Poster presented at the Fifth European Health Services Research Conference at Maastricht, (December 1993).
40. DEMICHELI V, LOMOLINO G, JEFFERSON T O. Audit of an environmental service in Italy. *Proceedings of the Summer Conference of the Faculty of Public Health Medicine, 1992, Eastbourne, Sussex, Inghilterra.*
41. JEFFERSON T O, DEMICHELI V. The costs of disease - a look at world literature. Presented at the "Meeting Internazionale sui costi delle malattie e della Salmonellosi", Pavia University (5-6 April 1993) (in press).
42. JEFFERSON T O, DEMICHELI V. Is vaccination against Hepatitis A and B cost-effective? A preliminary look at world literature. Presented at the "Meeting Internazionale sui costi delle malattie e della Salmonellosi", Pavia University (5-6 April 1993) (in press).
43. JEFFERSON T O, DEMICHELI V. Is vaccination against Hepatitis B efficient? A review of world literature. *Health Economics* 1994; 3:25-37. Paper presented at the Fifth European Health Services Research Conference at Maastricht, (December 1993).
44. JEFFERSON T O. Public Health and the war in Yugoslavia. In McKee M (ed): *Health for all in a changing Europe*. HFA 2000 News 1993; 25:4-5.

45. DEMICHELI V, JEFFERSON T O. Cost-benefit analysis of the introduction of mass vaccination against Hepatitis B in Italy (letter to the Editor). *Journal of Public Health Medicine* 1993; 14: 289-290.
46. JEFFERSON T O, MUGFORD M, GRAY A, DEMICHELI V. Purchasers and cost-effectiveness of interventions. Are secondary economic evaluations possible? Abstract presented at the Second Cochrane Colloquium, Hamilton, Ontario, October 1994.
47. JEFFERSON T O, BEHRENS R, DEMICHELI V. Should British soldiers be vaccinated against Hepatitis A? An economic analysis. *Vaccine* 1994; 12:1379-83.
48. JEFFERSON T O, PIERCE B, DEMICHELI V. Economic burden of an outbreak of a communicable disease of unknown aetiology in a military unit. *Journal of Epidemiology and Community Health* 1994; 48:423. (letter to the Editor).
49. AKEHURST R, GRAY A, BUXTON M, CHALMERS I, DONALDSON C, CHURNSIDE R, FENN P, FORBES J, GRIFFIN J, HOWARD S, JEFFERSON T, MC GUIRE A, MUGFORD M, O'BRIEN B, OXMAN A, TOWSE A. Assembling information in reviews of randomised controlled trials for subsequent cost-effectiveness analysis. Oxford: UK Cochrane Centre, Workshop Report, November 1993.
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303. Doshi P, Bourgeois F, Hong K, et al. Adjuvant-containing control arms in pivotal quadrivalent human papillomavirus vaccine trials: restoration of previously unpublished methodology. *BMJ Evidence-Based Medicine* Published Online First: 17 March 2020. doi: 10.1136/bmjebm-2019-111331
<https://doi.org/10.1136/bmjebm-2019-111331>
- Tom Jefferson: Covid-19—supermarket wisdom
<https://blogs.bmj.com/bmj/2020/03/20/tom-jefferson-covid-19-supermarket-wisdom/>
- COVID-19. Can Historical Antivirals Be of Use?

<https://www.cebm.net/covid-19/covid-19-can-historical-antivirals-be-of-use/>

COVID-19 – The Tipping Point

<https://www.cebm.net/covid-19/covid-19-the-tipping-point/>

COVID-19: What proportion are asymptomatic?

<https://www.cebm.net/covid-19/covid-19-what-proportion-are-asymptomatic/>

Problems in identifying the origins of an outbreak

<https://www.cebm.net/covid-19/problems-in-identifying-the-origins-of-an-outbreak/>

Covid 19 - Modelling the models

<https://www.cebm.net/covid-19/modelling-the-models/>

<https://www.cebm.net/covid-19/sars-cov-2-viral-load-and-the-severity-of-covid-19/>

Are COVID-19 patients in hospital or admitted to hospital?

<https://www.cebm.net/covid-19/are-covid-19-patients-in-hospital-or-admitted-to-hospital/>

303. Jefferson, T. (2020). Sponsorship bias in clinical trials: growing menace or dawning realisation? *Journal of the Royal Society of Medicine*, 113(4), 148–157.

<https://doi.org/10.1177/0141076820914242>

<http://journals.sagepub.com/share/2F3RYZGUQTJTADJT3AJW?target=10.1177/0141076820914242>

COVID-19 – The great plague of Lombardy – a not so distant resonance chamber

<https://www.cebm.net/covid-19/covid-19-the-great-plague-of-lombardy-a-not-so-distant-resonance-chamber/>

Is Lombardy the widow of Hampstead?

<https://www.cebm.net/covid-19/covid-19-is-lombardy-the-widow-of-hampstead/>

What does RCGP surveillance tell us about COVID-19 in the community

<https://www.cebm.net/covid-19/what-does-rcgp-surveillance-tell-us-about-covid-19-in-the-community/>

COVID-19 – Tracking European Mortality

<https://www.cebm.net/covid-19/covid-19-tracking-european-mortality/>

COVID 19 – The Widow of Hampstead Revisited

Effect of Latitude on COVID-19

Six Countries: Three-quarters of the COVID Deaths

COVID-19 Global Charts of Deaths

Covid 19 Epidemic “Waves”

<https://www.cebm.net/covid-19/covid-19-epidemic-waves/>

COVID 19 – Nova et Vetera: Lazarettos of Venice

<https://www.cebm.net/covid-19/covid-19-nova-et-vetera-lazarettos-of-venice/>

COVID-19: Unravelling the Uncertainties

<https://www.cebm.net/covid-19/covid-19-unravelling-the-uncertainties/>

COVID-19: Re-establishing ‘Fever Hospitals’

<https://www.cebm.net/covid-19/covid-19-reestablishing-fever-hospitals/>

COVID 19 - Understanding the Unknown in Acute Respiratory Infections

<https://www.cebm.net/covid-19/covid-19-understanding-the-unknown-in-acute-respiratory-infections/>

COVID-19: Have we forgotten our children in all this?

<https://www.cebm.net/covid-19/covid-19-have-we-forgotten-our-children-in-all-this/>

Let’s bring back Britain’s fever hospitals

<https://www.spectator.co.uk/article/Lets-bring-back-Britains-fever-hospitals>

Don’t place too much faith in models predicting another coronavirus wave

<https://www.telegraph.co.uk/politics/2020/05/16/dont-place-much-faith-models-predicting-another-coronavirus/>

Jefferson, T. Refining the E in EBM. Evid. Based Med. 2020 0: p. bmjebm-2020-111348v1-bmjebm-2020-111348

<http://ebm.bmjournals.com/cgi/content/full/bmjebm-2020-111348v1?ct>

Could mass testing for Covid-19 do more harm than good?

<https://www.spectator.co.uk/article/could-mass-testing-for-covid-19-do-more-harm-than-good->

Rome, 1 August 2020

Thames & Jefferson

EXHIBIT C

Curriculum vitae

for

Peter C. Gøtzsche

Updated October 2020

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Advisory Board member at international congresses	55
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Personal data

Peter Christian Gøtzsche, Kløvervang 39, 2970 Hørsholm, Denmark
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 Director, Institute for Scientific Freedom, Copenhagen
 Visiting Professor, Institute of Health & Society, University of Newcastle, England

Email: pcg@scientificfreedom.dk
 Mobile: +45 53 64 20 66
 Websites: scientificfreedom.dk and deadlymedicines.dk
 Twitter: [@PGtzsche1](https://twitter.com/PGtzsche1)

Date of birth: 26 November 1949
 Family relation: Married, 2 children
 Citizenship: Danish

Education

1968 Student exam, Næstved Gymnasium. Marks: 9.0.
 1970 First part of biology, University of Copenhagen. Marks: ug-
 1970-73 Studies at the universities of Uppsala and Lund.
 1973 MSc in biology and chemistry, University of Lund.
 1974 MSc in biology and chemistry, University of Copenhagen.
 Special subject in entomology. Marks: 10.
 1984 MD, University of Copenhagen. Marks: 10.0.
 1987 Diploma Course in Tropical Medicine, Copenhagen (2 months; passed).
 1990 Thesis, University of Copenhagen.
 1995 Specialist in internal medicine.

Appointments

Pregraduate

01.02.72 - 31.05.72 Teacher, Norrmalmsskolan, Piteå, Sweden (2 months).
 01.09.74 - 31.01.75 Teacher, Falkonergårdens Gymnasium.
 01.04.75 - 31.03.77 Drug representative and product manager, Astra Group A/S.
 01.04.77 - 31.08.83 Head of medical department, Astra-Syntex A/S.

Postgraduate

01.06.84 - 30.09.84 Registrar, Bispebjerg Hospital, Med Dept C
 01.10.84 - 31.12.85 Registrar, Herlev Hospital, Surgical Dept
 01.06.85 - 31.08.85 Registrar, Herlev Hospital, Med Dept F
 01.01.86 - 31.08.86 Registrar, Rigshospitalet, Dept of Infect Dis
 01.09.86 - 30.09.87 Registrar, Hvidovre Hospital, Dept of Hepatology
 01.09.87 - 31.05.95 Chief, Nordic coordination office for AIDS trials, Rigshospitalet
 01.09.88 - 31.01.90 Junior Lecturer, Theory of Medicine, University of Copenhagen
 01.02.89 - 28.02.90 Registrar, Herlev Hospital, Med Dept C
 01.03.90 - 28.02.91 Registrar, Rigshospitalet, Med Dept A
 01.03.91 - 31.08.91 Registrar, Rigshospitalet, Med Dept L
 01.09.91 - 29.02.92 Registrar, Rigshospitalet, Dept of Infect Dis
 01.03.92 - 30.06.93 Senior registrar, Hvidovre Hospital, Dept of Rheumatology
 01.09.92 - 30.06.93 Lecturer, internal medicine, Hvidovre Hospital
 01.07.93 - 31.08.95 Senior registrar, Rigshospitalet, Dept of Infect Dis
 01.10.93 - 31.05.97 Senior House Medical Officer, Rigshospitalet

01.03.92 - 31.12.98	Editor, Bibliotek for Læger
01.02.90 - 31.03.10	Lecturer, Theory of Medicine, University of Copenhagen
01.10.93 - 30.04.19	Director, The Nordic Cochrane Centre
01.06.97 - 30.04.19	Chief physician, Rigshospitalet
01.04.10 - 30.04.19	Professor, Clinical Research Design and Analysis, University of Copenhagen

Funding support

1987	Danish Medical Research Council
1988	Danish Medical Research Council
1989	Danish Medical Research Council
1990	Danish Medical Research Council
1990	Danish Arthritis Foundation
1992	Medical Society in Copenhagen
1992	Fund for progress in Medical Science
1992	Danish Arthritis Foundation
1992	Fonden til Lægevidenskabens Fremme
1992	Todelegatet
1993	Rigshospitalet
1993	Research Foundation for Greater Copenhagen, Faroe Islands and Greenland.
1993	Ministry of Health
1994	Rigshospitalet
1994	European Union, BIOMED I
1995	European Union, BIOMED II
1995	Nordic Council of Ministers
1995	Rigshospitalet
1995	Copenhagen Hospital Foundation
1996	Danish Medical Research Council
1996	Nordic Council of Ministers
1996	Apothecary Foundation
1997	Fonden "En god start i livet"
1997	Nordic Council of Ministers
1997	Sygekassernes Helsefond
1997	Research Fund, Leo Pharmaceuticals
1998	State Institute for Medical Health Technology Assessment
1998	European Union, BIOMED 2
1998	Nordic Council of Ministers
1998	Danish Medical Research Council
1999	Nordic Council of Ministers
1999	Danish Ministry of Health
2000	Nordic Council of Ministers
2000	Ministry of Health
2000	Mindelegat (Mrs. Kay Lynæs)
2001	Nordic Council of Ministers
2001	Mindelegat (Mrs. Kay Lynæs)
2002	Mindelegat (Mrs. Kay Lynæs)
2002	Nordic Council of Ministers
2003	Danish Medical Research Council
2003	Danish Ministry of Health
2003	Rigshospitalet
2003	Nordic Council of Ministers
2004	Nordic Council of Ministers
2005	Nordic Council of Ministers
2006	Nordic Council of Ministers
2006	IMK Charitable Fund
2007	Danish Medical Research Council
2007	The Cancer Foundation
2008	Nordic Council of Ministers
2008	Sygekassernes Helsefond

2008	Rigshospitalet
2008	Danish Medical Research Council
2009	Rigshospitalet
2009	Capital Region of Denmark
2009	Agnes and Poul Friis' Foundation
2010	Augustinus Foundation
2010	Oticon Foundation
2010	Rigshospitalet
2010	Lundbeck Foundation
2010	Kontorchef Gerhard Brønsted's Travel Grant
2010	Tryg Foundation
2010	University of Copenhagen
2010	Sygekassernes Helsefond
2010	Julie von Müllen's Foundation
2010	The Free Research Councils
2011	The Cochrane Collaboration
2011	Rigshospitalet
2012	Rigshospitalet
2012	Tryg Foundation
2012	Sygekassernes Helsefond
2012	The Cochrane Collaboration
2014	Laura and John Arnold Foundation, Houston, Texas, PhD stipend
2014	Laura and John Arnold Foundation, Houston, Texas, PhD stipend
2015	University of Copenhagen, PhD stipend
2020	Laura and John Arnold Foundation, Houston, Texas, research

Awards and other academic honours

1992	Farmer from Stenløse, Peder Laurids Pedersen's donation.
1993	Co-founder of the Cochrane Collaboration
1997	Award of the year from the foundation "A good start in life".
1999	Henrik R. Wulff's prize from Danish Society for Theory in Medicine
2001	Skrabanek Foundation Prize, Trinity College, Dublin.
2001	Niels A. Lassen's prize.
2003	Queen Ingrid's Lecture, Åbenrå Hospital.
2004	Harry Boström Lecture, Swedish Society for Internal Medicine, Annual Meeting.
2006	Top-ten peer reviewer for British Medical Journal for the year 2006.
2007	Winner of the 2007 Society of Medical Writers' Academic Writing Award (for: Jørgensen KJ, Gøtzsche PC. Content of invitations to publicly funded screening mammography. <i>BMJ</i> 2006;332:538-41).
2009	Michael Berger Award, Düsseldorf.
2012	Winner of the annual Prescrire Prize for medical and pharmaceutical books (for: Gøtzsche PC. Mammography screening: truth, lies and controversy. London: Radcliffe Publishing; 2012:1-388).
2014	Winner of the Annual LAP Award (psychiatry award), Denmark.
2014	Co-founder and member of the Board of the Council for Evidence-based Psychiatry, London.
2014	Winner of the British Medical Association's Annual Book Award in the category Basis of Medicine for <i>Deadly Medicines and Organised Crime: How big pharma has corrupted health care.</i>
2014	Award from the International Society of Ethical Psychology and Psychiatry for "intellectual honesty and bravery in tackling the biomedical-industrial complex."
2015	Honourable Award, Consul General Ernst Carlsen's Foundation.
2015	Book of the Year, US Tributaries Radio, for <i>Deadly Psychiatry and Organised Denial.</i>
2015	Top ten finalist for the award "Dane of the year," nominated by psychiatric patients.
2016	HealthWatch Award, London
2016	Protector for Stemmehøremetværket (Hearing Voices Network)
2016	Co-founder and member of the Board, International Institute for Psychiatric Drug Withdrawal.
2017	Elected member of the Cochrane Governing Board, with the most votes of the 11 candidates.
2017	Honored Guests Award in Ethical Human Sciences and Services. Breggin: <i>Psychiatric Drug Facts.</i>
2018	Member of the Advisory Council of International Center for the Study of Patient-Oriented Psychiatry.
2018	Member of the Advisory Council of the Center for the Study of Empathic Therapy, Education & Living.

2020 Award from the Danish Patient Association for being the bravest doctor in the last decade.

Some recent appearances in documentary films and satires

1. The Daily Show, New York. 2014; Sept 16.
2. Frank Wittig Frank.Wittig@swr.de Südwestrundfunk
3. Lægemedelindustrien, NRK1, 2014.
4. Danmark på piller. Tre dokumentarer i DR TV 2014.
5. TV fra en anden planet, kanal 1, juni 2015. <http://kanal-1.dk/tv-fra-en-anden-planet/>.
6. Crazywise, 2016.
7. ”Lykkepillen”. [Dokumentarfilm om Silje Marie Strandberg](#). 2017.
8. [Cause of death: unknown](#). Documentary film about filmmaker’s sister, Renate Hoel. 2017.
9. [Diagnosing psychiatry](#). Documentary film about Peter Gøtzsche. 2018.
10. Speed Demons: Dying For Attention. 2018.
11. sera@westernmassrlc.org
12. The drug industry. sejucer@gmail.com. Russia 1
13. Michael Siewierski, New Roots Films. info@foodchoicesmovie.com 2018 launch.
14. [Medicating normal](#). Periscope Moving Pictures. 2019.

Publications

My scientific works have been cited about 50,000 times. My H-index is 67 according to Web of Science, September 2018, which means that 67 papers have been cited at least 67 times.

DrMedSci thesis

Bias in double-blind trials. Dan Med Bull 1990;37:329-36. Defended 10 May 1990 at the University of Copenhagen, Faculty for Health Sciences. Examiners: Professor, DrMedSci Ib Lorenzen and chief physician, DrMedSci Henrik R. Wulff.

Academic books

- Wulff HR, Gøtzsche PC. Rationel klinik. Evidensbaserede diagnostiske og terapeutiske beslutninger, 4. udgave. København: Munksgaard; 1997.
- Wulff HR, Gøtzsche PC. Rational Diagnosis and Treatment. Evidence-Based Clinical Decision-Making, 3rd edition. Oxford: Blackwell Scientific; 2000. Translated into Swedish, Spanish and Polish.
- Wulff HR, Gøtzsche PC. Rationel klinik. Evidensbaserede diagnostiske og terapeutiske beslutninger, 5. udgave. København: Munksgaard Danmark; 2006.
- Gøtzsche PC. Rational Diagnosis and Treatment. Evidence-Based Clinical Decision-Making, 4th edition. Chichester: Wiley; 2007.
- Gøtzsche PC. Mammography screening: truth, lies and controversy. London: Radcliffe Publishing; 2012. Winner of the Prescire Prize 2012.
- Gøtzsche PC. Deadly medicines and organised crime: How big pharma has corrupted health care. London: Radcliffe Publishing; 2013. Winner, British Medical Association’s Annual Book Award, Basis of Medicine in 2014. Translated into 15 languages.
- Gøtzsche PC. Dødelig medicin og organiseret kriminalitet: Hvordan medicinalindustrien har korrumpet sundhedsvæsenet. København: People's Press; 2013.
- Gøtzsche PC. Deadly psychiatry and organised denial. Copenhagen: People’s Press; 2015. Translated into many languages.
- Gøtzsche PC. Dødelig psykiatri og organiseret fornægtelse. København: People’s Press; 2015.
- Gøtzsche PC. Overlevelse i en overmedicineret verden: Find selv evidensen. København: People’s Press; 2018.
- Gøtzsche PC. Survival in an overmedicated world: look up the evidence yourself. Copenhagen: People’s Press; 2019
- Gøtzsche PC. Death of a whistleblower and Cochrane's moral collapse. Copenhagen: People’s Press; 2019.
- Gøtzsche PC. Vaccines: truth, lies and controversy. Copenhagen: People’s Press; 2020.
- Gøtzsche PC. Mental health survival kit and withdrawal from psychiatric drugs. Copenhagen: Institute for Scientific Freedom; 2020.

Gøtzsche PC. *Mentalt overlevelsesskit og udtræning af psykofarmaka*. København: Institute for Scientific Freedom; 2020.

Travel book

Gøtzsche PC. *På safari i Kenya*. København: Samlerens forlag; 1985.

Articles in international journals with peer review

Total number of citations: about 50,000; H-index: 67 (Web of Science, September 2018).

1. Andersen LA, Gøtzsche PC. Naproxen and aspirin in acute musculoskeletal disorders: a double-blind, parallel study in sportsmen. *Pharmatherapeutica* 1984;3:535-41.
2. Sindet-Pedersen S, Petersen JK, Gøtzsche PC. Incidence of pain conditions in dental practice in a Danish county. *Community Dent Oral Epidemiol* 1985;13:244-6.
3. Geisler C, Gøtzsche PC, Hansen SS, Juul K, Plesner AM, Nissen NI. Naproxen has greater antipyretic effect on fever related to Hodgkin's disease than to other tumours or to infection. *Scand J Haematol* 1985;35:325-8.
4. Sindet-Pedersen S, Petersen JK, Gøtzsche PC, Christensen H. A double-blind, randomized study of naproxen and acetylsalicylic acid after surgical removal of impacted lower third molars. *Int J Oral Maxillofac Surg* 1986;15:389-94.
5. Gøtzsche PC, Hvidberg EF, Juul P. Rational choice of dose: insufficient background knowledge? *Ration Drug Ther* 1986;20:1-7.
6. Gøtzsche PC. Reference bias in reports of drug trials. *BMJ* 1987;295:654-6.
7. Fogh S, Schapira A, Bygbjerg IC, Jepsen S, Mordhorst CH, Kuijlen K, Ravn P, Rønn A, Gøtzsche PC. Malaria chemoprophylaxis in travellers to east Africa: a comparative prospective study of chloroquine plus proguanil with chloroquine plus sulfadoxine/pyrimethamine. *BMJ* 1988;296:820-2.
8. Gøtzsche PC, Hørding M. Condoms to prevent HIV transmission do not imply truly safe sex. *Scand J Infect Dis* 1988;20:233-4.
9. Gøtzsche PC, Andreasen F, Egsmose C, Lund B. Steady state pharmacokinetics of naproxen in elderly rheumatics compared with young volunteers. *Scand J Rheumatol* 1988;17:11-6.
10. Gøtzsche PC, Bygbjerg IC, Olesen B, Møller LH, Salim YS, Faber V. Yield of diagnostic tests of opportunistic infections in AIDS: a survey of 33 patients. *Scand J Infect Dis* 1988;20:395-402.
11. Andersson PG, Hinge HH, Johansen O, Andersen CU, Lademann A, Gøtzsche PC. Double-blind study of naproxen vs placebo in the treatment of acute migraine attacks. *Cephalalgia* 1989;9:29-32.
12. Gøtzsche PC. Patients' preference in indomethacin trials: an overview. *Lancet* 1989;i:88-91.
13. Gøtzsche PC. Methodology and overt and hidden bias in reports of 196 double-blind trials of nonsteroidal, antiinflammatory drugs in rheumatoid arthritis. *Controlled Clin Trials* 1989;10:31-56 (amendment:356).
14. Gøtzsche PC. Multiple publication in reports of drug trials. *Eur J Clin Pharmacol* 1989;36:429-32.
15. Gøtzsche PC. Review of dose-response studies of NSAIDs in rheumatoid arthritis. *Dan Med Bull* 1989;36:395-9.
16. Gøtzsche PC. Meta-analysis of grip strength: most common, but superfluous variable in comparative NSAID trials. *Dan Med Bull* 1989;36:493-5.
17. Hørding M, Gøtzsche PC, Bygbjerg I, Pedersen M, Faber V, Berg K. Lack of immunomodulating effect of disulfiram in HIV positive patients. *Internat J Immunopharmacol* 1990;12:145-7.
18. Pedersen C, Gerstoft J, Tauris P, Lundgren JD, Gøtzsche PC, Buhl M, Salim Y, Schmidt K. Opportunistic infections and malignancies in 231 Danish AIDS patients. *AIDS* 1990;4:233-8.
19. Jørgensen A, Shao J, Maselle S, Yangi E, Thomsen A, Matunda S, Bygbjerg I, Gøtzsche P, Svendsen J, Skinhøj P, Faber V. Evaluation of simple tests for detection of HIV antibodies: analysis of interobserver variation in Tanzania. *Scand J Infect Dis* 1990;22:283-5.
20. Jørgensen AF, Mwakyusa D, Cegielski P, Gøtzsche P, Hørding M, Lallinger G, Mbaga I, Pallangyo K, Richter C, Shao J, Bygbjerg I, Skinhøj P, Faber V. The effect of fusidic acid on Tanzanian patients with AIDS. *AIDS* 1990;4:1037-8.
21. Jørgensen AF, Jensen VG, Shao JF, Maselle S, Mbaga IM, Mwakyusa DH, Gøtzsche PC, Richter C, Pallangyo K, Cegielski P, Lallinger G, Bygbjerg I, Skinhøj P, Faber V. Beta-2-microglobulin as a prognostic marker for patients with AIDS in Dar es Salaam, Tanzania. *AIDS* 1990;4:1168-9.
22. Gøtzsche PC. Sensitivity of effect variables in rheumatoid arthritis: a meta-analysis of 130 placebo controlled NSAID trials. *J Clin Epidemiol* 1990;43:1313-8.
23. Hørding M, Gøtzsche PC, Christensen LD, Bygbjerg IC, Faber V. Double-blind trial of bestatin in HIV-positive patients. *Biomed Pharmacother* 1990;44:475-8.

24. Pedersen C, Gerstoft J, Tauris P, Lundgren JD, Gøtzsche PC, Buhl M, Salim Y, Schmidt K, Nielsen JO. Trends in survival of Danish AIDS patients from 1981 to 1989. *AIDS* 1990;4:1111-6.
25. Gøtzsche PC, Kelbæk H, Vissing SF, Nielsen SL, Munck O, Christensen NJ, Lyngsøe J, Mathiesen ER. Acute cardiovascular effects of insulin in hyperglycaemic type I diabetics. *Scand J Clin Lab Invest* 1991;51:93-7.
26. Gøtzsche PC. Patients' views on the least acceptable increase in survival with zidovudine treatment. *Scand J Infect Dis* 1991;23:509-10.
27. Gjørup IE, Gøtzsche PC, Baden H, Andersen B. Surgical treatment of morbid obesity: a survey of overall outcome 1968-89. *Dan Med Bull* 1991;38:405-7.
28. Nielsen C, Nielsen CM, Petersen JL, Gøtzsche PC, Pedersen C, Arendrup M, Vestergaard BF. Isolation of HIV from cultures of purified CD4+ lymphocytes. *J Virol Methods* 1991;35:15-25.
29. Gøtzsche PC, Lange B. Comparison of search strategies for recalling double-blind trials from MEDLINE. *Dan Med Bull* 1991;38:476-8.
30. Nordic Medical Research Councils' HIV Therapy Group. Double-blind dose-response study of zidovudine in AIDS and advanced HIV infection. *BMJ* 1992;304:13-7 (manuscript and scientific coordinator: PC Gøtzsche).
31. Gøtzsche PC, Pødenphant J, Olesen M, Halberg P. Meta-analysis of second-line antirheumatic drugs: sample size bias and uncertain benefit. *J Clin Epidemiol* 1992;45:587-94.
32. Nielsen C, Gøtzsche PC, Nielsen CM, Gerstoft J, Vestergaard BF. Development of resistance to zidovudine in HIV strains isolated from CD4+ lymphocytes and plasma during therapy. *Antiviral Res* 1992;18:303-16.
33. Gøtzsche PC, Nielsen C, Gerstoft J, Nielsen CM, Vestergaard BF. Trend towards decreased survival in patients infected with HIV resistant to zidovudine. *Scand J Infect Dis* 1992;24:563-5.
34. Gøtzsche PC, Pødenphant J, Olesen M, Halberg P. Critique of meta-analysis of second-line antirheumatic drugs. *J Clin Epidemiol* 1993;46:319-21.
35. Rasmussen MH, Andersen T, Breum L, Gøtzsche PC, Hilsted J. Cimetidine suspension as adjuvant to energy restricted diet in treating obesity. *BMJ* 1993;306:1093-6.
36. Gøtzsche PC. Zidovudine in HIV infection. *Ann Med* 1993;25:213-4.
37. Rasmussen MH, Andersen T, Breum L, Hilsted J, Gøtzsche PC. Observer variation in measurements of waist-hip ratio and the abdominal sagittal diameter. *Int J Obes* 1993;17:323-7.
38. Gøtzsche PC. Meta-analysis of NSAIDs: contribution of drugs, doses, trial designs, and meta-analytic techniques. *Scand J Rheumatol* 1993;22:255-60.
39. Gøtzsche PC. Is there logic in the placebo? *Lancet* 1994;344:925-6.
40. Gøtzsche PC. Steroids and peptic ulcer: an end to the controversy? *J Intern Med* 1994;236:599-601.
41. The Standards of Reporting Trials Group. A proposal for structured reporting of randomized controlled trials. *JAMA* 1994;272:1926-31 (member of writing committee).
42. Gøtzsche PC, Gjørup I, Bonnén H, Brahe NEB, Becker U, Burcharth F. Somatostatin v placebo in bleeding oesophageal varices: randomised trial and meta-analysis. *BMJ* 1995;310:1495-8.
43. Ullum H, Gøtzsche PC, Victor J, Dickmeiss E, Skinhøj P, Pedersen BK. Defective natural immunity: an early manifestation of human immunodeficiency virus infection. *J Exp Med* 1995;182:789-99.
44. Mulward S, Gøtzsche PC. Sample size of randomized double-blind trials 1976-1991. *Dan Med Bull* 1996;43:96-8.
45. Gøtzsche PC, Liberati A, Luca P, Torri V. Beware of surrogate outcome measures. *Int J Technol Ass Health Care* 1996;12:238-46.
46. Gøtzsche PC, Hansen M, Stoltenberg M, Svendsen A, Beier J, Faarvang KL, et al. Randomized, placebo controlled trial of withdrawal of slow-acting antirheumatic drugs and of observer bias in rheumatoid arthritis. *Scand J Rheumatol* 1996;25:194-9.
47. Ullum H, Diamant M, Victor J, Gøtzsche PC, Bendtzen K, Skinhøj P, Pedersen BK. Increased circulating levels of interleukin-6 in HIV seropositive subjects. *J AIDS* 1996;13:93-9.
48. Gøtzsche PC. Blinding during data analysis and writing of manuscripts. *Controlled Clin Trials* 1996;17:285-90.
49. Gøtzsche PC, Johansen HK. Antifungal prophylactic or empiric therapy vs placebo or no treatment in cancer patients with neutropenia (Cochrane Review). In: *The Cochrane Library, Issue 2*. Oxford: Update Software; 1997. Updated quarterly.
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322. Gøtzsche PC Prescription drugs are the third leading cause of death [Online] 2016 [Citeret 2016 jun. 16] <http://blogs.bmj.com/bmj/2016/06/16/peter-c-gotzsche-prescription-drugs-are-the-third-leading-cause-of-death/>
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Secondary publications in Danish

1. Gøtzsche PC. Reference-bias. Ugeskr Læger 1988;150:228-9.
2. Nordic Medical Research Councils' HIV Therapy Group. Dobbeltblind dosis-responsundersøgelse af zidovudin ved AIDS og fremskreden HIV-infektion. Ugeskr Læger 1993;155:104-7.
3. Gøtzsche PC, Nielsen C, Gerstoft J, Nielsen CM, Vestergaard BF. Patientoverlevelse ved zidovudinresistent HIV. Ugeskr Læger 1994;156:185-6.
4. Gøtzsche PC, Gjørup I, Bonnén H, Brahe NEB, Becker U, Burcharth F. Randomiseret undersøgelse og metaanalyse af somatostatin overfor placebo ved blødende øsofagusvaricer. Ugeskr Læger 1996;158:2393-6.
5. Gøtzsche PC. Vigtigheden af et bredt perspektiv på metaanalyse: kan have afgørende betydning for patienterne. Ugeskr Læger 2000;162:5601.
6. Gøtzsche PC. Bredt perspektiv på metaanalyse af afgørende betydning for patienten. Läkartidningen 2000;97:5882-3.
7. Gøtzsche PC. Bredt perspektiv på metaanalyse - kan have afgørende betydning for patienterne. Tidsskr Nor Lægeforen 2000;120:2810-1.
8. Hróbjartsson A, Gøtzsche PC. Hvad er effekten af placebobehandling? Ugeskr Læger 2002;164:329-33.
9. Jørgensen KJ, Gøtzsche PC. Information om brystkræftscreening på internetsider er ensidig og mangelfuld - sekundærpublikation. Ugeskr Læger 2005;167:174-8.
10. Gøtzsche PC. Forbedret rapportering af skadevirkninger i randomiserede forsøg: udvidelse af CONSORT-vejledningen. Ugeskr Læger 2005;167:1520-2.
11. Hróbjartsson A, Chan A-W, Haahr MT, Gøtzsche PC, Altman DG. Selektiv rapportering af effektmål i randomiserede forsøg. Sekundærpublikation. Ugeskr Læger 2005;167:3189-91.
12. Haug C, Gøtzsche PC, Schroeder T. Register og registrering af kliniske forsøg. Sekundærpublikation. Ugeskr Læger 2006;168:457-8.
13. Gøtzsche PC, Hróbjartsson A, Johansen HK, Haahr MT, Altman DG, Chan AW. Begrænsninger i publikationsrettighederne i industriinitierede kliniske forsøg - sekundærpublikation. Ugeskr Læger 2006;168:2467-9.
14. Jørgensen KJ, Gøtzsche PC. Er invitationer til mammografiscreening et rimeligt udgangspunkt for det informerede samtykke? Sekundærpublikation. Ugeskr Læger 2006;168:1658-60.

15. Gøtzsche PC. Er relative risici og oddsratioer i resumeer troværdige? Sekundærpublikation. Ugeskr Læger 2006;168:2678-80.

Teaching

Pregraduate courses

1988-89	Junior lecturer, Theory of Science, University of Copenhagen.
1990-2012	Lecturer, Theory of Science, University of Copenhagen.
1992-93	Lecturer, internal medicine, Hvidovre Hospital.
1993, 13 May	Course in research methodology, human biology, University of Copenhagen.
1994, 2-3 Feb	Course in research methodology, human biology, University of Copenhagen.
2003, 2 Sept	When is one drug better than another? Denmark's Pharmaceutical University.
2003, 20 Oct	Meta-analyses and their role in systematic reviews. Students in Public Health, Copenhagen.
2015, 15 April	Lectures on Theory of Science for pharmacy students.
2016, 8 Dec	Vore lægemidler er den 3. hyppigste dødsårsag. Farmaceutstuderende, København.
2017, 7 Dec	Kliniske forsøg. Farmaceutstuderende, København.
2018, 30 Apr	Psykiatriske diagnoser og depressionsmedicin. Psykologistuderende, København.
2018, 11 Oct	Kliniske forsøg. Farmaceutstuderende, København.

See also Lectures below, which include many for students.

Postgraduate courses

C: course manager.

- Controlled clinical trials of drugs, Rigshospitalet, 3-5 Nov 1986.
- C Statistics and epidemiology. Scandinavian Diploma Course in Tropical Medicine, University of Copenhagen, 28 Oct 1987.
- A-course in research methodology. National Board of Health, 15 Nov 1988.
- A-course in clinical decision theory. National Board of Health, 17 Apr 1989.
- C Statistics and epidemiology. Scandinavian Diploma Course in Tropical Medicine, University of Copenhagen, 2 Nov 1989.
- C Transdisciplinary course in medical ethics. Danish Society for Theory in Medicine, Copenhagen, 29 Apr 1989.
- C Transdisciplinary course in medical ethics. Danish Society for Theory in Medicine, Copenhagen, 29 Apr 1990.
- Course on meta-analyses. Medicom, Copenhagen, 21 May 1990.
- C Transdisciplinary course in medical ethics. Danish Society for Theory in Medicine, Copenhagen, 10 Nov 1990.
- PhD course in medical ethics. University of Southern Denmark, 17 May 1991.
- Course on rheumatoid arthritis. Danish Rheumatological Society, 27 Okt 1991.
- Course in clinical trials. Apothecary Society, Hillerød, 5 Nov 1991.
- C Litterature evaluation for pharmacists, Hillerød, 2-4 Dec 1991.
- Bias. Course in pharmacodynamics. Danish Society for Clinical Pharmacology, 6 Dec 1991.
- C Rigshospitalet's course in clinical trials. Hillerød, 2-6 Mar 1992.
- A-course in clinical pharmacology. National Board of Health, 3 Mar 1992.
- Research methodology for back diseases. Back research group, Copenhagen, 2 Apr 1992.
- A-course in clinical pharmacology. National Board of Health, 5 May 1992.

19. PhD course in medical ethics. University of Southern Denmark, 8 May 1992.
20. A-course in clinical pharmacology. National Board of Health, 6 Oct 1992.
21. C Rigshospitalet's course in clinical trials. Hillerød, 19-23 Oct 1992.
22. A-course in rheumatology. National Board of Health, 24 Nov 1992.
23. A-course in clinical pharmacology. National Board of Health, 8 Dec 1992.
24. A-course in rheumatology. National Board of Health, 9 Feb 1993.
25. A-course in clinical pharmacology. National Board of Health, 2 Mar 1993.
26. PhD course in medical ethics. University of Southern Denmark, 26 Mar 1993.
27. C Rigshospitalet's course in clinical trials. Hillerød, 31 Mar-2 Apr 1993.
28. Course on Systematic Reviews. Swedish Council for Technology Assessment in Health Care, Stockholm, 19-20 Oct 1993.
29. A-course in clinical pharmacology. National Board of Health, 1 Mar 1994.
30. C PhD course in systematic reviews. Panum Institute, 11-12 Apr 1994.
31. C PhD course in systematic reviews. Panum Institute, 13-14 Apr 1994.
32. C Rigshospitalet's course in clinical trials. Hillerød, 18-22 Apr 1994.
33. Rigshospitalet's research policy. Rigshospitalet, 18 Aug 1994.
34. Course in biological psychiatric research. Bispebjerg Hospital, 17 Jan 1995.
35. Scientific dishonesty. University hospitals' Centre for Nursing Research. Rigshospitalet, 23 Feb 1995.
36. Course on Systematic Reviews. Swedish Council for Technology Assessment in Health Care, Copenhagen, 27-29 Mar 1995.
37. Post Conference Course in Evidence-based Health Care: critical appraisal of evidence. International Society for Technology Assessment in Health Care, Dalarna, Sweden, 7-10 June 1995.
38. Use of research results. Rigshospitalet's course in quality development, 15 June 1995.
39. Course on Systematic Reviews. Swedish Council for Technology Assessment in Health Care, Stockholm, 29-31 Oct 1995.
40. Course in quality development. Rigshospitalet, 13 Dec 1995.
41. C Course on systematic reviews. Panum Institute, 14-15 Dec 1995.
42. Meta-analyses and evaluation of the quality of research. Danish Society for Internal Medicine. Sundby Hospital, 27 Mar 1996.
43. C Workshop on Handsearching. Nordic Cochrane Centre, 16 Apr 1996.
44. C Workshop on Systematic Reviews for Cochrane Reviewers. Protocol development. Nordic Cochrane Centre, 17 Apr 1996.
45. C Workshop on Systematic Reviews for Cochrane Reviewers. Getting a review into Review Manager. Nordic Cochrane Centre, 18 Apr 1996.
46. Workshop on Systematic Reviews. Swedish Council for Technology Assessment in Health Care, Stockholm, 12-14 May 1996.
47. C Workshop on Systematic Reviews for Cochrane Reviewers. Protocol development. Nordic Cochrane Centre, 12 Sept 1996.
48. C Workshop on Systematic Reviews for Cochrane Reviewers. Getting a review into Review Manager. Nordic Cochrane Centre, 13 Sept 1996.
49. Course on systematic reviews. Swedish Council for Technology Assessment in Health Care, Stockholm, 4-6 Dec 1996.
50. C Course on systematic reviews. Swedish Council for Technology Assessment in Health Care, Göteborg, 17 Dec 1996.
51. The controlled clinical trial and meta-analysis. Danish Society for Internal Medicine. Sundby Hospital, 10 Mar 1997.
52. Meta-analyses and the international Cochrane Collaboration. PhD course in clinical intervention research. MEDIF/MEFA, 13 Mar 1997.
53. Second Nordic Course in Evidence-based Medicine. Oslo, 1-5 June 1997.
54. Minicourse in evidence-based medicine and the Cochrane Library. Rigshospitalet, 5 Nov 1997.
55. C Workshop on Handsearching. Nordic Cochrane Centre, 12 Nov 1997.

56. C Workshop on Systematic Reviews for Cochrane Reviewers. Protocol development. Nordic Cochrane Centre, 13 Nov 1997.
57. Course in evidence-based medicine. Rigshospitalet, 30 Apr-2 May 1998.
58. Workshop on Systematic Reviews for Cochrane Reviewers. Protocol development. Nordic Cochrane Centre, 27 May 1998.
59. C Workshop on Handsearching. Nordic Cochrane Centre, 9 July 1998.
60. C Workshop on Systematic Reviews for Cochrane Reviewers. Protocol development. Helsinki, 21 Sept 1998.
61. Course in evidence-based medicine. Rigshospitalet, 9-12 Nov 1998.
62. C Workshop on Systematic Reviews for Cochrane Reviewers. Protocol development. Nordic Cochrane Centre, 1 Mar 1999.
63. C Workshop on Handsearching. Nordic Cochrane Centre, 3 Mar 1999.
64. Course in evidence-based medicine. Panum, 14-17 June 1999.
65. Workshop on Systematic Reviews for Cochrane Reviewers. Protocol development. Nordic Cochrane Centre, 21 Mar 2000.
66. Workshop on Handsearching. Nordic Cochrane Centre, 22 Mar 2000.
67. C Evidence-based medicine. Ringe Back Centre, 14 Apr 2000.
68. C Evidence-based cardiology. Society for Younger Cardiologists, 15 Apr 2000.
69. Workshop on controversial issues related to clinical trials and systematic reviews. Barcelona, 30 June 2000.
70. Workshop on Handsearching. Nordic Cochrane Centre, 11 Sept 2000.
71. Quantitative epidemiology: perspectives and limitations. Research School for Animal Reproduction and Health, 31 Jan 2001.
72. Workshop on Systematic Reviews for Cochrane Reviewers. Protocol development. Nordic Cochrane Centre, 27 Mar 2001.
73. Meta-analyses - use and misuse. Danish Drug Industry Association, 30 May 2001.
74. C Workshop on Cochrane editing. Hotel Marina, 6-8 Sept 2001.
75. Quantitative epidemiology: perspectives and limitations. Research School for Animal Reproduction and Health, Karrebæksminde, 6 Feb 2002.
76. Workshop on Systematic Reviews for Cochrane Reviewers. Protocol development. Nordic Cochrane Centre, 23 Apr 2002.
77. Course in evidence-based medicine. Rigshospitalet, 3-4 og 17-18 June 2002.
78. C Workshop on Cochrane editing. Hotel Marina, 12-14 Sept 2002.
79. Workshop on Systematic Reviews for Cochrane Reviewers. Protocol development. Nordic Cochrane Centre, 7 Oct 2002.
80. Meta-analysis and potential and limitations of evidence-based medicine. 6. Lübecker course, Lübeck, 9-10 Oct 2002.
81. PhD course, Panum Institute, 12 Dec 2002.
82. Quantitative epidemiology: perspectives and limitations. Research School for Animal Reproduction and Health, Tune Landbrugsskole, 29 Jan 2003.
83. Prioritisation and evidence-based medicine. Nordjyllands Amtsråd, Ålborg, 13 Feb 2003.
84. C Workshop on Cochrane editing. Nordic Cochrane Centre, 18-19 Sept 2003.
85. Workshop on Systematic Reviews for Cochrane Reviewers. Protocol development. Nordic Cochrane Centre, 6 Oct 2003.
86. C Quality of allocation concealment. 11th Cochrane Colloquium, Barcelona, 28 Oct 2003.
87. PhD course, Panum Institute, 24 Nov 2003.
88. Workshop on research in alternative medicine, Rigshospitalet, 30-31 Mar 2004.
89. Course in evidence-based medicine. Panum Institute, 1-2 og 14-15 June 2004.
90. C PhD course in systematic reviews and meta-analyses. Rolighed, 8-11 Nov 2004.
91. PhD course, Panum Institute, 1 Dec 2004.

92. Quantitative epidemiology: perspectives and limitations. Research School for Animal Reproduction and Health, KVL, 24 Aug 2005.
93. Course in infection pathogenesis. Rigshospitalet, 5 Sept 2005.
94. Doctors' Annual Gathering (Lægedage). Copenhagen, 18 Nov 2005.
95. PhD course in planning clinical research. Panum Institute, 21 Feb 2006.
96. PhD course in epidemiology. Køge, 30 Mar 2006.
97. Reporting of harms. GCP units in Denmark, Nyborg, 31 Mar 2006.
98. PhD course. Pharmaceutical University, 13 June 2006.
99. Doctors' Annual Gathering (Lægedage). Copenhagen, 11 Nov 2006.
100. Systematic reviews. Advanced seminar, Madrid, 16-17 Nov 2006.
101. Seminar on peer review and scientific misconduct. Karolinska Institute, Stockholm, 30 Nov 2006.
102. PhD course, Research ethics. Copenhagen Business School, 19 Mar 2007.
103. Course in clinical decision theory. National Board of Health, Copenhagen, 8 May 2007.
104. PhD course, Ethics in science. Faculty of life sciences, Copenhagen, 13 Aug 2007.
105. Evidence-based medicine. WHO, delegation from Uzbekistan, Hillerød, 21 Sept 2007.
106. Course for clinical microbiologists. National Board of Health, Copenhagen, 24 Sept 2007.
107. PhD course, Research ethics. Copenhagen Business School, 31 Oct 2007.
108. PhD course, Research ethics. Copenhagen Business School, 31 Mar 2008.
109. Course in Clinical Pharmacology, National Board of Health, 17 April 2008.
110. PhD course in planning clinical research. University of Copenhagen, 31 May 2008.
111. Workshop: Clinical trials registration & results reporting: The CONSORT guidelines and beyond. 2nd South Asian Regional Symposium on Evidence Informed Health Care. Vellore, India, 9 April 2008.
112. Course in clinical decision theory. National Board of Health, Copenhagen, 7 and 20 May 2007.
113. PhD course in clinical epidemiology. Køge, 9 Oct 2008.
114. Course in clinical decision theory. National Board of Health, Copenhagen, 19 Nov 2008.
115. Course in clinical decision theory. National Board of Health, Copenhagen, 24 Nov 2009.
116. PhD course in planning clinical research. University of Copenhagen, 21 Jan 2010.
117. Course in clinical decision theory. National Board of Health, Copenhagen, 18 May 2010.
118. Course in clinical pharmacology. National Board of Health, Copenhagen, 1 Apr 2011.
119. Forskeruddannelsesnetværket. Korsør, 17 May 2011.
120. PhD course. Herlev, 16 June 2011.
121. Highlights i reumatologien. Korsør, 1 Sept 2011.
122. PhD course, systematic reviews. University of Copenhagen, 26-29 Sept 2011.
123. Lægemiddelinformation – fup eller fakta? DULM-kursus, 20 April 2012.
124. PhD course, Good scientific practice and reporting, University of Copenhagen, 26-28 Sept 2012.
125. Screening. Speciallægeuddannelsen, Sundhedsstyrelsen, Rigshospitalet, 12 May 2016.
126. Screening. Speciallægeuddannelsen, Sundhedsstyrelsen, Bispebjerg, 10 Nov 2016.
- 127.C Myter, misforståelser og skader i psykiatrien. Heldagsseminar, Sydhavnen, 15 Dec 2016.
- 128.C Myter, misforståelser og skader i psykiatrien. Heldagsseminar, Fredericia, 25 April 2017.
- 129.C Udtræpning af psykofarmaka. Heldagskursus, København, 12 June 2017.
130. Withdrawal of psychiatric drugs, Göteborg, 18-20 Oct 2017.
131. Varför SSRI & liknande antidepressiva bör utgå. Swedish Psychiatrists, Göteborg, 25 Jan 2018.
- 132.C Seminar om udtræpning af psykofarmaka. Nyborg, 16 March.
- 133.C Seminar om udtræpning af psykofarmaka. Nyborg, 16 March. (seminar held twice the same day).
- 134.C Research seminar about depression pills. Copenhagen, 14 June.
135. Power versus rationality: fighting conflicts of interest. Oxford, 19 June 2019.
- 136.C Vejen ud af medicinens fængslende greb. Heldagsseminar, Kolding, 9 June 2020.

Lectures

IS: invited speaker; more recent titles have been translated into English, for convenience.

1. IS Steady state pharmacokinetics of naproxen in rheumatoid arthritis. XV congrès international de rheumatologie, Paris, 21-27 June 1981.
2. Dosis-respons forhold ved rheumatoid artrit. Ribe amts lægekredsförening, 5 nov 1982.
3. Klinisk farmakologi af naproxen (Naprosyn). Aftenmøder den 7, 11, 12, 19, 25 og 26 april 1983 på hhv. Store Kro, Fredensborg, Hotel H. C. Andersen, Odense, Hotel Impala, Silkeborg, Mogenstrup kro, Hotel Sheraton, København og Rold Storkro.
4. Månedens forskningsproblem: bedre end sig selv. Staff-meeting, amtssygehuset i Herlev, 24 okt 1985.
5. IS Reference bias. En undersøgelse af litteraturreferencemønstret i offentliggjorte lægemiddelundersøgelser. Dansk Selskab for Klinisk Farmakologi, 27 jan 1987.
6. IS Værdien af mikrobiologiske undersøgelser hos HIV-inficerede patienter. Dansk Selskab for Klinisk Mikrobiologi, 7 dec 1987.
7. Yield of diagnostic investigations of opportunistic infections in 33 AIDS patients. European Conference on Clinical Aspects of HIV Infection, Bruxelles, 10-11 Dec 1987.
8. IS Bias i dobbeltblinde undersøgelser af NSAID's med perspektiver for meta-analyser. Dansk Selskab for Medicinsk Reumatologi, 17 feb 1989.
9. IS Meta-analyse af antirheumatica behandling. Møde om den kontrollerede kliniske undersøgelses metodologi: status og perspektiver. Rigshospitalet, 28 apr 1989.
10. IS Meta-analyse af non-steroide antiinflammatoriske stoffer. Dansk Selskab for Intern Medicin, amtssygehuset i Herlev, 13 okt 1989.
11. IS Hvordan stiller man forsøg op, og hvordan analyserer man resultaterne? Årsmøde i Den Danske Klub for Centralsterilisering og Sygehushygiejne, Hotel Frederik II, Slagelse, 10 nov 1989.
12. IS Valg af NSAID ud fra kliniske studier. Specialistmøde for reumatologer, Novo Nordisk, København, 3 maj 1990.
13. IS Meta-analysis of second-line antirheumatic drugs: sample size bias and uncertain benefit. 23rd Nordic Congress of Rheumatology, Tampere, 15 June 1990.
14. IS Bias. Fællesundervisning for den medicinske blok, Hvidovre Hospital, 19 sept 1990.
15. IS Bias in NSAID trials. Italian Meeting on Meta-analysis within Hepatology. Erice, Sicilien, 3-5 Dec 1990.
16. IS Meta-analysis of multiple clinical trials: biases revealed by analysis of trials on first- and secondline antirheumatic drugs. 75th Anniversary of the Danish Association for Internal Medicine, København, 24 Jan 1991.
17. IS Muligheder og farer ved meta-analyser. Dansk Selskab for Medicinsk Filosofi, Etik og Metode, København, 13 feb 1991.
18. IS Hvilket NSAID er bedst? Møde arrangeret af medicinsk afdeling C med de praktiserende læger, amtssygehuset i Herlev, 9 apr 1991.
19. IS Præliminære resultater fra AIDSDOSE studiet. Dansk Selskab for Infektionsmedicin, Rigshospitalet, 30 apr 1991.
20. IS Detection of bias problems through the use of meta-analysis with examples from drug trials in rheumatology. Society for Clinical Drug Trials and Society for Medical Statistics, Stockholm, 22 May 1991.
21. IS Meta-analysis of DMARD's: are they effective? DAK's Rheuma Meeting in Tivoli, 23 Aug 1991.
22. IS Dobbelt-blind dosis responsundersøgelse af zidovudin ved AIDS og fremskreden HIV infektion, Statens Sundhedsvidenskabelige Forskningsråd, 12 nov 1991.
23. IS Internationella och nordiska erfarenheter av zidovudinbehandling. XLVIII Läkaresällskapets Riksstämman, Stockholm, 27 nov 1991.
24. Clinimetric problems in arthritis. Seminar on Bias and Controversies in Clinical Research, Rigshospitalet, 28 Feb 1992.
25. IS Problems and opportunities in drug trials with DMARDs. 24th Scandinavian Congress of Rheumatology, Malmö, 1 June 1992.

26. Meta-analysis is more than a combination of odds ratios. 13th International Meeting of International Society for Clinical Biostatistics, København, 18 Aug 1992.
27. IS Faldgruber i den klinisk kontrollerede undersøgelse. Medicinsk Selskab for Fyns Stift, Odense, 2 nov 1992.
28. IS Statistiske og filosofiske aspekter ved score systemer. Reumatologisk symposium, Nyborg, 12 mar 1993.
29. IS Good Clinical Practice. Ph.d.-studerende på Hvidovre Hospital, 30 sept 1993.
30. The Scandinavian Cochrane Centre. Dansk Selskab for Medicinsk Filosofi, Etik og Metode og Dansk Selskab for Medicinsk Prioritering, København, 13 okt 1993.
31. Det etiske grundlag for det danske sundhedsvæsen. Folkeuniversitetet, 9 november 1993.
32. IS NSAID og gastrointestinal tractus. Metodologiske problemer: er der forskelle mellem midlerne af klinisk relevans? Dansk Gastroenterologisk Selskabs E-kursus, København, 11 jan 1994.
33. IS Clinical practice should reflect clinical science. EU meeting, AIMCOM, Bruxelles, 24 Apr 1994.
34. IS Systematic reviews of clinical trials in policy making and health planning. Nordisk konference om kritiske valg i sundhedssektoren, Dansk Sygehus Institut, 26 Apr 1994.
35. IS Bias in statistical reporting: should the data analyst be blinded? Society for Clinical Trials, 15th annual meeting, Houston, Texas, 9 May 1994.
36. IS Meta-analyses in rheumatology. 25th Scandinavian Congress of Rheumatology, Lillehammer, 2 June 1994.
37. IS Cochrane Center på Rigshospitalet - meta-analyser i klinikken. Dansk Medicinsk Selskabs 75-års jubilæumsmøde, København, 26 aug 1994.
38. IS Orientering om Det Nordiske Cochrane Center. GCP-selskabet, Gentofte, 2 feb 1995.
39. IS Forskningen som prioriteringsgrundlag. Dansk Selskab for Medicinsk Prioritering, Svendborg, 28 apr 1995.
40. IS Meta-analysis of continuous data - NSAIDs as an example. Dansk Epidemiologisk Selskab, København, 2 June 1995.
41. IS Philosophy of sciences - in meta-analysis. 4th Nordic Conference for Medical Libraries, København, 24 Aug 1995.
42. IS Det internationale Cochrane-samarbejde. Nordisk medicinaldirektørmøde, Hornbæk, 1 sept 1995.
43. IS Cochrane Collaboration: implementering i *evidence based medicine*. Prioritering i sundhedsvæsenet, Ringkøbing amtskommune, 27 sept 1995.
44. Cochrane centres. 3rd Annual Cochrane Colloquium, Oslo, 6 Oct 1995.
45. IS Meta-analyses: assets and limitations. Recent Advances in Breast Cancer, Scandinavian Breast Cancer Group, Hindsgavl, 13 Oct 1995.
46. IS A randomized trial of withdrawal of slow acting antirheumatic drugs. Dansk Reumatologisk Selskab, København, 20 okt 1995.
47. IS Forskning som grundlag for indførelse af nye behandlingsmetoder. Temadag om prioritering i sundhedsvæsenet. Nordjyllands amt, Rebild, 1 nov 1995.
48. IS What is sound evidence for decision making? *Medicine* 96, Finnish Medical Association (Duodecim), Helsinki, 10 Jan 1996.
49. IS Cochrane Collaboration and the health care technology assessment. *Medicine* 96, Finnish Office for Health Care Technology Assessment, Helsinki, 11 Jan 1996.
50. IS Metaanalyse og kvalitetssikring. Dansk Selskab for Medicinsk Onkologi, Helsingør, 19 jan 1996.
51. Cochrane Centret, Rigshospitalet. Staff-meeting, Sundby Hospital, 23 jan 1996.
52. IS Nordic Cochrane Centre. H:S Forskningsråd, København, 12 mar 1996.
53. Cochrane-samarbejdet. Staff-meeting, Sankt Elisabeths Hospital, 9 apr 1996.
54. IS Bibliometrisk analyse af publikationer udgået fra danske intern medicinske afdelinger 1988-92. Dansk Selskab for Intern Medicins konference om forskningens vilkår i intern medicin, Hillerød, 12 apr 1996.
55. IS Hvad ved vi, og hvad gør vi? Temadag om tværfaglige specialeråd, Rigshospitalet, 2 maj 1996.
56. IS The Cochrane Collaboration. Cochrane Hepato-Biliary Group Meeting, Genève, 25 Aug 1996.
57. IS Medicinsk teknologivurdering og lægemidler. MEDIF's direktørseminarium, Hornbæk, 4 sept 1996.
58. Cochrane-samarbejdet. Staff-meeting, Hvidovre Hospital, 17 sept 1996.

59. IS Meta-analyser. Det Medicinske Selskab i København, Domus Medica, 24 sept 1996.
60. IS Debate: Within ten years, all health decisions will be evidence-based. 4th Annual Cochrane Colloquium, Adelaide, 24 Oct 1996.
61. IS Hvad skal diagnosen bruges til? Dansk Selskab for Klinisk Mikrobiologi, Kolding, 8 nov 1996.
62. Omsorg som effektiv behandling? Næstekærlighed, placebo og alternativ medicin. Dansk Selskab for Medicinsk Filosofi, Etik og Metode, Domus Medica, 14 nov 1996.
63. IS MTV - en nødvendighed i sundhedsvæsenet. Dansk Selskab for Sygehusledelse, Kolding, 28 nov 1996.
64. IS Is the Norwegian Minister of Health correct in saying that the Cochrane Collaboration has made a fetish of the randomised controlled trial? Annual Meeting for The Nordic Cochrane Centre and Network, Oslo, 17 Jan 1997.
65. IS Det Nordiske Cochrane Center. H:S Bestyrelse, København, 29 jan 1997.
66. IS Cochrane centeret. Sundhedsministeriet, København, 30 jan 1997.
67. IS Evidensbaseret medicin. Foreningen af Læger i Erhvervslivet, København, 19 mar 1997.
68. IS The Cochrane Collaboration. Svensk Internmedicinsk förenings vårmöte, Umeå, 20 mar 1997.
69. IS Hvilken sundhedsforskning har vi brug for? (paneloplæg). Forskningsudvalgets og Sundhedsudvalgets høring om sundhedsforskning, Folketinget, 2 apr 1997.
70. IS Nordiska Cochrane-centrat i Köpenhamn. Karolinska Institutet och Stockholm läns landsting, 3 apr 1997.
71. IS Beware of surrogate outcome measures. Dansk hypertensionsselskabs årsmøde, Svendborg, 11 Apr 1997.
72. IS The Cochrane Collaboration. 3rd Cochrane Hepato-Biliary Group meeting, 32nd annual EASL meeting, London, 12 Apr 1997.
73. IS Systematic review: somatostatin and octreotide in bleeding oesophageal varices. 3rd Cochrane Hepato-Biliary Group meeting, 32nd annual EASL meeting, London, 12 Apr 1997.
74. IS Quality and relevance of clinical trials. European Headache Federation 5th Summer School. Rungsted, 25 Apr 1997.
75. IS Sammenfattende vurderinger af behandlingsmetoders værdi - metaanalyser. Møde mellem medlemmerne af de regionale videnskabetiske komiteer og Den Centrale Videnskabetiske Komité. Kolding, 21 aug 1997.
76. IS "Evidence Based Medicine". Overlægeföreningens Årsmøde. Nyborg Strand, 29 Aug 1997.
77. The Cochrane Collaboration. WHO's European Office, Programme Manager's Meeting. København, 3 Sept 1997.
78. Cochrane-samarbejdet. Lægemeddelstyrelsen. København, 16 sept 1997.
79. IS Rigshospitalets forskningsproduktion i 1994-96. Temadag om budgettering af forsknings- og udviklingsmidler, Rigshospitalet, 23 sept 1997.
80. IS Scopes and topic lists of Review Groups. 5th Annual Cochrane Colloquium, Amsterdam, 9 Oct 1997.
81. IS Hjælp til selvhjælp: Hvad kan Cochrane-samarbejdet tilbyde sundhedsvæsenet, og hvad kan sundhedsvæsenet tilbyde Cochrane-samarbejdet? Institut for Sundhedsvæsen, Symposium, Køge, 24 okt 1997.
82. IS Evidence based medicine - oplæg og diskussion. H:S Sundhedsfaglige råd, Rigshospitalet, 28 okt 1997.
83. IS Vad är - och hur arbetar - Cochrane Collaboration? Regiondag om Evidence Based Medicine, Södra sjukvårdsregionen, Malmö, 21 nov 1997.
84. Cochrane-samarbetet. Läkemedelsverket, Uppsala, 5 dec 1997.
85. IS Evidence-based medicine: the present and the future. Duodecim, 10th Anniversary Seminar of the Physician's Desk Reference and Database, Helsinki, 28 Jan 1998.
86. IS Ethical aspects in the use of systematic reviews in health care. Workshop on systematic reviews, Stakes & FinOHTA, Helsinki, 30 Jan 1998.
87. IS Præsentation af Cochrane-projektet. Nordisk Ministerråd, Hellerup, 25 mar 1998.
88. IS Getting the message across. 7th European Stroke Conference, Edinburgh, 29 May 1998.
89. IS RCT, status og visioner. Dansk Selskab for Medicinsk Filosofi, Etik og Metode. Festmøde, København, 17 sept 1998.
90. IS Evidensbaseret medicin. Farmaciens Dag, Danmarks Farmaceutiske Selskab, København, 2 okt 1998.

91. IS Demonstrating evidence in action: a case study. 6th Annual Cochrane Colloquium, Baltimore, 25 Oct 1998.
92. IS Bias i randomiserade försök och meta-analyser. Svenska Läkarsällskapets Riksstämman, Göteborg, 24 nov 1998.
93. IS Det Nordiske Cochrane Center og dets samarbejde med klinisk praksis. Statens Sundhedsvidenskabelige Forskningsråd og Statens Institut for Medicinsk Teknologivurdering, Middelfart, 11 feb 1999.
94. IS Evidens fra systematiske reviews. Dansk Endokrinologisk Selskab, Domus Medica, 22 feb 1999.
95. IS Overall status of the Cochrane Collaboration. Cochrane Colorectal Cancer Group meeting, København, 19 Mar 1999.
96. Det Nordiske Cochrane Center og evidensbaseret medicin. Folketingets Sundhedsudvalg, 24 mar 1999.
97. IS Evidensbaseret klinisk praksis. Områdeledelsens Stab og Sekretariat, Odense Universitetshospital, 8 apr 1999.
98. IS Hvad kan Cochrane-databasen bruges til? Dansk Kirurgisk Selskabs Forårsmøde, Herlev, 15 apr 1999.
99. Presentation of The Cochrane Collaboration. Exploratory meeting to consider establishing a Russian Branch of The Nordic Cochrane Centre. Hotel Akademicheskaya, Moskva, 7-8 June 1999.
100. IS Mega-trials or meta-analysis? European Society for Paediatric Research, Panum Institutet, 28 June 1999.
101. IS Hvad er rationel farmakoterapi? Dansk Selskab for Medicinsk Filosofi, Etik og Metode, København, 22 okt 1999.
102. IS The Cochrane Collaboration i Norden. SBU, Evidensbaseret sjukvård. Stockholm, 27 jan 2000.
103. IS Hvad vil det sige, at behandlingen er evidensbaseret? Jydsk Medicinsk Selskab, Århus, 5 apr 2000.
104. IS Meta-analyser, systematiske reviews. Kursus i evidensbaseret klinik. Frederiksberg hospital, 9 juni 2000.
105. IS Systematic review of breast cancer screening. Meeting with local minister of health and specialist societies. Barcelona, 29 June 2000.
106. IS History of The Cochrane Collaboration. 8th Cochrane Colloquium, Cape Town, 25 Oct 2000.
107. IS Er det alvorlige mangler ved det vitenskapelige grunnlaget for mammografi-screeningen? Årsmøde i Norsk Patologforening, Oslo, 10 nov 2000.
108. IS Är mammografiscreening värdefull? Svensk förening för radiologisk bröstdiagnostik, Rigshospitalet, 16 nov 2000.
109. IS Systematic review of mass screening for breast cancer with mammography. Dansk Selskab for Medicinsk Onkologi, Panum, 20 Nov 2000.
110. IS Hvornår er ændret klinisk praksis nødvendig? Dansk Selskab for Medicinsk Filosofi, Etik og Metode, København, 23 nov 2000.
111. IS Evidensbaseret medicin. KAS Herlev, 28 nov 2000.
112. IS Fallstudie Mammographie Screening. Bern's Universität, 6 Dec 2000.
113. IS Cochrane Collaboration. SBU, Stockholm, 7 feb 2001.
114. IS Utility of mammographic screening for detection of breast cancer and the measurement of the placebo effect. São Paulo, 23 Feb 2001.
115. IS Screening for breast cancer with mammography: a systematic review. Breast and Cervical Cancer Screening Conference, Bielefeld, 6 Apr 2001.
116. IS Concept and methods in Cochrane reviews. Dansk Selskab for Psykiatrisk Epidemiologi, 20 apr 2001.
117. IS Putting the evidence into breast cancer care - challenges and controversies for the future. National Breast Cancer Coalition's Annual Meeting, Washington, 6 May 2001.
118. IS Ankelligament-metaanalyse. Dansk Fod- og Ankelkirurgisk Selskab, Gjern, 18 aug 2001.
119. Misleading publications of major mammography screening trials in major medical journals. Fourth International Congress on Peer Review in Biomedical Publication, Barcelona, 14 Sept 2001.
120. IS Cochrane reviews - the clinical application of evidence. Skandinavisk Forening af Oral og Maxillofacial Kirurger, 21 Sept 2001.
121. IS Hvilke problemer ved screeningsmetoder er politikere ikke blevet informeret om? Dansk Selskab for Medicinsk Prioritering og Dansk Selskab for Almen Medicin, København, 30 okt 2001.

122. IS Mammografiscreening - undersøgt i en metaanalyse. Dansk Selskab for Almen Medicins Risikogruppe, Silkeborg, 23 nov 2001.
123. IS Metaanalyse. Foredrag efter modtagelse af Niels A Lassen prisen, Bispebjerg Hospital, 7 dec 2001.
124. IS Metaanalyse, styrke og svaghed, metodologiske betragtninger. Gruppen af Yngre Gastroenterologer På Vej, København, 12 dec 2001.
125. IS Metaanalyser - hvad kan og skal de bruges til? Selskabet for Teoretisk og Anvendt Terapi, København, 7 feb 2002.
126. IS The old vs the new review. Second Asian-Pacific Conference on Evidence Based Medicine, Chengdu, China, 9 Apr 2002.
127. IS The importance of the published, peer reviewed protocol. Second Asian-Pacific Conference on Evidence Based Medicine, Chengdu, China, 9 Apr 2002.
128. IS Problemer ved vurderingen af lægemiddelundersøgelser. Dansk Reumatologisk Selskab, Horsens, 19 apr 2002.
129. IS Conflict of interest. Cochrane Colorectal Cancer Group's Status Meeting, København, 19 Apr 2002.
130. IS Lægers videnskabelige yringsfrihed, interkollegiale problemer. Dansk Selskab til Sikring af Lægers Ytringsfrihed, København, 3 juni 2002.
131. IS Things to be cautious about when making policy recommendations based on systematic reviews, randomised trials, cohort studies, and expert opinion. Delegates from The Ministry of Health, China, Rigshospitalet, 20 Aug 2002.
132. IS Forskning er ikke fuldstændig objektiv - den kan drejes og vendes, så den passer politisk. Kursus for journalister, København, okt 2002.
133. IS Mammascreeing: a critical analysis. Wenckebach Symposium, Groningen, 5 Nov 2002.
134. IS Dissemination experiences in the Cochrane Collaboration. Nordic Campbell Center inauguration seminar, Helsingør, 13 Nov 2002.
135. IS Hva kan epidemiologer bidra med i deatten om mammografiscreening? Den tiende norske epidemiologikonferansen, Trondheim, 14 nov 2002.
136. IS Unambiguous and comparable results as quality measures in health related research. Is randomisation a necessity to obtain reliable knowledge? How are self-selection and self-conscious efforts handled? Konfernce arrangeret af Videns- og Forskningscenter for Alternativ Behandling, Århus, 27 Nov 2002.
137. IS Ten years of the Cochrane Collaboration. Seminar for Finnish doctors, Biomedicum, Helsinki, 23 Jan 2003.
138. IS Dronning Ingrid's Festforelæsning. Hvad er vore behandlinger værd? Åbenrå Sygehus, 8 maj 2003.
139. IS Temaeftermiddag. Evidensbaseret forebyggelse og behandling. Ålborg Sygehus, 9 sept 2003.
140. IS Plenary lecture. Pitfalls in evidence based medicine. 4th Congress, European Federation of Internal Medicine, Berlin, 11 Sept 2003.
141. IS Debate. Population based breast cancer screening. ECCO 12, Federation of European Cancer Societies, København, 25 Sept 2003.
141. Evidensbaseret forbrugeroplysning. Konference arrangeret af Forbrugerrådet og Det Nordiske Cochrane Center, Christiansborg, København, 22 okt 2003.
142. IS Plenary lecture. Conflicts of interest. XIth Cochrane Colloquium, Barcelona, 27 Oct 2003.
143. IS Evidensbaseret medicin: eksempler og betydning. Møde om medicinforsøg, arrangeret af Institut for Rationel Farmakoterapi, København, 19 nov 2003.
144. Discrepancies between protocols and publications: Evidence of outcome reporting bias in randomised trials. De Videnskabetiske komitéer for Københavns og Frederiksbergs kommuner, 11 dec 2003.
145. IS Experiences within the Cochrane Collaboration. WHO workshop on grading of evidence, København, 16 Dec 2003.
146. IS Evidensbaseret medicin. Sosial- og helsedirektoratet, Oslo, 15 jan 2004.
147. IS Why is the practice of evidence-based medicine more difficult than it seems? Læknadager 2004, Reykjavik, 23 Jan 2004.
148. IS Doctor, should I have a mammography? (debate). Læknadager 2004, Reykjavik, 23 Jan 2004.
149. IS The management of hypertension, should we rely on the good old drugs? (debate). Læknadager 2004, Reykjavik, 23 Jan 2004.

150. IS Evidence-based microbiology. Dansk Selskab for Klinisk Mikrobiologi, uddeling af Wyeth-prisen for 2003, København, 27 jan 2004.
151. IS Mammografi-screening, contra. Foreningen af Yngre Gynækologer og Obstetrikere Forårsmøde, Odense, 18 marts 2004.
152. IS Evidensgrundlag. Institut for Rationel Farmakoterapi, møde om kriterier for rationelt valg af lægemidler, Kolding, 30 april 2004.
153. IS Hvad er vore behandlinger værd? Gentofte-Vangede Rotary Klub, 26 aug 2004.
154. IS Empirical evidence for selective reporting of outcomes in randomised trials. Den Centrale Videnskabetiske Komité, København, 27 aug 2004.
155. IS Risikovurdering og formidling omkring screening, og industrisponsoreret forskning. Det Ethiske Råd, København, 16 sept 2004.
156. IS Fortsat udbredelse af mammografiscreening. Nordjyllands amtsråd, Ålborg, 19 nov 2004.
157. IS Harry Boström föreläsningen: Cochrane-samarbetet och evidensbaserad medicin. Riksstämman, Svensk Internmedicinsk Förening, Göteborg 25 nov 2004.
158. IS Nutidens og fremtidens krav om evidens for det lægelige arbejde. Nordjyllands Lægekredsforenings 150 års jubilæum, Ålborg, 26 nov 2004.
159. IS Blinding. Expert Discussion Workshop. Institute of Public Health, Cambridge, 17 maj 2005.
160. Sponsorship, bias and methodology: Cochrane Reviews compared with industry-sponsored meta-analyses of the same drugs. 5th International congress on peer review and biomedical publication, Chicago, 17 Sept 2005.
161. Are relative risks and odds ratios in abstracts believable? 5th International congress on peer review and biomedical publication, Chicago, 18 Sept 2005.
162. IS Medical statistics in practice: Dr Jekyll and Mr Hyde. 10 year celebration, Centre for Statistics in Medicine, Oxford, 20 Sept 2005.
163. IS Introduction to key concepts and principles of evidence-based medicine. Moscow Medical Academy, 13 Oct 2005.
164. Constraints on academic freedom in industry-initiated clinical trials. XIII Cochrane Colloquium, Melbourne, 22-26 Oct 2005.
165. IS Should we believe in epidemiology? Scientific seminar, Royal Veterinary and Agricultural University, Copenhagen, 14 Nov 2005.
166. IS Evidence in health care. Health Administration, Copenhagen County, 28 April 2006.
167. IS Commercial interests versus common goods. Nordic Committee on Bioethics, Malmö, 16 Oct 2006.
168. Far too many excluded studies listed in Cochrane Reviews. XIV Cochrane Colloquium, Dublin, 23-26 Oct 2006.
169. IS Cochrane Library. Ministry of Health, Warszawa, 18 Dec 2006.
170. IS Editorial misconduct. Finnish Medical Association, Helsinki, 25 Jan 2007.
171. IS Evidence-based health care. Institute for Competence Development, Copenhagen, 27 Feb 2007.
172. IS Commercial interests. Institute of Technology, Copenhagen, 14 Mar 2007.
173. IS Screening. Danish Society for Pathology, Copenhagen, 23 Mar 2007.
174. IS Selective reporting. Dutch Cochrane Centre's 12.5-year anniversary, Amsterdam, 18 April 2007.
175. IS Evidence-based health care. Aalborg University Hospital, 26 Sept 2007.
176. IS Bias in drug trials. Eur Assoc Clin Pharmacol, Amsterdam, 29 Aug 2007.
177. IS Commercial influence on clinical research. University of Southern Denmark, 15 Nov 2007.
178. IS Evidence-based medicine. Clinical microbiologists, Copenhagen, 21 Nov 2007.
179. IS Evidence for prevention. National Board of Health, Nyborg, 26 Nov 2007.
180. IS Can we trust clinical research results? Medical Society of Copenhagen, 27 Nov 2007.
181. IS Tainted evidence: drug companies and the power of marketing. 2nd South Asian Regional Symposium on Evidence Informed Health Care. Vellore, India, 9 April 2008.
182. IS Research collaboration. Danish Society for Theory in Medicine, Panum, 21 Apr 2008.
183. IS Mammography screening. Dept of Obstetrics, Rigshospitalet, 15 May 2008.
184. IS The corruption of drug research. Swiss Soc Intern Med, Lausanne, 21 May 2008.

185. IS Credibility of clinical research. Central Ethics Committee, Copenhagen, 13 June 2008.
186. IS The burdens of screening. Euroscience Open Forum, Barcelona, 21 July 2008.
187. IS Unhealthy health care. Distinguished scholar lecture, University of Minneapolis, 9 Sept 2008.
188. IS Unhealthy health care. Visiting scientist, University of Dartmouth, 11 Sept 2008.
189. IS Off-label use of drugs. Danish Pharmaceutical Society, Copenhagen, 29 Oct 2008.
190. IS Bias in drug trials. Danish Society for Psychiatric Epidemiology, Copenhagen, 6 Nov 2008.
191. IS Screening for lung cancer. Symposium, Focus on Lung Cancer, Copenhagen, 17 Nov 2008.
192. IS Screening for lung cancer. Danish Society for Pulmonary Medicine, Kolding, 28 Nov 2008.
193. IS Commercial interests. Institute of Technology, Copenhagen, 17 Dec 2008.
194. IS Screening and ethics. Clinical Ethics Committee, Frederiksberg Hospital, 2 Apr 2009.
195. IS Reflexions on screening. Region Middle Jutland, 15 Apr 2009.
196. IS Is the university trustworthy? LIFE, The Bioscientific Faculty, 6 May 2009.
196. IS Mammography screening. Nordic Congress in General Medicine, Copenhagen, 15 May 2009.
197. IS Opening lecture, Evidence-Based Medicine. 8th Congress of European Federation of Internal Medicine, Istanbul, 27 May 2009.
198. IS Cancer screening. Heinrich-Heine University, Düsseldorf, 17 June 2009.
199. IS Overdiagnosis of breast cancer. Cancer Intervention and Surveillance Modelling Network (CISNET), Rotterdam, 24 June 2009.
200. IS Good quality of drug trials. GCP meeting, Gentofte Hospital, 21 Sept 2009.
201. IS Forskningspolitisk debat, cancer screening. Forskningsens dag, Herlev Hospital, 28 Okt 2009.
202. IS Breast screening. Norwegian-Danish Seminar, Oslobåden, 2 Nov 2009.
203. IS Breast screening - the facts. Royal College of Obstetricians, London, 9 Nov 2009.
204. IS Er det dyreste det bedste? Region Sjælland, Sørup Heregård, 1 Dec 2009.
205. IS Randomisering i praksis. Trygfondens Forebyggelsescenter, 14 Jan 2010.
206. IS Mammographie-Screening. Berlin, German Cancer Society, 25 Feb 2010.
207. IS Klinisk relevans, hvad er det? Danish Society for Clinical Pharmacology, 2 Mar 2010.
208. IS Evidence: conflict of interest. Auckland, 22 Mar 2010.
209. IS Lægers interaktioner med medicinalindustrien. Region Nordjylland, 4 May 2010.
210. IS Fungal infections. Rigshospitalet, 12 May 2010.
211. IS Arguments for RCTs. Nordic Gastroenterology Congress, Copenhagen, 11 June 2010.
212. IS Ghostwriting is scientific misconduct. Polish Academy of Sciences, 8 Oct 2010.
213. IS Conflicts of interest. Danish University Antidepressant Group, Nyborg, 5 Nov 2010.
214. IS Bioethics: access to data and mammography screening. EU Parliament, Strassbourg, 24 Nov 2010.
215. IS Hvem har mest gavn af lægens medicinudskrivning? Patientforeningen Danmark, 18 Jan 2011.
216. IS Ethical aspects of public vs private research. Nordic Committee on Bioethics, Helsinki, 1 Nov 2011.
217. IS Strengthening and opening up EU's health research. EU Parliament, Brussels, 30 Nov 2011.
218. IS Medicinalindustrien. EU Parliament, Brussels, Social democrats, 1 Feb 2012.
219. IS Access to data from regulatory authorities. Paris, 19 April 2012.
220. IS European Drug Regulators' meeting. Why we need easy access to all data from all clinical trials and how to accomplish it. Copenhagen, 26 April 2012.
221. IS Why we need to open up health research by sharing our raw data. EU Parliament, Brussels, 6 June 2012.
222. IS Access to medical research data in the EU. HAI Europe, Amsterdam, 12 Oct 2012.
223. IS Rethinking clinical practice. Danish University Antidepressant Group, Nyborg, 9 Nov 2012.
224. IS Open access to all data is a moral obligation towards the patients. EU Parliament, Brussels, 13 Nov 2012.
225. IS Introductory statement. European Medicines Agency, London, 22 Nov 2012.
226. IS Time to stop mammography screening. Selling sickness, Washington DC, 21 Feb 2013.
227. IS Transparency saves lives. EU Parliament, Brussels, 10 Apr 2013.

228. IS Medical data transparency. Ombudsman meeting, EU Parliament, Brussels, 23 Apr 2013.
229. IS Overblik over børn med psykisk sygdom/diagnoser. Sundhedsudvalget, Folketinget, 27 May 2013.
230. IS Gavnige og skadelige virkninger ved medicinering af børn med psykisk sygdom. Sundhedsudvalget, Folketinget, 27 May 2013.
231. IS Mammografiscreening er skadelig og bør stoppes. Dagens Medicin, Folketinget, 31 May 2013.
232. IS What will we do about overdiagnosis? Dartmouth Institute for Health Policy & Clinical Practice, 12 Sept 2013.
233. IS Deadly medicines and organised crime. Johns Hopkins School of Public Health, Baltimore, 13 Sept 2013.
234. IS Deadly medicines and organised crime. Georgetown University, Washington DC, 16 Sept 2013.
235. IS Why drugs are the third leading cause of death. University College, London, 2 Oct 2013.
236. IS Early diagnosis. University College, London, 2 Oct 2013.
237. IS Psykiatri: medicinalindustriens paradys. Dispuk, Helsingør, 3 Oct 2013.
238. IS Working with evidence. Dansk Selskab for Obstetrik og Gynækologi, Roskilde, 7 Oct 2013.
239. IS 12 usandheder om depression til skade for patienterne. Psykovision, København, 7 Nov 2013.
240. IS Deadly medicines and organised crime. Harvard University, Safra Center for Ethics, 5 Dec 2013.
241. IS Deadly medicines and organised crime. McGill University, Montreal, 6 Dec 2013.
242. IS Deadly medicines and organised crime. Quebec University, Quebec, 9 Dec 2013.
241. IS Deadly medicines and organised crime. Ottawa Hospital, 10 Dec 2013.
243. IS Deadly medicines and organised crime. Women's College Hospital, Toronto, 11 Dec 2013.
244. IS Deadly medicines and organised crime. Toronto University, 12 Dec 2013.
245. IS Dødelig medicin og organiseret kriminalitet. Patientforeningen Danmark, Rigshospitalet, 14 Jan 2014.
246. IS Myter og facts om antidepressiva. Plastikkirurgisk afd., 16 Jan 2014.
247. IS Lægers samarbejde med industrien, Overlægeföreningen, Hvidovre Hospital, 23 Jan 2014.
248. IS Receptpligtig medicin – den tredjehyppigste dødsårsag. FoF København, 25 Feb 2014.
249. IS Dødelig medicin og organiseret kriminalitet. Ølstykke Bibliotek, 27 Feb 2014.
250. IS Dødelig medicin og organiseret kriminalitet. JP Læserarrangement, 4 Mar 2014.
251. IS Psykofarmaka. Psykologisk Studenterforum, Århus Universitet, 4 Mar 2014.
252. IS Dødelig medicin og organiseret kriminalitet. Enhedslisten, Region Hovedstaden, 6 Mar 2014.
253. IS Psykofarmaka og andre lægemidler. Plan & Handling, Socialt-Lægeligt Seminar, Valby, 10 Mar 2014.
254. IS General health checks in adults. Deutsche EBM Netzwerk, Halle, 14 Mar 2014.
255. IS Why mammography screening should be stopped. Deutsche EBM Netzwerk, Halle, 14 Mar 2014.
256. IS Dødelig medicin og organiseret kriminalitet. Gentofte Bibliotek, 18 Mar 2014.
257. IS Why are prescription drugs the third leading cause of death? Panama City, 2 Apr 2014.
258. Health checks, what were the reactions? Nordic Cochrane Centre, 8 Apr 2014.
259. IS Set all data free. Young Investigators Network, Faculty Club, Panum, 10 Apr 2014.
260. IS Receptpligtig medicin – den tredjehyppigste dødsårsag. FoF København, 22 Apr 2014.
261. IS Why the use of psychiatric drugs may be doing more harm than good. House of Lords, UK, 30 Apr 2014.
262. IS This is not a symptom. South London Gallery, 30 Apr 2014.
263. IS Hvorfor er lægemidler den 3. hyppigste dødsårsag? Studenterforeningen, København, 2 May 2014.
264. IS Good scientific practice. Institute for Public Health, Copenhagen, 7 May 2014.
265. IS Dødelig medicin og organiseret kriminalitet. Praktiserende læger, Hotel Hesselet, 9 May 2014.
266. IS Psykiatri. Sundhedspolitisk Netværk, Ingeniørforeningen, 12 May 2014.
267. IS Psykiatri på afveje. Psykovision, Bethesda, København, 14 May 2014.
268. IS Interessekonflikter i lægeverdenen. Panum Institut, 19 May 2014.
269. IS Lægers relation til medicinalindustrien. Roskilde Sygehus, 21 May 2014.
270. IS Psychiatric drugs: does the way we use them cause more harm than good? Distinguished seminars in neuroscience and pharmacology. Panum Institute, 28 May 2014.

- 271 IS Håndtering af kommercielle interesser. Københavns Universitet, 10 June 2014.
- 272 IS Psychiatric drugs: does the way we use them cause more harm than good? Amsterdam, 13 June 2014.
- 273 IS Psykiatri på afveje. Stemmehørernetværket, Christiansborg, 17 June 2014.
- 274 IS Academia and industry. Annual Nobel Laureate meeting, Lindau, 3 July 2014.
- 275 IS Overdiagnosis and overtreatment in psychiatry. Finnish Psychological Association, Helsinki, 1 Sept 2014.
- 276 IS Deadly medicines and organised crime. Helsinki University, 2 Sept 2014.
- 277 IS Medicamentos que matan y crimen organizado. Barcelona, Institut d'Estudis Catalans, 8 Sept 2014.
- 278 IS Medicamentos que matan y crimen organizado. Madrid, Organización de Consumidores y Usuarios (OCU), 9 Sept 2014.
- 279 IS Psykofarmaka-debat. Århus Universitet, 11 Sept 2014.
- 280 IS What are the true benefits and harms of our drugs? Jagiellonian University, Krakow, 7 Oct 2014.
- 281 IS Cochrane reviews and their importance for evidence-based medicine. Jagiellonian University, Krakow, 7 Oct 2014.
- 282 IS Deadly medicines and organised crime. Maynooth University, Dublin, 8 Oct 2014.
- 283 IS Deadly medicines and organised crime. Stillorgan Park Hotel, Dublin, 8 Oct 2014.
- 284 IS Danmark på lykkepiller. Herstedøster Forsamlingshus, 21 Oct 2014.
- 285 IS Kan kræft forsvinde af sig selv? Mølholm Forsikring, Carlsberg, 23 Oct 2014.
- 286 IS Danskernes mentale sundhed. Folkeuniversitetet, Panum, 3 Nov 2014.
- 287 IS Kliniske forsøg. Pharmaschool, Copenhagen, 5 Nov 2014.
- 288 IS Dødelig medicin og organiseret kriminalitet. Lægeforeningen Syddanmark, Kolding, 5 Nov 2014.
- 289 IS Kan kræft forsvinde af sig selv? Mølholm Forsikring, Århus, 5 Nov 2014.
- 290 IS Mammography screening: why it hasn't lived up to expectations. Santa Rosa, California, 8 Nov 2014.
- 291 IS Why very few patients benefit from the drugs they take and why many are killed by them. Santa Rosa, California, 9 Nov 2014.
- 292 IS Why very few patients benefit from the drugs they take and why many are killed by them. Stanford Medical School, 11 Nov 2014.
- 293 IS Why very few patients benefit from the drugs they take and why many are killed by them. University of British Columbia, Vancouver, 11 Nov 2014.
- 294 IS Mammography screening: why it hasn't lived up to expectations. University of British Columbia, Vancouver, 12 Nov 2014.
- 295 IS How to reduce big pharma's influence on guidelines. Kaiser Permanente, Los Angeles, 13 Nov 2014.
- 296 IS Transforming mad science, reimagining mental health care. International Society of Ethical Psychology and Psychiatry, Los Angeles, 15 Nov 2014.
- 297 IS Medisinering av psyken – mer skade enn gagn? Cinemateket, Oslo, 25 Nov 2014.
- 298 IS Global Health. Univ. of Copenhagen, 6 Jan 2015.
- 299 IS Depression. Young Psychiatrists, Rigshospitalet, 19 Jan 2015.
- 300 IS Psychiatry. Nurses, Silkeborg 20 Jan 2015.
- 301 IS Selective publication. Joanna Briggs Institute, Adelaide, 9 Feb 2015.
- 302 IS Drugs. Grand round. Royal Adelaide Hospital, Adelaide, 10 Feb 2015.
- 303 IS Psychiatry. Univ. of Adelaide, Adelaide, 10 Feb 2015.
- 304 IS Drug crimes. Alfred Hospital, Melbourne, 11 Feb 2015.
- 305 IS Psychiatry. State Library of Victoria, Melbourne, 11 Feb 2015.
- 306 IS Mammography screening. Alfred Hospital, Melbourne, 12 Feb 2015.
- 307 IS Drug crimes. Grand round. Royal Melbourne Hospital, Melbourne, 12 Feb 2015.
- 308 IS Antidepressants. Garvan Institute, Sydney, 12 Feb 2015.
- 309 IS Drug crimes. Concord Hospital Clinical School, Sydney, 13 Feb 2015.
- 310 IS Mammography screening. Dougherty Community Centre, Sydney, 13 Feb 2015.
- 311 IS Psychiatric drugs. University of Sydney Law School, Sydney, 14 Feb 2015.
- 312 IS Drug crimes. Grand round. Princess Alexandra Hospital, Brisbane, 16 Feb 2015.

- 313 IS Drug crimes. RACGP College House, Brisbane, 16 Feb 2015.
- 314 IS Drug crimes. Univ. of Queensland Medical School, Brisbane, 17 Feb 2015.
- 315 IS Psychiatry. Lady Cilento Children's Hospital, Brisbane, 18 Feb 2015.
- 316 IS Psychiatry. Adina Apartment Hotel, Brisbane, 18 Feb 2015.
- 317 IS Drug crimes. Grand round. Gold Coast University Hospital, 19 Feb 2015.
- 318 IS Lægemedler. Medicinsk Studenterforskning, Nyborg, 12 Mar 2015.
- 319 IS Depression. Rigshospitalet, 16 Apr 2015.
- 320 IS Psychiatric drugs. Lansing, Michigan, 17 Apr 2015.
- 321 IS Antidepressiva. Ålborg Sygehus, 21 Apr 2015.
- 322 IS Drugs. Danish National Board of Health, 27 Apr 2015.
- 323 IS The Maudsley Debate. London, 13 May 2015.
- 324 IS Drugs. Robert-Bosch-Stiftung, Berlin 22 May 2015.
- 325 IS Psychiatry. General Practitioners Annual Meeting, Bergen 27 May 2015.
- 326 IS Lægemedler. Læger fra Lolland, 29 May 2015.
- 327 IS Regulatory data. Int Soc Drug Bull, Pamplona, 29 June 2015.
- 328 IS Overdiagnosis and overtreatment. Int Soc Drug Bull, Pamplona, 30 June 2015.
- 329 IS Psykofarmaka. Dansk Psykologforening, København, 12 Sep 2015.
- 330 IS Antidepressants. Int Meeting, Copenhagen, 16 Sep 2015.
- 331 IS Forced treatment. Int Meeting, Copenhagen, 16 Sep 2015.
- 332 IS Antidepressants. Univ. of Roehampton, London, 18 Sept 2015.
- 333 IS Drugs. Katowice, 19 Sept 2015.
- 334 IS Mammography screening. Cochrane Colloquium, Wien, 3 Oct 2015.
- 335 IS Drugs. Oslo 20 years Anniversary Seminar, 19 Oct 2015.
- 336 IS Tvangsmedicinering. Litteraturhuset, Oslo, 19 Oct 2015.
- 337 IS Lægemedler. Guldborgsund Bibliotekerne, Nykøbing F, 21 Oct 2015.
- 338 IS Psykofarmaka. Benzorådgivningen, Middelfart, 23 Oct 2015.
- 339 IS Psykofarmaka. Enhedslisten, København, 23 Oct 2015.
- 340 IS Lægemedler. Norsk Studenterforening, Tromsø, 30 Oct 2015.
- 341 IS Psykofarmaka. Dansk Psykologforening, København, 7 Nov 2015.
- 342 IS Drugs. Medical Centre in Leiden, 11 Nov 2015.
- 342 IS Drugs. Arminius, Rotterdam, 12 Nov 2015.
- 343 IS Lægemedler. FOF Hvalsø, 23 Nov 2015.
- 344 IS Cancer screening. Gemeinschaftskrankenhaus Havehöhe, Berlin, 25 Nov 2015.
- 345 IS Psykofarmaka. Dansk Socialrådgiverforening, Fredericia, 30 Nov 2015.
- 346 IS Deadly medicines. Roma, Italy, 1 Dec 2015.
- 347 IS Deadly medicines. Univ. of Verona, 2 Dec 2015.
- 348 IS Deadly medicines. Gruppo Abele, Torino, 3 Dec 2015.
- 349 IS Deadly medicines. Alba, 3 Dec 2015.
- 350 IS Psykofarmaka. LAP, København, 18 Dec 2015.
- 351 IS Global Health. Univ. of Copenhagen, 6 Jan 2016.
- 352 IS Psykofarmaka. Hvidovre og Glostrup Psykiatri, 7 Jan 2016.
- 353 IS Psykofarmaka. Bedre Psykiatri, Odense, 14 Jan 2016.
- 354 IS Läkemedel. Stockholm läns landstings läkemedelskomité, 20 Jan 2016.
- 355 IS Psykofarmaka. Socialmedicinsk Enhed, Frederiksberg Hospital, 22 Jan 2016.
- 356 IS Vore overmedicinerede ældre. Assens Ældreråd, 26 Jan 2016.
- 357 IS Vore overmedicinerede ældre. School of Culture and Society, Karup, 11 Feb 2016.
- 358 IS Dødelig medicin og organiseret kriminalitet, LOF Slagelse, 29 Feb 2016.
- 359 IS Receptpligtig medicin – den tredjehyppigste dødsårsag, Tåstrup Bibliotek, 29 Feb 2016.

- 360 IS Antidepressants Do More Harm Than Good, Tampa, Florida, Adlerian Society, 4 March 2016.
- 361 IS Mammography screening, European Breast Cancer Meeting, Amsterdam, 9 March 2016.
- 362 IS Hvorfor gør psykofarmaka større skade end gavn? FOF Gladsaxe, 15 March 2016.
- 363 IS Drugs: the Dutch Medicines vision. Dutch Parliament, 29 March 2016.
- 364 IS Medicinsk behandling af psykiske sygdomme. Danske Regioner, Aarhus, 6 April 2016.
- 365 IS Psykofarmaka gør langt større skade end gavn. Aarhus Universitet, Aarhus, 6 April 2016.
- 366 IS Fup og fakta om antidepressiv medicin. Folkeuniversitetet i Aalborg, 7 April 2016.
- 367 IS Dødelig psykiatri. Sind på Frederiksberg, 10 May 2016.
- 368 IS Hvorfor gør psykofarmaka større skade end gavn? FOF Gladsaxe, 17 May 2016.
- 369 IS Without data sharing, there is no science, only marketing. Krakow University, 20 May 2016.
- 370 IS Den psykiatriske epidemi. National Neurokonference, Middelfart, 26 May 2016.
- 371 IS Dødelig biologisk psykiatri. Dansk Retspsykologisk Selskab, 30 May 2016.
- 372 IS Forced Psychiatric Treatment Must Be Abolished. Anchorage, 2 June 2016.
- 373 IS Prescription drugs are the third leading cause of death. Evidence Live, Oxford, 21 June 2016.
- 374 IS Mortality and drugs (top-3). 50th Anniversary of the Geneesmiddelenbulletin, Leiden, 30 June 2016.
- 375 IS What is wrong with research and treatment in psychiatry? 50th Anniversary, Leiden, 30 June 2016.
- 376 IS Hvorfor så få har gavn af psykofarmaka? Social- og Sundhedsskolen. Middelfart, 30 Aug 2016.
- 377 IS Varning för psykofarmaka! Stockholm, ABF-huset, 5 Sept 2016.
- 378 IS Deadly psychiatry. Spanish Association for Mental Health, Madrid, 19 Sept 2016.
- 379 IS Deadly psychiatry. Alibri Llibreria, Barcelona, 20 Sept 2016.
- 380 IS Varning för psykofarmaka! Bokmässan, Göteborg, 23 Sept 2016.
- 381 IS Why is it controversial to tell the truth about health care? HealthWatch Award, London, 20 Oct 2016.
- 382 IS Mammography screening. Cochrane Colloquium, Seoul, 25 Oct 2016.
- 383 IS Why so few patients benefit from the drugs they take. 21th WONCA, Rio de Janeiro, 3 Nov 2016.
- 384 IS Varning för psykofarmaka! Stockholm, ABF-huset, 22 Nov 2016.
- 385 IS Hvorfor er udtrapning af psykofarmaka så vigtigt? Høring i Folketinget, 13 Dec 2016.
- 386 IS Deadly psychiatry. De Balie, Amsterdam, 19 Dec 2016.
- 387 IS Myter, misforståelser og skader i psykiatrien. Pædagogisk Psykiatrisk Vejledning, Greve, 4 Jan 2017.
- 388 IS Psychiatric drugs. Sherbrooke, education for doctors, 20 Jan 2017.
- 389 IS Myten om den biologiske psykiatri. Christiansborg, 3 March 2017.
- 390 IS Prescription drugs are the third leading cause of death. University of Helsinki, 9 March 2017.
- 391 IS Forskning; med eller uden industri. Medicinsk Studenterforskning, Nyborg, 17 March 2017.
- 392 IS Psykofarmaka. Diplomuddannelsen for socialarbejdere, Faxe Ladeplads, 23 March 2017.
- 392 IS Dödlig psykiatri och organiserad förnekelse. ISPS, Stockholm, 31 March 2017.
- 393 IS Vi kan leve uden antipsykotika. Stemmehørernetværket, Odense Rådhus, 27 April 2017.
- 394 IS Psykofarmaka slår mange ihjel og forkrobler langt flere. Slagelse Kommune, 3 May 2017.
- 395 IS Psykofarmaka, psykoterapi og udtrapning. Psykoterapeuter, København, 22 Aug 2017.
- 396 IS Psykofarmaka, psykoterapi og udtrapning. Psykoterapeuter, Vejle, 28 Aug 2017.
- 397 IS Overdiagnostik og overbehandling i psykiatrien. Bedre Psykiatri, Odense, 31 Aug 2017.
- 398 IS Myter om psykofarmaka? København, 26 Sept 2017.
- 399 IS Myter, misforståelser og skader i psykiatrien. Socialpædagoger, Kolding, 2 Oct 2017.
- 400 IS Den biologiske psykiatri bygger på en række misforståelser og myter. SIND, Aalborg, 10 Oct 2017.
- 401 IS International Institute for Psychiatric Drug Withdrawal. World Congress in Psychiatry, Berlin, 11 Oct.
- 402 IS Psychiatric drugs are the third leading cause of death. World Congress in Psychiatry, Berlin, 11 Oct.
- 403 IS Psykofarmaka. Neurologisk afd., Herlev Sygehus, 1 Oct.
- 404 IS How to survive in an over-medicated world. Columbus, Ohio, 11 Nov.
- 405 IS Harmful drugs you should know about. Columbus, Ohio, 12 Nov.
- 406 IS Afhængighed af og udtrapning af psykofarmaka. BBH, Klinisk Farmakologisk afd., 1 Dec.

- 407 IS Mental health in crisis. Sydney, 24 Feb 2018.
- 408 IS Mental health in crisis. Christchurch, 26 Feb 2018.
- 409 IS Mental health in crisis. Wellington, 27 Feb 2018.
- 410 IS Mental health in crisis. Hamilton, 28 Feb 2018.
- 411 IS Mental health in crisis. Auckland, 2 March 2018.
- 412 IS Psykofarmaka bør undgås, især til børn og unge. FADD, Slangerup, 7 March.
- 413 IS How to survive in an overtreated world. Public health course, Madrid, 10 March.
- 414 IS Why you should usually avoid cancer screening. Cambridge University, 5 April.
- 415 IS Depressionspiller gør mer skada än nytta. Stockholm, 13 April.
- 416 IS Complaint to the European Ombudsman and maladministration at EMA. Dublin 21 April via Skype.
- 417 IS Benefits and harms of depression pills. Copenhagen, 14 June.
- 418 IS Heroes of Science: Survival of a Whistleblower. Berlin, Max Planck Institute, 27 June.
- 419 IS Why the current usage of psychiatric drugs does far more harm than good. Berlin, Charité, 28 June.
- 420 IS Why systematic reviews of published drug trials lead to too much medicine. Helsinki, 17 Aug.
- 421 IS Overlevelse i en overmedicineret verden. Hillerød, 27 Sept.
- 422 IS Hvordan overlever man i en overmedicineret verden? Odense, Seniorhøjskolen, 3 Oct.
- 423 IS Why did we get a Cochrane Collaboration and what is it like today? Rigshospitalet, 12 Oct.
- 424 IS Chemical and physical interventions for house dust mites: why not? Rigshospitalet, 12 Oct.
- 425 IS Survival in an overtreated world: Look up the evidence yourself. Univ. of Groningen, 22 Oct.
- 426 IS Survival in an overtreated world: Look up the evidence yourself. Patiëntenfederatie, Utrecht, 23 Oct.
- 427 IS Survival in an overtreated world: Look up the evidence yourself. De Balie, Amsterdam, 23 Oct.
- 428 IS Survival in an overtreated world: Look up the evidence yourself. Ministry of Health, den Haag, 24 Oct.
- 429 IS Psykofarmaka gør større skade end gavn. Thisted, 31 Oct.
- 430 IS We need a revolution in psychiatry, the only medical specialty that does more harm than good. Berlin, Charité Hospital, 27 Nov.
- 431 IS Open science for better health-care for all. Bruxelles, EU Parliament, 29 Nov.
- 432 Death of a whistleblower: scientific censorship in action. Copenhagen, 9 Mar 2019.
- 433 IS Evidensbasert medisin. Trondheim, 20 Mar.
- 434 IS Myter, misforståelser og skader i psykiatrien. København, 13 May.
- 435 IS Death of a whistleblower and Cochrane's moral collapse. Santa Cruz, California, 9 June.
- 436 IS Mammography screening should be stopped. Barcelona, 15 June.
- 437 IS Death of a whistleblower and Cochrane's moral collapse. Madison, Wisconsin, 30 July.
- 438 IS Critical thinking about psychiatric drugs. Tromsø, 5 Sept.
- 439 IS Myter, misforståelser og skader i psykiatrien. Århus, 3 Oct.
- 440 IS The Cochrane affair and conflicts of interest. Paris, 11 Oct.
- 441 IS Hvordan overlever man i en overmedicineret verden? Esbjerg, 30 Oct.
- 442 IS Breast cancer screening: state of the art. Porto, 4 Nov.
- 443 IS General health checks: state of the art. Porto, 5 Nov.
- 444 IS Forskning og interessekonflikter. Udvalget til Beskyttelse af Videnskabeligt Arbejde. København, 7 Nov.
- 445 IS Sundhedsvæsen og politik. Helsingør, 21 Nov.
- 446 IS Does long term use of psychiatric drugs cause more harm than good? Newcastle University, 22 Jan 2020.
- 447 IS Vacciner, sandhed, løgn og kontroverser. Patientforeningen Danmark, 6 Feb.
- 448 IS Why prescription drugs are the third leading cause of death. Teleseminar, Madrid, 7 June.
- 449 IS Hvordan overlever man i en overmedicineret verden? Egmonthøjskolen, Odder, 14 July.
- 450 IS Uddeling af diagnoser og overmedicinering. Mariehjemmene, København, 4 Sept.
- 451 IS Science and Society in the Pandemia war. Teleconference, Athens Medical Association, 19 Sept.
- 452 IS Mental health survival kit. Stanford, METRICS, telelecture, 1 Oct.

453 IS Hvordan overlever man i en overmedicineret verden? Favrskov aftenskole, 26 okt.

Research mentorships

PhD and other degrees

1992 - 1994	Pia Therkildsen. Clinical research behaviour in Denmark. Main tutor. PhD not finished.
1993 - 1994	Flemming Ørnkov. Drug treatment. Main tutor. PhD not finished (emigration).
1996 - 2001	Asbjørn Hróbjartsson. The placebo concept. Main tutor. PhD defended 8 June 2001 at the University of Copenhagen.
2001 - 2004	Jan Peter Kösters (German doctor). Breast cancer screening. Main tutor. Doktors der Medizin defended 17 Sept 2004 at the University of Hamburg.
2000 - 2004	Lise Lotte Kjærgaard. The randomised clinical trial. PhD, changed to DrMedSci, defended 19 Aug 2005 at the University of Copenhagen.
2001 - 2005	Bodil Als-Nielsen. Hepatic encephalopathy. PhD defended 13 May 2005 at the University of Copenhagen.
2001 - 2005	Julie Pildal. Bias in systematic reviews. Main tutor. PhD defended 6 Sept 2005 at the University of Copenhagen.
2004 - 2013	Karsten Juhl Jørgensen. Screening for breast cancer. Main tutor. PhD changed to DrMedSci, defended 11 Jan 2013 at the University of Copenhagen.
2008 - 2009	Marija Barbateskovic. Impact factors and sponsorship. Main tutor. Candidate in science. Marks 12 (top on new scale)
2007 - 2010	Britta Tendal. Standardised mean difference in meta-analysis. Main tutor. PhD defended 26 Aug 2010 at the University of Copenhagen.
2007 - 2011	Anders W. Jørgensen. Robustness of results and conclusions in systematic reviews, trials and abstracts. Main tutor. PhD defended 16 Nov 2011 at the University of Copenhagen.
2007 - 2013	Margrethe Nielsen. Selective serotonin reuptake inhibitors. Main tutor. PhD defended 19 April 2013 at the University of Copenhagen.
2008 - 2013	Andreas Lundh. Conflicts of interest in biomedical publishing. Main tutor. PhD defended 25 April 2013 at the University of Copenhagen.
2010 - 2015	Lasse Teis Krogsbøll. Health checks. Main tutor. PhD defended.
2011 - 2015	Jeppe Schroll. Coding of harms in randomised trials. Main tutor. PhD defended.
2011 - 2016	Emma Maund. Harms of Selective serotonin reuptake inhibitors. Main tutor. PhD defended.
2012 - 2016	Michelle Ogden. Are randomised trials ethical? Main tutor. Stopped 2016.
2012 - 2018	Tarang Sharma. Suicidality and violence on SSRIs. Main tutor. PhD defended.
2016 - 2018	Kristine Rasmussen. Conflicts of interest. Main tutor. PhD defended.
2014 - 2018	Pia Danborg. Psychiatric animal studies. Main tutor.
2016 - 2018	Camilla Hansen. Conflicts of interest. Tutor.
2016 - 2019	Lars Jørgensen. HPV vaccines. Main tutor. PhD defended.
2016 -	Anders Sørensen. Psychiatry. Main tutor.
2016 -	Marie Bohlbro. Psychiatry. Main tutor.
2017-	Kim Boesen. ADHD drugs. Main tutor.

Training students in research

2003	Troels Wienecke. OSVAL II, marks 9, ref. 153 in reference list above.
2003	Karsten Juhl Jørgensen. OSVAL II, marks 10, ref. 154 in reference list above.
2003	Mette Haahr, scholar student, ref. 157 in reference list above.
2003	Lasse Schmidt. OSVAL II, marks 10, ref. 169 in reference list above.
2003	Katrine Karmisholt, scholar student, ref. 172 og 173 in reference list above.
2004	Anne Due, OSVAL II, marks 10, ref. 189 in reference list above.
2004	Anders Jørgensen, OSVAL II, marks 10, ref. 190 in reference list above.
2005	Anders Klahn, OSVAL II, marks 10, ref. 198 in reference list above.
2006	Britta Tendal, scholar student, ref. 196 in reference list above.
2006	Katja Maric, scholar student, ref. 196 in reference list above.
2007	Matias Vested Madsen, OSVAL II, marks 9, ref. 215 in reference list above.
2007	Lasse Krogsbøll, OSVAL II, marks 10, ref. 221 in reference list above.
2007	Jørgen Jacob Eschen, OSVAL II, marks 11. No journal manuscript.
2009	Marija Barbateskovic, manuscript under preparation.

- 2009 Jeppe Lerche Hansen, manuscript under revision.
 2009 Jeppe Schroll, manuscript under revision.
 2010 Ann-Sofia Skou Thomsen, OSVAL II, marks 12
 2010 Frida Samuelsson, OSVAL II, marks 12
 2010 Christian Grønhøj Larsen, OSVAL II, marks 12
 2010 Nino Ortner, OSVAL II, marks 12 (Hróbjartsson tutor)
 2011 Kristine Rasmussen, special subject, marks 12
 2011 Anine Skibsted, special subject, marks 12
 2011 Jon Egelund Jensen, special subject, marks 10
 2012 Julie Bindslev, special subject, marks 12
 2012 Marie Damkjær Hansen, special subject, marks 10 (Hróbjartsson tutor)
 2014 Mikkel Marquardsen, special subject, marks 12
 2014 Andreas Bielefeldt, special subject, marks 12
 2014 Jakob Jensen, special subject, marks 7
 2014 Louise Jensen
 2014 Nana Freund, no special subject
 2014 Asmus Mortensen, special subject, marks 10
 2015 Asger Paludan-Müller, bachelor subject, marks 12
 2015 Kim Boesen, special subject, marks 12
 2015 Anders Simonsen, special subject, marks 12

Expert, Medical Research Council's Statistical Aid Service

- 1991 Nick Rasmussen. Randomised trial, steroids in periarthrosis.
 1991 Holger Sørensen. Randomised trial, haloperidol vs. oxazepam.
 1991 Arne Gam. Meta-analysis, soft laser treatment.
 1992 Søren Eiskjær. Meta-analysis, osteosynthesis methods in collum fracture.
 1993 Arne Gam. Meta-analysis, ultrasound in musculoskeletal disorders.
 1993 Hanne Olesen. Meta-analysis, oxygen deficit by anaerobic training.
 1993 Kim Brøsen. Meta-analysis, genetic polymorphism and disease risk.
 1993 Anita Rønn. Randomised trial, Maloprim vs. placebo in malaria.
 1993 Mette Bitsch-Christensen. Immune therapy of children with allergy.
 1993 Anne-Lise Christensen. Comparison of methods to diagnose pneumonia.
 1993 Anne-Cathrine Halvorsen. Diagnostic methods in bleeding disorders.
 1993 Michael Hansen. Biochemical markers for bone formation and resorption.
 1994 Robin Bohlen. Treatment of fibromyalgia based on psychomotoric theory.
 1994 Helle Rask. Randomised trial, volume expansion in surgery.
 1995 Allan Ibsen Sørensen. Meta-analysis of endoscopic carpal tunnel dissection.
 1996 Hanne Sørensen. Randomised trial, physiotherapy in back pain.
 1997 Judith Kongsted. Healing in breast cancer.
 1998 Poul Sindberg Eriksen. Risks after laser conisation of cervix uteri.
 1998 Niels Petri. Orthodontic treatment of sleep apnoea.
 2000 Hanne Sørensen. Training for back pain.
 2002 Lars Højgaard-Rasmussen. Asthma and osteopathy.
 2002 Mette Pedersen. Vocal cord nodules: non-surgery vs. surgery.
 2004 Thorkil Christensen. Randomised trial, herbal cream for pain.

Scientific assignments

General

- 1988 - 1990 Secretary, Danish Society for Theory in Medicine.
 1990 Examiner, prize report in medicine, University of Copenhagen.
 1990 Member of WHO's expert group in Bukarest, evaluation of AIDS trial in children.
 1991 Member of drug committee's quality group, Rigshospitalet.
 1992 Member of Ministry of Education's group in Latvia, research evaluation.
 1991 - 1998 Expert, Medical Research Council's Statistical Aid Service.
 1992 - 1996 Chairman, Danish Society for Theory in Medicine.

- 1993 - 2005 Examiner, PhD applications, Rigshospitalet.
 1993 - 2005 Member of Research Council, Rigshospitalet.
 1993 - 2010 Member of Drug Committee, Rigshospitalet.
 1995 Member of HS's working group on clinical databases.
 1998 Examiner, PhD thesis (Rasmus Licht).
 1998 Chairman and examiner, PhD thesis (Palle Valentiner-Brandt).
 1998 Member of ad hoc committee, Office for Scientific Integrity.
 1998 - 2005 Expert, Medical Research Council's Statistical Aid Service for East Denmark.
 1999 Member of ad hoc committee, Office for Scientific Integrity.
 2001 Member of ad hoc committee, Office for Scientific Integrity.
 2008 Examiner of case of suspected scientific misconduct in Iran for The Oxford Health Alliance.
 2008 Examiner of case of suspected scientific misconduct in Norway.
 2011 Examiner, PhD thesis (Bendt Johansen), University of Southern Denmark
 2013 Chairman, assessment of candidates for a professorship, University of Copenhagen
 2014 Chairman and examiner, PhD thesis (Robert Eriksson), University of Copenhagen
 2015 Chairman and examiner, PhD thesis (Bruno Heleno), University of Copenhagen
 1993 - Member CONSORT (Consolidated Standards of Reporting Trials), see www.consort-statement.org.
 2004 - Member of STROBE (Developing Standards of Reporting for Observational Studies in Epidemiology), see www.strobe-statement.org.
 2005 - Member of PRISMA (Quality of reporting of meta-analyses), see <http://www.prisma-statement.org/>.
 2005 - Member of SPIRIT (Standard Protocol Items for Randomised Trials), see www.spirit-statement.org/.

Editorial work

- 1992 - 1998 Editor, Bibliotek for Læger.
 1995 - 2002 Member of Editorial Board, British Medical Journal.
 1995 - Member of Editorial Advisory Board, Scandinavian Journal of Rheumatology.
 1995 - Member of Editorial Advisory Board, The Cochrane Collaboration.
 1997 - 2014 Editor, Cochrane Methodology Review Group
 1997 - Member of Advisory Board, Clinical Evidence, BMJ Publishing.
 2000 - Editorial advisor, BioMedCentral (supports PubMedCentral, USA).
 2000 - 2010 Member of Scientific Board, Ugeskrift for Læger
 2004 - Member of Editorial Board, BioMedCentral Medical Research Methodology
 2004 - Member of BMJ Knowledge Advisory Board
 2007 - Academic editor, PLoS Medicine

Performed peer reviews for:

Acta Neuropsychiatrica
 Annals of Internal Medicine
 BioMed Central Medical Research Methodology
 BioMed Central Family Practice
 BioMed Central Infectious Diseases
 Bibliotek for Læger
 BMJ
 BMJ Open
 Breast Cancer Research and Treatment
 Canadian Medical Association Journal
 Cancers
 Clinical Evidence
 Clinical Trials
 Clinical Trials and Meta-analysis
 Cochrane Airways Group
 Cochrane Anaesthesia Group
 Cochrane Gynaecological Cancer Group
 Cochrane Hepato-Biliary Group
 Cochrane Infectious Diseases Group

Cochrane Musculoskeletal Group
 Cochrane Musculoskeletal Injuries Group
 Cochrane Oral Health Group
 Controlled Clinical Trials
 Danish Medical Bulletin
 European Journal of Neurology
 Hong Kong Government Research Council
 International Journal of Cancer
 International Journal of Epidemiology
 International Journal of Risk and Safety in Medicine
 International Journal of Technology Assessment in Health Care
 JAMA
 Journal of Clinical Epidemiology
 Journal of Medical Ethics
 Lancet
 La revue Précrire
 Medical Journal of Australia
 Medical Research Council, UK
 Medicine, Philosophy and Health Care
 Nature Reviews Nephrology
 New England Journal of Medicine
 PLoS Medicine
 Politik
 Pharmacogenetics
 PharmacoEconomics
 Radiotherapy and Oncology
 Scandinavian Journal of Gastroenterology
 Scandinavian Journal of Medicine and Science in Sports
 Scandinavian Journal of Rheumatology
 Scandinavian Journal of Social Medicine
 Science
 Statens beredning för medicinsk utvärdering
 Statistics in Medicine
 Tobacco Control
 Ugeskrift for Læger
 Vetenskapsrådet, Sverige
 Women's Health

Chairman at congresses and meetings

1. Seminar on Bias and Controversies in Clinical Research. Rigshospitalet, 28 Feb 1992.
2. Pharmacotherapy I - methodological aspects. 25th Scand Congr Rheumatol, Lillehammer, 2 June 1994.
3. Reviews of data on continuous scales. Workshop, 2nd Cochrane Colloq, Hamilton, Canada, 1 Oct 1994.
4. Reviews and Syntheses. 11th Meeting, International Society of Technology Assessment in Health Care, Stockholm, 6 June 1995.
5. Cochrane Hepato-biliary Review Group Meeting. European Association for the Study of the Liver, København, 19 Aug 1995.
6. Cochrane Tuberculosis Review Group Meeting. International Union against Tuberculosis and Lung Disease, Paris, 9 Sept 1995.
7. Scientific presentations. 3rd Annual Cochrane Colloquium, Oslo, 4-8 Oct 1995.
8. Cochrane Depression/Neurosis Review Group Meeting. 3rd Annual Cochrane Colloq, Oslo, 8 Oct 1995.
9. Cochrane Placebo Methods Working Group Meeting. 4th Annual Cochrane Colloq, Adelaide, 21 Oct 1996.
10. Cochrane Colorectal Cancer Group Pre-exploratory Meeting. Cochrane Cancer Network Meeting, Bruxelles, 1 Feb 1997.
11. Cochrane Colorectal Cancer Group Exploratory Meeting. København, 12-13 Sept 1997.
12. 50 years of clinical trials: past, present and future. BMA/BMJ, London, 29-30 Oct 1998. Conference chair and chair of session: Quality and relevance of randomised controlled trials.
13. Evidence based medicine: How do we implement research results effectively? Annual meeting for the Nordic Cochrane Centre and Network, Rigshospitalet, 28 Jan 1999.

14. Exploratory meeting for the Cochrane Anaesthesia Group. 7th Annual Meeting of the European Society of Anaesthesiologists, Amsterdam, 29-30 May 1999.
15. Medical Editors. Second Asian-Pacific Conference on Evidence Based Medicine, Chengdu, China, 8-10 Apr 2002.
16. Scientific presentations. 15th Annual Cochrane Colloquium, São Paulo, 23-27 Oct 2007.
17. Influenza symposium. Rigshospitalet, 23 Sept 2008.
18. Scientific presentations. 16th Annual Cochrane Colloquium, Freiburg, 3-7 Oct 2008.
19. International Cochrane Symposium: EBM and Cochrane reviews. Rigshospitalet, 22 April 2009.
20. Investigating bias. 19th Cochrane Colloquium, Madrid, 21 Oct 2011.
21. Nordic Cochrane Centre's 25th Anniversary Research Symposium. Rigshospitalet, 12 Oct 2018.
22. Institute for Scientific Freedom, inaugural symposium. Copenhagen, 9 March 2019.

Advisory Board member at international congresses

- 2nd Cochrane Colloquium, Hamilton, Ontario, 1-4 Oct 1994.
- 3rd Cochrane Colloquium, Oslo, 4-8 Oct 1995.
- 4th Cochrane Colloquium, Adelaide, Australia, 20-24 Oct 1996.
- 7th Cochrane Colloquium, Rome, Italien, 5-9 Oct 1999.
- 8th Cochrane Colloquium, Cape Town, Sydafrika, 25-29 Oct 2000.
- 9th Cochrane Colloquium, Lyon, 9-13 Oct 2001.
- 11th Cochrane Colloquium, Barcelona, 26-31 Oct 2003.
- 12th Cochrane Colloquium, Ottawa, 2-6 Oct 2004.
- 5th Congress on Peer Review and Biomedical Publication, Chicago, 15-17 Sept 2005.
- 15th Cochrane Colloquium, São Paulo, 23-27 Oct, 2007, Scientific Program Committee.
- 6th Congress on Peer Review and Biomedical Publication, Vancouver, 10-12 Sept 2009.
- 7th Congress on Peer Review and Biomedical Publication, Chicago, 8-10 Sept 2013.
- Psychiatric drugs do more harm than good. Copenhagen, 16 Sept 2015.
- 8th Congress on Peer Review and Biomedical Publication, Chicago, 10-12 Sept 2017.

Expert witness in court cases

- 2014 Danish High Court, double homicide attempt on methylphenidate.
- 2014 Norwegian High Court, forced treatment with olanzapine.
- 2015 Norwegian High Court, Patient Harms Council, oseltamivir for influenza.
- 2016 Dutch High Court, double homicide case on paroxetine.
- 2016 Alaska High Court, forced retention and medication of a psychiatric patient.
- 2019 New York, effects of the DTP vaccine on mortality.
- 2019 Canada, harms caused by psychiatric drugs.
- 2019 California, harms of an HPV vaccine.
- 2020 Australia, harms after psychiatric drugs.
- 2020 California, forced influenza vaccination
- 2020 California, harms of an HPV vaccine

Management experience

- 1967 Co-founder, local fraction of a political party, cashier 1967-68.
- 1975 - 1977 Cashier, Frederiksberg Athletics Association.
- 1977 - 1983 Founder and head, medical department, Astra-Syntex.
- 1987 - 1995 Founder and head, Nordic coordination office for AIDS trials, Rigshospitalet.
- 1993 Co-founder of the Cochrane Collaboration
- 1993 - 2019 Founder and head, The Nordic Cochrane Centre (39 people employed in 2014, incl. those in Copenhagen Trial Unit).
- 1993 - 1996 Member of the Steering Group, the Cochrane Collaboration.
- 1996 - 2001 Founder and head, Cochrane Placebo Methods Group.
- 2002 SHL leadership course.
- 2008 - 2009 Cashier and board member, Hørsholm Swimming Club.
- 2018 - 2019 Member of the Cochrane Governing Board.

EXHIBIT D

CURRICULUM VITAE

Carl J Heneghan

Title: Professor
Surname: Heneghan
Forename(s): Carl James

Dob: 23/01/1968

Email: carl.heneghan@phc.ox.ac.uk
Tel: +44 (0)1865 289299
GMC: 4731643

Current Positions:

- Professor of Evidence-Based Medicine, Nuffield Dept. of Primary Care University of Oxford
- Director, Centre for Evidence-Based Medicine
- Honorary Senior Academic General Practitioner, NHS England
- General Practitioner (MRCP)
- NHS Urgent Care GP Oxford NHS Foundation Trust
- Director Evidence Based Healthcare Programs, University of Oxford (Masters and DPhil)
- NIHR Senior Investigator

Education and Qualifications:

- DPhil, New College, University of Oxford 2009: Incidence, prevention and treatment of acute coronary events in a population study: The Oxford Vascular Study (OXVASC)
- MA (Hons), New College, University of Oxford 2007
- MRCP (Merit) Royal College of General Practice 2004
- BM, BCH, Medicine and Surgery, New College, University of Oxford 2000
- BA (Hons) 2:1 Physiological Sciences, New College, University of Oxford 1997

Research Fellowships

- NCCRD Research Development Fellowship: NIHR Department of Health 2005-2008
- Clinical Research Fellow, University of Oxford 2003–2005

Past posts:

- Clinical Reader, Clinical Lecturer, Department of Primary Care University of Oxford 2008-2013
 - Senior Clinical Research Fellow, Department of Primary Care University of Oxford 2005-2008
 - Deputy Director Clinical Fellow CEBM, University of Oxford 2005-10
 - General Practice Registrar Thames Valley Primary Care Agency 2003 – 2005
 - Senior House Officer 2001– 2003, House Officer Oxford Radcliffe NHS Trust, 2000- 2001
-

Further positions:

- Director WHO Collaboration Centre
- Chair of Examiner MSc in Evidence-Based healthcare, University of Oxford, External examiner MSc in Primary Care University of Birmingham
- Advisor to WHO International Clinical Trials Registry Platform
- Editor in Chief BMJ Evidence-Based Medicine

Professional memberships

- British Medical Association (BMA)
 - Member of the Royal College of General Practice (MRCP) Specialist register 2005
 - Medical Defence Union of Scotland (MDDUS)
 - General Medical Council (GMC 4731463) registered 2000
-

Awards

- University of Oxford, Medical Sciences Division, Lifetime Achievement Award 2019
- NIHR Senior Investigator Award 2017
- ACCEA consultant clinical excellence awards – SILVER Award, April 2017
- HSJ- top 100 NHS clinical leaders 2013 and 2015
- Brisbane Initiative Fellowship July 2007.

CV: Carl Heneghan BM, BCH, BA, MA (Hons) Oxon, MRCP, DPhil

- Department of Health Research Development Award 2005-8
- Royal College of General Practitioners: Scientific Foundation Board Award 2004
- Goldsmiths Scholarship Award 2000

20 impact Publications (full list of over 400 publications available on request H index 70, I 10 index 232; 23415 citations)

1. Zanamivir for influenza in adults and children: systematic review of clinical study reports and summary of regulatory comments. Heneghan CJ, Onakpoya I, Thompson M, Spencer EA, Jones M, Jefferson T. *BMJ*. 2014 Apr 9;348:g2547.
2. Oseltamivir for influenza in adults and children: systematic review of clinical study reports and summary of regulatory comments. Jefferson T, Jones M, Doshi P, Spencer EA, Onakpoya I, Heneghan CJ. *BMJ*. 2014 Apr 9;348:g2545.
3. Neuraminidase inhibitors for preventing and treating influenza in healthy adults and children. Jefferson T, Jones MA, Doshi P, Del Mar CB, Hama R, Thompson MJ, Spencer EA, Onakpoya I, Mahtani KR, Nunan D, Howick J, **Heneghan CJ**. *Cochrane Database Syst Rev*. 2014 Apr 10;4:CD008965.
4. Evidence for non-communicable diseases: analysis of Cochrane reviews and randomised trials by World Bank classification. Heneghan C, Blacklock C, Perera R et al. *BMJ Open*. 2013 Jul 6;3(7). pii: e003298. doi: 10.1136/bmjopen-2013-003298. Print 2013.
5. Hayward G, Thompson MJ, Perera R, Glasziou PP, Del Mar CB, **Heneghan CJ**. Corticosteroids as standalone or add-on treatment for sore throat. *Cochrane Database Syst Rev*. 2012 Oct 17;10:CD008268. doi: 10.1002/14651858.CD008268.pub2. PMID: 23076943
6. Friedemann C, **Heneghan C**, Mahtani K, et al. Cardiovascular disease risk in healthy children and its association with body mass index: systematic review and meta-analysis. *BMJ*. 2012 Sep 25;345:e4759. doi: 10.1136/bmj.e4759. PMID: 23015032
7. Blacklock C, **Heneghan C**, Mant D, Ward AM. Effect of UK policy on medical migration: a time series analysis of physician registration data. *Hum Resour Health*. 2012 Sep 25;10(1):35. PMID: 23009665
8. Balla J, **Heneghan C**, Goyder C, Thompson M. Identifying early warning signs for diagnostic errors in primary care: a qualitative study. *BMJ Open*. 2012 Sep 13;2(5). Print 2012. PMID: 22983786
9. Heneghan C, Jefferson T, Doshi P. Antivirals for treatment of influenza. *Ann Intern Med*. 2012 Sep 4;157(5):385-6. PMID: 22944882
10. Hayward G, Thompson MJ, Perera R, Del Mar CB, Glasziou PP, **Heneghan CJ**. Corticosteroids for the common cold. *Cochrane Database Syst Rev*. 2012 Aug 15;8:CD008116. PMID: 22895973
11. **Heneghan C**, Thompson M, Perera-Salazar R, Gill P, O'Neill B, Nunan D, Howick J, Lasserson D, Mahtani K. Authors' reply to Betts, Stokes, and Kleiner. *BMJ*. 2012 Aug 14;345:e5431. PMID: 22893647
12. **Heneghan C**, Howick J, O'Neill B, Gill PJ, Lasserson DS, Cohen D, Davis R, Ward A, Smith A, Jones G, Thompson M. The evidence underpinning sports performance products: a systematic assessment. *BMJ Open*. 2012 Jul 18;2(4). pii: e001702. doi: 10.1136/bmjopen-2012-001702. PMID: 22815461
13. **Heneghan C**, Gill P, O'Neill B, Lasserson D, Thake M, Thompson M. Mythbusting sports and exercise products. *BMJ*. 2012 Jul 18;345:e4848. doi: 10.1136/bmj.e4848. PMID: 22810389
14. **Heneghan C**, Perera R, Nunan D, Mahtani K, Gill P. Forty years of sports performance research and little insight gained. *BMJ*. 2012 Jul 18;345:e4797. doi: 10.1136/bmj.e4797. PMID: 22810388
15. Thompson M, **Heneghan C**, Cohen D. How valid is the European Food Safety Authority's assessment of sports drinks? *BMJ*. 2012 Jul 18;345:e4753. doi: 10.1136/bmj.e4753. PMID: 22810387
16. Nunan D, Wassertheurer S, Lasserson D, Hametner B, Fleming S, Ward A, **Heneghan C**. Assessment of central haemodynamics from a brachial cuff in a community setting. *BMC Cardiovasc Disord*. 2012 Jun 26;12(1):48.
17. **Heneghan C**, Thompson M. Rethinking medical device regulation. *J R Soc Med*. 2012 May;105(5):186-8.
18. Bettiol S, Wang K, Thompson MJ, Roberts NW, Perera R, **Heneghan CJ**, Harnden A. Symptomatic treatment of the cough in whooping cough. *Cochrane Database Syst Rev*. 2012 May 16;5:CD003257.
19. Hayward G, **Heneghan C**, Perera R, Thompson M. *Ann Fam Med*. Intranasal corticosteroids in management of acute sinusitis: a systematic review and meta-analysis. 2012 May;10(3):241-9.
20. Banerjee A, Newman DR, Van den Bruel A, **Heneghan C**. Diagnostic accuracy of exercise stress testing for coronary artery disease: a systematic review and meta-analysis of prospective studies. *Int J Clin Pract*. 2012 May;66(5):477-92.

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.

SUPERIOR COURT
CIVIL ACTION NO. _____

TAMAR MASSOYAN-ARTINIAN, on behalf of
her children, and MADISON SCHILTZ,

Plaintiffs,

v.

MONICA BHAREL, in her official capacity as
Commissioner of the Massachusetts
Department of Public Health and the
MASSACHUSETTS DEPARTMENT OF
PUBLIC HEALTH,

Defendants.

EXPERT AFFIDAVIT OF P. AABY AND C. STABELL BENN

We, Peter Aaby and Christine Stabell Benn, state as follows:

1. We submit this affidavit in support of Plaintiffs' Motion for a preliminary injunction. We have personal knowledge of the facts set forth herein and if called to testify, each of us could competently testify as to the following:

EXPERIENCE & CREDENTIALS

2. I, Christine Stabell Benn, am a medical doctor (1996), PhD (2003), and DMSc (2011), Professor in Global Health at University of Southern Denmark (since 2013), Chair at the Danish Institute for Advanced Study (since 2017), and member of the *Academia Europaea* (since 2020). My research focuses on how vaccines affect the immune system in more general ways than

previously thought. I have published 293 articles, mainly about vaccines, in peer-reviewed journals. My CV is attached in Exhibit A.

3. I, Peter Aaby, an anthropologist, who has studied vaccination policy in West Africa for more than 40 years, am a PhD (1974), DMSc (1988), Professor (1995), Doctor Honoris Causa (Universidade Nova de Lisboa), and member of the *Academia Europaea*. I showed in 1980-1990 that WHO's new high-titer measles vaccine (HTMV) was associated with two-fold increased female mortality in spite of being fully protective against measles infection. This conundrum led to the discovery that vaccines have nonspecific effects, unrelated to protection against the vaccine-targeted infection. WHO had to withdraw the HTMV (1992). My CV is attached in Exhibit B.

4. We have not received any compensation, either directly or in-kind, for this affidavit.

UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS

5. UNESCO's Universal Declaration on Bioethics and Human Rights¹ aims to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics. Article 6.1 of the Declaration states: "*Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.*" **Accordingly, vaccines cannot be forced upon anybody**, directly or

¹ http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html.

indirectly through deprivation of privileges the individual would otherwise have had (*e.g.*, the right to go to school, to have a job, or to earn a living), all of which can be equated with coercion.

COMPARISON WITH DENMARK

6. Denmark has never recommended an influenza vaccine for all ages. Currently, influenza vaccine is only recommended to the elderly above 65 years of age, people with chronic diseases, people working with vulnerable people, and pregnant women. The Danish Health Authority has evaluated the need for other groups to receive influenza vaccine. The report is currently in public hearing.² It establishes that it may be cost-beneficial to offer (but not mandate; no vaccines are mandated in Denmark) influenza vaccine to children aged 0-6 years and to health care workers, but there is no reason to vaccinate older children or adults below 65. ***Thus, The Danish Health Authority does not find it indicated to recommend influenza vaccine to healthy people aged 6 to 65 years.***

7. Denmark is praised for its COVID-19 response, the mortality rate by 13 December being 16/100,000,³ yet has not changed its recommendations with respect to influenza vaccine as a way of fighting COVID-19.

VACCINES HAVE NON-SPECIFIC EFFECTS THAT MAY BE HARMFUL

8. Following the studies showing that new measles vaccine (HTMV) was associated with increased all-cause mortality for females, numerous studies have documented that all the commonly used vaccines have nonspecific effects.⁴ Sometimes the effects are beneficial, reducing susceptibility to unrelated infections. However, sometimes the vaccine effects are deleterious,

²<https://prodstoragehoeringspo.blob.core.windows.net/c161d76d-572e-4fa5-8b85-a380b9acc084/H%C3%B8ringsversion%20-%20MTV%20for%20influenzavaccination.pdf>.

³ <https://covid19.who.int/region/euro/country/dk>.

⁴ Benn et al, Lancet Infect Dis 2020: [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(19\)30742-X/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(19)30742-X/fulltext).

enhancing susceptibility to unrelated infections and increasing mortality. The general pattern seems to be that live vaccines (Measles vaccine, Measles-mumps-rubella vaccine, oral polio vaccine, BCG, smallpox vaccine) have beneficial effects. However in contrast, six non-live vaccines (DTP, HBV, IPV, pentavalent vaccine, H1N1 influenza vaccine, and RTS,S malaria vaccine) have negative effects, particularly for females.⁵

CONCLUSION

9. Mandating vaccines goes against UNESCO’s Universal Declaration on Bioethics and Human Rights. Other countries like Denmark, with free universal health care, high average mean age and good population health, are not recommending universal influenza vaccines. Vaccines may have negative nonspecific effects; however, these have not been thoroughly investigated for influenza vaccine.

SIGNED UNDER THE PAINS AND PENALTIES OF PERJURY,



Christine Stabell Benn



Peter Aaby

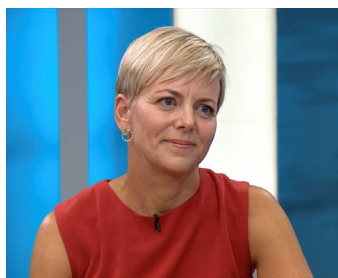
Signed this 16th day, December 2020.

⁵ *Id.*

EXHIBIT A

PERSONAL INFORMATION

Christine Stabell Benn



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Date of birth 15/06/1968 | Nationality Danish | ORCID [0000-0001-6102-3810](https://orcid.org/0000-0001-6102-3810)

WORK EXPERIENCE

2013->	Professor, OPEN, University of Southern Denmark (USD)/Odense University Hospital
2012->	Center leader, Research Center for Vitamins and Vaccines (CVIVA)
2012->	Head, Bandim Health Project Copenhagen Division (hosted at SDU from 2020)
2008-2015	External associate professor, University of Copenhagen, Denmark (UCD)
2007-2011	Senior researcher, Bandim Health Project (BHP), Statens Serum Institut (SSI)
2005-2007	Post-doc, Bandim Health Project, SSI, and Dept. of Infectious Diseases, Rigshospitalet
2003-2004	Post-doc, Dept. of Epidemiology Research, SSI
1999-2003	PhD-student, Dept. of Epidemiology Research, SSI
1998	Maternity leave (March 1998-December 1998)
1996-98	Residence in Surgery, Internal Medicine and GP, Copenhagen
1995	Maternity leave (September 1995-February 1995)
1993	12 months' scholarship, Institute of Epidemiology and Social Science, University of Aarhus, Denmark (UAD) and BHP, Guinea-Bissau

EDUCATION AND TRAINING

2014	Advanced course in responsible research conduct, SSI
2011	Doctor of Medical Science, UCD
2006	One month at Pediatric Immunology Department, Stanford University, US
2003	PhD, UCD
1996	MD, UCD
1994	Diploma in Medical Research, UAD
1987-96	Medical Student, UAD and UCD

HONOURS AND AWARDS

2019	University of Southern Denmark's "Innovation Prize"
2018	Selected to give a TEDx talk (https://www.youtube.com/watch?v=_d8PNIXHJ48)
2017	Chair, Danish Institute for Advanced Studies
2015	Prize for Best Publications, Department of Clinical Research, USD
2014	Nominated for "Best Danish research result of the year"
2011	Selected by the Danish National Research Foundation for a "Center of Excellence"
2010	Received an ERC Starting Grant
2009+2011	2 nd prize: "Best Danish research result of the year"
2009	Received a Female Research Leader Grant (Danish Council for Independent Research)
2005	Awarded Young Research Leader Grant (Strategic Research Council) as one among the 19 most talented young Danish Researchers
2004	Nominated for EURYI award as one among the 9 most talented Danish Researchers

ORGANISATIONAL SKILLS/ MENTORING

- **Responsible for a team of ~15 people at SDU, Denmark**
- **One of seven member of the Steering Board of the Bandim Health Project, Guinea-Bissau**
- **The principal investigator/co-investigator for many large-scale randomised trials in Guinea-Bissau, e.g.:**
 - 1993-1995: The effect of vitamin A supplementation on the antibody-response to measles vaccine (*Lancet* 1997, *Lancet* 2002)
 - 2002-2004 : The effect on mortality of 50,000 IU vitamin A given with BCG at birth to normal-birth-weight neonates (*BMJ* 2008)
 - 2005-2008: The effect on mortality of 25,000 IU vitamin A given with or without BCG to low-birth-weight-neonates (*BMJ* 2010)
 - 2007-2011: An evaluation of the WHO vitamin A policy: Vitamin A given with vaccines after 6 months of age (*Pediatrics* 2014)
 - 2008-2012 : The effect on mortality of providing oral polio vaccine at birth (*Clin Inf Dis* 2015)
 - 2008-2014: The effect on mortality of providing early BCG vaccine to children with low weight (*Clin Inf Dis* 2017)
- **The previous or current supervisor of 26 PhD students and >40 Research year/Masters students.**

OTHER QUALIFICATIONS

- **Member of the Scientific Advisory Committee for EDCTP 2019->**
- **Member of the Life Science assessment panel of ERC Starting Grants 2019**
- PI for a Nordic project "Childhood morbidity and potential non-specific effects of the childhood vaccination programmes", involving the National Immunization Programs in Denmark, Norway, Sweden and Finland (with funding from "NordForsk"), 2017-2022
- Participant, EDCTP Stakeholder Meeting on Co-infections and Co-morbidities, Den Haag 2017
- Member of the PhD grant assessment committee, Odense University Hospital, 2014-2016
- **Technical Advisor, WHO** (Neonatal vitamin A policy), 2008, 2014-16
- **Member of WHO/SAGE working group** on non-specific effects of vaccines 2013-2014 (www.who.int/immunization/sage/sage_wg_non_specific_effects_vaccines_march2013/)
- **Expert member of working group, NIH** (INSPIRE), USA, 2012-2014
- Co-funder of "OPTIMMUNIZE", a consortium which aims to investigate the immunological mechanisms behind the non-specific and sex-differential effects of health interventions, 2010->

SCIENTIFIC INTERESTS

My research focusses on **epidemiological studies** of **health interventions** and their **effect on overall health** in real life. We have observed that that vitamins and vaccines affect **the immune system** in much more general ways than previously thought. Vitamins and vaccines have so-called **non-specific effects**. Based to a large extent on work done in one of the world's poorest countries, Guinea-Bissau, I have formulated the hypothesis that these **health interventions interact**, the interventions and the interactions are **sex-differential**, and the effect of a given intervention may depend more on these interactions than on the specific effects of the interventions.

My main contribution has been to take the observations on non-specific effects forward to **randomised controlled trials**. I have also bridged to **immunological studies**, and explored the **biological mechanisms** underlying the non-specific effects of vitamins and vaccines. Furthermore, we have taken the observations back to Denmark, to test in randomised trials and observational **register-based studies** whether non-specific effects of vaccines are important in high-income settings. Most recently, we are testing whether non-specific effects of BCG vaccine and oral polio vaccine can provide partial protection against COVID-19. I am the **author of 293 scientific articles for peer-reviewed journals**.

Total number of publications in peer reviewed journals (not abstracts): 293. H-index=43 (Web of Science)

1. **Stabell C**, Balé C, da Silva AP, Olsen J, Aaby P. No evidence of fontanelle-bulging episodes after vitamin A supplementation of 6- and 9-months old infants in Guinea-Bissau. *Eur J Clin Nutr* 1995; 49: 73-74
2. **Benn CS**, Whittle H, Aaby P, Balé C, Michaelsen KF, Olsen J. Vitamin A and measles. *Lancet* 1995; 346: 503-504
3. **Benn CS**, Aaby P, Balé C, Olsen J, Michaelsen KF, George E, Whittle H. Randomised trial of effect of vitamin A supplementation on antibody response to measles vaccine in Guinea-Bissau, West Africa. *Lancet* 1997; 350: 101-105
4. **Benn CS**, Lisse IM, Balé C, Michaelsen KF, Olsen J, Hedegaard K, Aaby P. No strong long-term effect of vitamin A supplementation in infancy on CD4 and CD8 T-cell subsets. A community study from Guinea-Bissau, West Africa. *Ann Trop Paediatr* 2000; 20: 259-264.
5. **Benn CS**, Jeppesen DL, Hasselbalch H, Olesen AB, Nielsen J, Björkstén B, Lisse IL, Aaby P. Thymus size and head circumference at birth and development of allergic diseases. *Clin Exp Allergy* 2001; 31: 1862-1866.
6. **Benn CS**, Bager P, Jensen H, Lisse I, Aaby P. Measles and atopy – rash on rash? *Allergy* 2001; 56: 800-801.
7. **Benn CS**, Balde A, George E, Kidd M, Whittle H, Lisse IM, Aaby P. Long-term effect of vitamin A supplementation with measles vaccine in infancy on measles-specific antibody levels in Guinea-Bissau, West Africa. *Lancet* 2002; 359: 1313-14.
8. **Benn CS**, Bendixen M, Krause TG, Olesen, AB. Questionable coexistence of Th1 and Th2-related diseases. *J Allergy Clin Immunol* 2002; 110: 328-29.
9. **Benn CS**, Thorsen P, Jensen JS, Kjær BB, Bisgaard H, Andersen M, Rostgaard K, Björkstén B, Melbye M. Maternal vaginal microflora during pregnancy and risk of asthma hospitalization and anti-asthma medication in early childhood. *J Allergy Clin Immunol* 2002; 110: 72-77.
10. Bager P, Westergaard T, Rostgaard K, **Benn CS**, Melbye M. Mode of delivery and risk of allergic rhinitis and asthma. *J Allergy Clin Immunol* 2003; 111: 51-6.
11. Westergaard T, Begtrup K, Rostgaard K, Krause TG, **Benn CS**, Melbye M. Reproductive history and allergic rhinitis among 31,145 Danish Women. *Clin Exp Allergy* 2003; 33:301-5.
12. **Benn CS**, Benfeldt E, Andersen PK, Olesen AB, Melbye M, Björkstén B. Atopic Dermatitis in Young Children: Diagnostic criteria for Use in Epidemiological Studies Based on Telephone Interviews. *Acta Derm Venereol* 2003; 83: 347-350.
13. **Benn CS**, Balé C, Sommerfelt H, Friis H, Aaby P. Vitamin A supplementation and childhood mortality: Amplification of the non-specific effects of vaccines? *Int J Epidemiol* 2003; 32:822-8.
14. Aaby P, Jensen H, Rodrigues A, Garly ML, **Benn CS**, Lisse IM, Simondon F. Divergent female-male mortality ratios associated with different routine vaccinations among female-male twin pairs. *Int J Epidemiol* 2004; 33:367-73.
15. **Benn CS**, Böttcher MF, Pedersen BV, Filteau SM, Duchén K. Mammary epithelial paracellular permeability in atopic and non-atopic mothers versus childhood atopy. *Pediatr Allergy Immunol* 2004; 15:123-6.
16. **Benn CS**, Melbye M, Wohlfahrt J, Björkstén B, Aaby P. The sibling effect, infectious diseases, and risk of atopic dermatitis before 18 months of age. *BMJ* 2004; 328:1223-8.
17. Aaby P, Rodrigues A, Biai S, Martins C, Veirum JE, **Benn CS**, Jensen H. Oral polio vaccine and low case fatality at the paediatric ward in Bissau. *Vaccine* 2004; 22: 3014-7.
18. **Benn CS**, Wohlfahrt J, Aaby P, Westergaard T, Benfeldt E, Michaelsen KF, Björkstén B, Melbye M. Breastfeeding and Risk of Atopic Dermatitis During The First 18 Months of Life by Parental History of Allergy. *Am J Epidemiol* 2004; 160:217-23.
19. Linneberg A, Petersen J, Grønbæk M, **Benn CS**. Alcohol during pregnancy and atopic dermatitis in the offspring. *Clin Exp Allergy* 2004; 34: 1678-1683.
20. Nielsen J, **Benn CS**, Bale C, Martins C, Aaby P. Vitamin A supplementation during war-emergency in Guinea-Bissau 1998-1999. *Acta Trop* 2005; 93: 275-82.
21. Aaby P, Rodrigues A, Biai S, Martins C, Veirum JE, **Benn CB**, Jensen H. Vaccines and unexpected observations: Flaws or cause for concern? *Vaccine* 2005; 23: 2407-8.
22. **Benn CS**, Melbye M, Wohlfahrt J, Björkstén B, Aaby P. [Kohortestudie af effekten af søskende og infektionssygdomme på udvikling af atopisk dermatitis]. *Ugeskr Laeger* 2005;167 :1754-7
23. Aaby P, Jensen H, **Benn CS**, Lisse IM. Non-specific effects of vaccination: survival bias may explain findings. *BMJ* 2005; 330:844-5.
24. Jensen H, **Benn CS**, Aaby P. Diphtheria-tetanus-pertussis vaccination in low-income countries: improved child survival or survival bias? *BMJ* 2005; 330:845-6.
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26. **Benn CS**, Michaelsen KF. Does the effect of breast-feeding on atopic dermatitis depend on family history of allergy? *J Pediatr* 2005;147(1):128-9.
27. **Benn CS**, Martins C, Rodrigues A, Jensen H, Lisse IM, Aaby P. Randomised study of the impact of different doses of vitamin A on childhood morbidity and mortality. *BMJ* 2005; 331:1428-32.
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30. **Benn CS**, Diness B, Fisker AB, Christoffersen D, Friis H. [Høj-dosis vitamin A tilskud sænker børnedødeligheden i lavindkomstlande – kan det blive bedre?]. *Ugeskr Laeger* 2006; 168: 2442- 2445.
31. Aaby P, Gustafson P, Roth A, Rodrigues A, Fernandes M, Sodemann M, Holmgren B, **Benn CS**, Garly ML, Lisse IM, and Jensen H. Vaccinia scars associated with better survival for adults. An observational study from Guinea-Bissau. *Vaccine* 2006; 24:5718-25.
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Miscellaneous:

Reports

Mutua M, Welega P, Zandoh C, Kagoné M, Hanifi MA, Ravn H, Fisker A, Andersen A, **Benn CS**, Thysen S, Martins C, Aaby P. Analysis of Coverage of Fully Immunized Child, Associated Factors, Outcomes, and Impact Using Routinely Collected Population Cohort Data 2001-2014. Report to Global Alliance for Vaccine Implementation (2015).

Book chapters

Benn CS, Rieckmann A, Jensen KJ, Aaby P. The role of maternal priming and boosting for the non-specific effects of BCG vaccine. Chapter. In: The Value of BCG and TNF in Autoimmunity, 2nd Edition. Editor: Denise Faustmann, Director of Immunology, Massachusetts General Hospital, Harvard. Elsevier. <http://elsev.spi-bpo.com/books/EComp/FAUSTMAN978-0-12-814603-3/1/OTc4LTAtMTIt/index.php?Type=E> (2018)

Articles in “The Conversation”

Christine Stabell Benn: Vaccines have health effects beyond protecting against target diseases. <https://theconversation.com/vaccines-have-health-effects-beyond-protecting-against-target-diseases-1063832019> (2019)

[More than 57000 reads]

Christine Stabell Benn: Declaring vaccine hesitancy one of the ten biggest health threats in 2019 is unhelpful
<https://theconversation.com/declaring-vaccine-hesitancy-one-of-the-ten-biggest-health-threats-in-2019-is-unhelpful-123628> (2019) [More than 46000 reads]

TEDx talk: How vaccines train the immune system in ways no one expected | Christine Stabell Benn | TEDxAarhus.
https://www.youtube.com/watch?v=_d8PNIXHJ48 (2019) [More than 57000 views]

EXHIBIT B

Peter Aaby, DMSc, professor

Education/training

1974 Mag. Scient., Social Anthropology, University of Copenhagen

1988 Dr. Med. Sc., University of Copenhagen

Positions and Employment

1968-1991 Institute of Anthropology, University of Copenhagen; Associated with SAREC, Sweden (1978-1981); Associated with Danish Church Aid (1987-1991)

1991- Statens Serum Institut; Research Professor DANIDA/SSVF (1995-2001); Novo Nordisk Foundation professorship grant (2002-2014)

Honours

2000 Novo Nordisk prize for "Ground-breaking epidemiological research especially with regard to vaccinations against measles infection"

2009 Ministry of Foreign Affairs: 5th most important Dane for fighting global poverty

2009 + 2011+ 2014: Nominated as one of 10 best Danish research result of the year; on two occasions 2nd prize

2010 Step 2 for ERC, Advanced Grant, not funded

2012-2016 Adjunct Professor, University of Southern Denmark

2012-2017 Co-organiser of Research Center for vitamins and vaccines (CVIVA), center of excellence sponsored by the DNRF (Centre leader: Christine S Benn)

2015 Doctor Honoris Causa, Universidade Nova de Lisboa

2017 SEB Pensions Hæderpris

2017-2022 Adjunct Professor, University of Southern Denmark

2020 Member Academia Europaea

Scientific Focus

Since 1978 I have built a large health and demographic surveillance system in Guinea-Bissau. Under-5 child mortality was 500/1000 when we started. Contrary to all expectations, the high measles case fatality (25%) was not due to malnutrition but to the intensity of exposure as a secondary case within the family. Intensity of exposure was subsequently shown to explain severity in many childhood infections including pertussis, chickenpox, polio and RSV.

We were the first to introduce measles vaccine (MV) in Bissau in 1979. The MV campaign reduced overall child mortality by two-thirds, an effect not explained by prevention of measles infection.

This led to a series of discoveries contradicting the specific-disease paradigm. Vaccines affect susceptibility to unrelated infections and these non-specific effects (NSEs) are far more important

for child survival than the specific preventive effects. Live vaccines, including MV, BCG, OPV and smallpox vaccination, have major beneficial NSEs, whereas non-live vaccines, including DTP, inactivated polio vaccine (IPV), hepatitis B vaccine (HBV), Pentavalent, H1N1 influenza vaccine and RTS,S malaria vaccine have negative effects for female survival.

We have also found that boosting with live vaccines, as happens in eradication campaigns, enhances the beneficial NSEs. Under-5 mortality has now declined to 65-70/1000. The numerous eradication campaigns with OPV and MV are responsible for much of this decline. We have also found for both BCG and MV that maternal priming enhances the beneficial NSEs of these vaccines.

An important implication of the NSEs is that if we eradicate a disease and then stop the corresponding live vaccine, we may have done more harm by stopping beneficial immune-training than the good we did by eradicating the disease and preventing the disease-related deaths. We have shown in both Guinea-Bissau and Denmark that smallpox vaccination had beneficial effects on survival long after smallpox was eradicated (1977). A similar problem is likely to occur with polio (to be eradicated 2019-2020) and measles (within the next 10-15 years). If we stop live OPV and MV without finding replacement vaccines we may see increases in child mortality.

A new paradigm emphasizing the immune system as a learning entity which can be trained to reduce susceptibility or misdirected to enhance susceptibility to unrelated infections is needed. Pursuing this paradigm can lead to major reductions in child mortality in low-income countries and to health care cost-savings in the high-income countries.

Peer reviewed publications

Since I started in epidemiology, I have published 613 papers in the medical field; 165 first authored; 202 last/corresponding author; H-index: 89 (Google Scholar): i10:487; 30,110 citations.

Research training

Experience in research training based on work in West Africa: 9 researchers have obtained a doctoral degree, 59 have obtained a PhD degree. The first PhD from Guinea-Bissau, Amabelia Rodrigues became the first director of the National Institute of Health, Guinea-Bissau. Kåre Mølbak became the state epidemiologist of Denmark. Christine S Benn has become the first Danish physician to receive an ERC starting grant and has received a Danish National Research Foundation Centre of Excellence grant. Many previous students are professors or senior registrars.

International collaboration

Extensive international collaboration with the INDEPH Network of demographic surveillance sites in low-income countries and with immunologists within the OPTIMMUNIZE network which focuses on potential biological mechanism for the non-specific effects of vaccines.

PUBLICATIONS: PETER AABY

1981

1. Aaby P, Bukh J, Lisse IM, Smits AJ. Measles vaccination and child mortality. *Lancet* 1981; ii:93.
2. Aaby P, Bukh J, Lisse IM, Smits AJ, Smedman L, Jeppson O, Lindeberg A. Breastfeeding and measles mortality in Guinea-Bissau. *Lancet* 1981; ii:1231

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3. Aaby P, Bukh J, Lisse IM, Smits AJ. Measles mortality, state of nutrition, and family structure: A community study from Guinea-Bissau. *J Infect Dis* 1983; 147:693-701
4. Aaby P, Bukh J, Lisse IM, Smits AJ. Spacing, crowding, and child mortality in Guinea-Bissau. *Lancet* 1983; ii:161
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8. Aaby P, Bukh J, Lisse IM, Smits AJ, Gomes J, Fernandes MA, Indi F, Soares M. Determinants of measles mortality in a rural area of Guinea-Bissau: Crowding, age, and malnutrition. *J Trop Pediatr* 1984; 30:164-69
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10. Aaby P, Bukh J, Lisse IM, Smits AJ. Measles vaccination and reduction in child mortality: a community study from Guinea-Bissau. *J Infect* 1984; 8:13-21
11. Aaby P, Bukh J, Lisse IM, Smits AJ. Risk factors in subacute sclerosing panencephalitis(SSPE): Age- and sex-dependent host reactions or intensive exposure. *Rev Infect Dis* 1984; 6:239-250

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12. Aaby P. Epidemics among Amerindians and Inuits. A preliminary interpretation. In: Brøsted J, Dahl J, Gray A, Gulløv HC, Henriksen G, Jørgensen JB, Kleivan I(eds): *Native Power*. Bergen: Universitetsforlaget, 1985; 329-339.
13. Aaby P, Bukh J, Lisse IM, Smits AJ. Introduction of measles into a highly immunised West African community: the role of health care institutions. *J Epidemiol Comm Hlth* 1985; 39:113-116
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15. Aaby P, Bukh J, Lisse IM, Smits AJ. Severe measles in Sunderland, 1885: A European-African comparison of causes of severe infection. *Int J Epidemiol* 1986; 15:101-7
16. Aaby P, Bukh J, Lisse IM, Smits AJ. Cross-sex transmission of infection and increased mortality due to measles. *Rev Infect Dis* 1986; 8:138-43.
17. Smedman L, Aaby P, Lindeberg A, Zetterstrom R. Survival 0-6 years of age in a periurban community in Guinea-Bissau: a longitudinal assessment. *Ann Trop Pediatr* 1986;6:67-72
18. Aaby P, Bukh J, Lisse IM, Smits AJ, da Silva C. Determinants des formes severes de rougeole: consequences au niveau de l'action preventive. In: Cantrelle P, Dormont S, Fargues Ph, Goujard J, Guignard J, Rumeau-Rouquette (eds): *Estimation de a mortalite du jeune enfant(0-5 ans) pour guider les actions de sante dans les pays en developpement*. Paris: INSERM, 1986: 429-442.
19. Aaby P, Bukh J, Hoff G, Leerhøy J, Lisse IM, Mordhorst CH, Pedersen IR. High measles mortality in infancy related to intensity of exposure. *J Pediatr* 1986; 109:40-4
20. Aaby P, Bukh J, Leerhøy J, Lisse IM, Mordhorst CH, Pedersen IR. Vaccinated children get milder measles infection: a community study from Guinea-Bissau. *J Infect Dis* 1986; 154:858-63

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22. Aaby P, Clements J, Cohen N. Key issues in measles immunization research: A review of the literature. WHO, EPI, 1987

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23. Aaby P. Observing the unexpected. Nutrition and child mortality in Guinea-Bissau. In: Caldwell JC, Hill A, Hull VJ(eds): *Micro approaches in demographic research*. London: Kegan Paul, 1988:278-296
24. Aaby P. Introduction to community studies of severe measles: Comparative test of the crowding/exposure hypothesis. *Rev Infect Dis* 1988;10:451
25. Aaby P. Severe measles in Copenhagen, 1915-1925. *Rev Infect Dis* 1988;10:452-456
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27. Aaby P. Malnutrition and overcrowding-exposure in severe measles infection. A review of community studies. *Rev Infect Dis* 1988;10:478-491

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32. Morley D, Aaby P. Severe measles : A new understanding. *Medical Digest* 1988
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34. Whittle H, Hanlon P, O'Neill K, Hanlon L, Marsh V, Jupp E, Aaby P. Trial of high-dose Edmonston-Zagreb measles vaccine in The Gambia: Antibody response and side-effects. *Lancet* 1988;2:811-814
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