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## CINEMEDUCATION: A RIGOROUS METHOD TO TEACH PHARMACOVIGILANCE PROCEDURES IN CLINICAL PHARMACOLOGY

*Cine-educación: una metodología rigurosa para enseñar los procedimientos de farmacovigilancia en farmacología clínica*

Irene CAMBRA-BADII<sup>1,2</sup>; Maria de LLUC FRANCÉS<sup>3</sup>; Magí FARRÉ<sup>4</sup>; Josep-E BAÑOS<sup>5</sup>

<sup>1</sup>Bioethics Chair, Universitat de Vic - Universitat Central de Catalunya, Vic (Spain). <sup>2</sup>School of Health and Life Sciences, Universitat Pompeu Fabra, Barcelona (Spain). <sup>3</sup>School of Medicine, Universitat Autònoma de Barcelona, Barcelona (Spain). <sup>4</sup>Clinical Pharmacology Service, Germans Trias i Pujol Hospital, Barcelona. Department of Pharmacology, Therapeutics and Toxicology, Universitat Autònoma de Barcelona (Spain). <sup>5</sup>School of Medicine, Universitat de Vic - Universitat Central de Catalunya, Vic (Spain).

E-mail address: [irenecambrabadii@gmail.com](mailto:irenecambrabadii@gmail.com)

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### Abstract

The use of commercial films in medical education is an increasingly widespread pedagogical resource, and particularly the Cinemeducation method provides a theoretical basis as well as documented background on this pedagogical innovation. In this paper, we propose the use of a commercial film for teaching pharmacology, particularly pharmacovigilance and adverse effects of drugs, topics that are usually very complex for medical students. The rigorous method followed in the choice of the film and its scenes is detailed, as well as the methodological sequence of its use in class. The selected film, *La fille de Brest* by Emmanuelle Bercot, is based on the true story of Irène Frachon, a French doctor who begins to detect cases of cardiotoxicity associated with the consumption of a drug and undertakes a legal battle against the pharmaceutical company that produces and distributes it. The film reveals in detail the epidemiological study carried out at Brest Hospital and also the role of safety, pharmacovigilance and public health agencies in a complex plot that allows key aspects of pharmacovigilance to be discussed with medical students.

**Key words:** cinemeducation; education; pharmacology; adverse drug reactions; pharmacovigilance.

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### Resumen

El uso de películas comerciales en la educación médica es un recurso pedagógico cada vez más extendido, y particularmente el método de Cinema-educación proporciona tanto una base teórica como antecedentes documentados sobre esta forma de innovación pedagógica. En esta ocasión, proponemos la utilización de una película comercial para la enseñanza de la farmacología, particularmente de la farmacovigilancia y los efectos indeseables de los medicamentos, temas que suelen ser muy complejos para estudiantes de Medicina. Se detalla el método riguroso de selección del film y sus escenas, así como la secuencia metodológica de su utilización en clase. La película elegida, *La doctora de Brest* (2016) de Emmanuelle Bercot, se basa en la historia real de Irène Frachon, una médica francesa que comienza a detectar casos de cardiotoxicidad asociados al consumo de un medicamento y libra una batalla judicial contra la compañía farmacéutica que lo produce y comercializa. El film revela en detalle el estudio epidemiológico llevado a cabo en el Hospital de Brest y también el papel de las agencias de seguridad, farmacovigilancia y salud pública en una trama compleja que permite debatir con los estudiantes de Medicina aspectos clave de la farmacovigilancia.

**Palabras clave:** cinema-educación; educación; farmacología; reacciones adversas a medicamentos; farmacovigilancia.

### Technical details

**Title:** *150 milligrams*.

**Original title:** *La fille de Brest*.

**Country:** Francia.

**Year:** 2016.

**Director:** Emmanuelle Bercot.

**Music:** Martin Wheeler.

**Photography:** Guillaume Shiffman.

**Film editor:** Julien Leloup.

**Screenwriter:** Emmanuelle Bercot.

**Cast:** Sidse B. Knudsen (Irène Frachon), Benoît Magimel (Antoine Le Bihan), Patrick Ligardes (Bruno Frachon), Raphaël Ferret (biostatistical), Christophe Meynet (research collaborator), Nicolas Moreau (professor Launay), Luc Gentil (Chairman of the Afssaps commission (Pharmaco)), Alain Cauchi (Chairman of the Afssaps commission (AMM)), Claire Conty (Chairman of the Afssaps commission, Risk management), Ahmed Khalifa (cardiac surgeon), Philippe Ménasché (expert cardiologist, Afssaps commission), Bruno Rodet (Director CNAM), Nicolas Buchoux (AMM commission laboratory expert), Eric Toledano (expert laboratory of the Pharmacology commission), Emilie Martin-Ozanne (legalistic doctor), Mireille Lescouet (legalistic

medical assistant), Patricia Baley (research nurse), Aurélia Le Hir (research nurse), Lydia Le Vourc'h (research nurse), Sylvie Le Gouil (smoking patient), Charlotte David (young asthmatic), Aurélie Mestrius (resuscitation nurse), Hafida Benyagoub (CHU secretary), Philippe Sprang (*Le Figaro* journalist).

**Color:** Color.

**Runtime:** 128 minutes.

**Genre:** Drama.

**Language:** French.

**Productions companies:** Haut et Court, France 2 Cinéma, Canal+,...

**Synopsis:** The film is based on Dr. Irène Frachon's book *Mediator® 150mg. Combien de morts?*, that describe the research that faces disdain and threats from those who prioritize their economic interests and belittle the health problems of French consumers. In 2010, the French Social Security estimated that at least 500 people would have died; but according to forensic reports, Mediator® could have caused 2,100 deaths during the 30 years that was in the market.

**Awards:** César Award (Francia, 2017): Nomination for Best Actress (Sidse Babet Knudsen), Best

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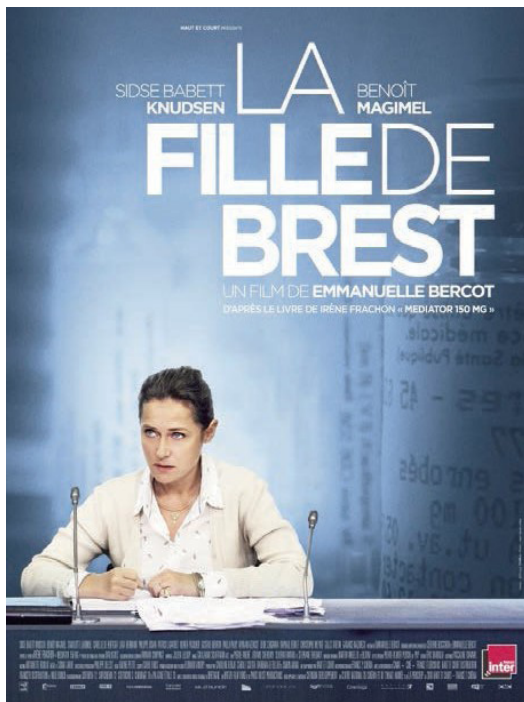
Adapted Screenplay (Séverine Bosschem and Emmanuelle Bercot). Lumière Award (Francia, 2017): Nomination for Best Actress (Sidse Babet Knudsen).

## Links:

<https://www.imdb.com/title/tt5247544>

<https://www.filmaffinity.com/es/film406770.html>

## Trailer



French poster.

## Background

Since the birth of cinema, feature films have been used as a teaching tool in medicine<sup>1-3</sup>. Films are a rich resource that allows viewers to engage deeply with biomedical subjects, favoring the assimilation of complex concepts and sparking interest in the object of study<sup>4</sup>. They

also portray different perspectives of the medical experiences<sup>3,5,6</sup> and offer models of behaviour and professionalism.

The term *Cinemeducation* refers to the use of films or video clips in medical education<sup>7,8</sup>. A literature review shows many experiences using this activity for teaching different knowledge areas such as psychiatry and mental health<sup>9-11</sup>, acquisition of communication tools<sup>5</sup>, understanding of disease<sup>12</sup> or the resolution of bioethical conflicts<sup>13</sup> but there is scarce literature regarding its use in basic medical sciences such as pharmacology<sup>14-16</sup>.

Pharmacology may be a difficult subject for medical students because it is very wide and varied, with a large number of drugs that they should know and remember. Moreover, some aspects of drug use might be difficult to understand for naïve students. The use of cinema in teaching pharmacology is relatively recent<sup>17</sup>. In most of the cases, feature films have been used to deepen in social aspects of the use of drugs or their use in the clinical research process as well as the ethical aspects linked to them.

Pharmacovigilance is one of the most important activities of clinical pharmacology. It is devoted to the detection, assessment, understanding and prevention of adverse effects associated with the use of drugs<sup>18</sup>. Some students may find most of the processes of pharma-covigilance hard to understand, especially those related to how the decisions about a safety concern are taken, as well as the different leading roles in the decision to recommend changes in the Summary of Product Characteristics or to advise the withdrawal of the drug.

Since *Cinemeducation* may enhance students' learning and understanding of pharmacovigilance processes and the adverse drug reactions, we present our methodological proposal<sup>19</sup> regarding film choices, their use in the teaching activity *Cinemeducation* and its evaluation for a Pharmacology course in medical schools.

### Choice of the film

The first step was the choice of the feature film to be used in the teaching activity. A systematic search of films of interest regarding adverse drug reactions and pharmacovigilance was performed using the IMDb platform (Internet Movie Database), the most complete and currently accessible online movie database. To begin with, a keyword search was carried out, duplicates were eliminated and exclusion criteria were applied. Horror or science fiction films, titles in production or discontinued and films not dubbed or subtitled in Spanish were excluded, as they might hinder the teaching activity. Their synopsis and plots were reviewed to select the final list of films. Systematic search and selection of the film for the didactic activity is shown in Table 1 and the final list of 15 selected films appears in Table 2.

**Table 1. Search process and selection of films by keywords.**

Search by keywords		RD	EC+RS	SM
Side effects	4	4	0	
Medication side-effects	6	5	2	
Side effect	20	20	4	
Pharmaceutical	20	20	2	
Pharmaceutical companies	3	3	0	
Pharmaceutical industry	21	17	2	
Pharmaceutical company	36	30	3	
Pharmaceuticals	25	17	2	
Adverse-reaction	3	3	0	
Drug testig	15	14	1	
Drug test	15	13	0	
Experimental drug	36	28	0	
Drug trial	6	2	0	
Total	195	176	16	15

RD: Removing duplicates.

EC+RS: Application of the exclusion criteria + Review of synopsis and arguments. SM: Selected movies.



**Photo 1.** The French doctor Irène Frachon.

*La fille de Brest* by Emmanuelle Bercot<sup>20</sup> was chosen due to the relevance that the drug adverse reactions play in the plot. It tells the true story of Irène Frachon, a French physician (Photo 1), who was faced with the first cases of cardiotoxicity associated with the consumption of *Mediator*, an anorectic, which were diagnosed in the Hôpital de Brest where she worked. After an investigation carried out in the hospital (Photo 2), Dr. Frachon requested the withdrawal of the drug, of which the active substance was benfluorex, and that was sold massively in France for more than thirty years. It caused the death of more than 500 people. The film showed the legal process she undertook in 2009 against the French pharmaceutical company Servier that marketed the drug (Photo 3).

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**Table 2. List of films chosen.**

Title	Release year	Country	Genre
<i>Bigger than life</i>	1956	United States	Drama
<i>Awakenings</i>	1990	United States	Biography, Drama
<i>A beautiful mind</i>	2001	United States	Biography, Drama
<i>I am alive today: history of an AIDS drug</i>	2002	France, Belgium	Documentary
<i>Side-effects</i>	2005	United States	Comedy, Drama, Romance
<i>The drugging of our children</i>	2005	United States	Documentary
<i>The constant gardener</i>	2005	United Kingdom	Drama, Mystery, Romance
<i>Dying for drugs</i>	2005	United Kingdom	Documentary
<i>Bigger, Stronger, Faster*</i>	2008	United States	Documentary
<i>Dallas Buyers Club</i>	2013	United States	Biography, Drama
<i>Side effects</i>	2013	United States	Crime, Drama, Mystery
<i>The big lie: american addict 2</i>	2016	United States	Documentary
<i>La fille de Brest</i>	2016	France	Biography, Drama
<i>Cause of death: unknown</i>	2017	Norway	Documentary
<i>120 battements par minute</i>	2017	France	Drama

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Nowadays, Servier is going on trial over this drug Mediator with the *Agence nationale de sécurité du médicament* (ANSM) and 21 defendants. They are facing more than 2,600 plaintiffs who believe the drug maker has deliberately misled patients for decades, helped by lenient authorities<sup>21</sup>.

The film also shows other important factors such as the relevance of a signal alert, the studies needed to confirm/reject the causality of an adverse drug reactions, the role played by the pharmaceutical industry and the public health agencies, the portrait of the investigation and the confrontation events among the doctor, the hospital team in charge of the epidemiological study and the staff of French agency of pharmacovigilance<sup>22</sup>. This combination of clinical, pharmacological and psychosocial aspects was considered of high didactic interest.

The film was reduced to a fifty-minute edition, suppressing secondary scenes to adjust it to the duration of the session and to focus students' attention on the subject of interest.

### The teaching activity

The first educative step after choosing the feature film was to define the general and specific objectives of the activity. Working with cinematic material is not meant to be a form of entertainment:

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the focus must remain on education. In order to follow these principles, we defined a list of educational objectives for the activity (Table 3).

The list of objectives allowed us to elaborate a list of items that should have been addressed in the material presented to students before they viewed the film and in the discussion afterwards. We prepared a short introduction to the film, including comments about technical characteristics, a summary of the plot, and the historical context of the story of the production.

The discussion took place immediately after the viewing, when the events in the film and the emotions they stirred were still fresh in students' minds. The moderator asked questions to prod students to discuss the issues dealt with in the film.



**Photo 2.** In the movie, Irène Frachon and Antoine Le Bihan during the investigation carried out in Brest's hospital.



**Photo 3.** In the movie, Irène Frachon in the legal process against the French pharmaceutical company Servier.

**Table 3. Learning objectives of the *Cinemeducation* activity.**

- + To learn the mechanisms of pharmacovigilance through the case of *Mediator*.
- + To discuss the social implications of pharmacovigilance.
- + To emphasize the importance of the signal alert and the studies needed to confirm / reject the causality of an adverse drug reaction.
- + To analyze the epidemiological study needed to prove the adverse drug reactions.
- + To establish drug's contraindications, interactions and precautions to take into account.
- + To reflect about the difficulties to take a decision to withdraw a drug.

### The evaluation

It is crucial to assess the effectiveness of the film-based activity in relation to our teaching goals. Students need to know from the start how the activity will be assessed and its weight in their final grade for the course. This emphasizes the fact that the film-based activity is an academic activity like any other. On the other hand, it is necessary to define the objective of this evaluation. We prepared a multiple choice questionnaire on the topics that students have observed in the film to compare the baseline knowledge before the activity and the knowledge gain after the intervention.

### Conclusions

In our experience of using cinema in teaching medicine, human biology and pharmacology, we have observed that, although there are theoretical bases to justify the importance of working with films, publications about rigorous experiences are scarce<sup>3,23</sup>. This is true for many innovations in teaching. As innovation in education is a complex process, it often stays in the classrooms and university meetings, and the experiments carried out do not always transfer to scientific publications. Educational innovation is a constant challenge, because it requires educators to be

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both creative and rigorous. The use of films is well valued in theory, but systematic studies providing empirical evidence of its pedagogical effectiveness are scarce.

Using films as a teaching strategy implies that they can constitute the main material of the class and are not just an entertaining component to complement other materials. In this direction, we consider that the use of a similar methodological approach may help to compare the results obtained by different research groups and to learn the comparative value of each feature film. In the present article we have suggested a simple sequence of actions that may help to carry out such common method, regarding the choice of the film, the *Cinemeducation* approach and the final evaluation. In this way we believe that the pre-post assessment using an objective tool, like multiple-choice questionnaires, may help to determine the knowledge gain that the activity provides.

*La fille de Brest* is a good example of how contextualizing pharmacological issues may give the students the possibility of understanding how to detect adverse drug reactions, the difficulties of establishing a causal relationship and the importance of pharmacovigilance to protect society against such undesirable effects of otherwise useful therapies. Empirical studies will show if this beliefs may translate in useful pedagogical tools.

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	<p>Irene Cambra Badii: Licenciada y Doctora en Psicología. Durante más de diez años, fue investigadora y profesora en la Universidad de Buenos Aires (Argentina). Completó su formación postdoctoral en la Universitat Pompeu Fabra (Barcelona) donde es miembro del Grupo de Investigación en Educación en Ciencias de la Salud (GRECS) en el Departamento de Ciencias Experimentales y de la Salud. Desde 2019 es investigadora en la cátedra de Bioética de la Universitat de Vic - Universitat Central de Catalunya.</p>
	<p>María de Lluç Francés: graduada en Medicina por la Universidad Pompeu Fabra de Barcelona. Colaboró con el Grup de Recerca en Educació en Ciències de la Salut (GRECS) como parte de su trabajo de fin de grado. Actualmente se encuentra preparando el examen MIR para continuar con su formación especializada.</p>
	<p>Magi Farre Albaladejo: Médico especialista en Farmacología Clínica. Catedrático de Farmacología en la Universitat Autònoma de Barcelona y Jefe del Servicio de Farmacología Clínica del Hospital Universitario Germans Trias i Pujol en Badalona (Barcelona). Anteriormente fue Consultor en el Instituto Hospital del Mar de Investigaciones Médicas-IMIM. Sus áreas de trabajo son la neuropsicofarmacología clínica, las drogas de abuso y las propiedades de los antioxidantes naturales. En el ámbito académico tiene interés en los métodos de innovación docente en Farmacología y Bioética.</p>
	<p>Josep-Eladi Baños: Doctor en Medicina. Ha sido profesor de Farmacología en la Facultad de Ciencias de la Salud y de la Vida de la Universitat Pompeu Fabra (2002-2018). Vicerrector de Docencia y Ordenación Académica en dicha Universidad (2005-2013). Ha dirigido el Grupo de Investigación Educativa en Ciencias de la Salud de la Universitat Pompeu Fabra (2016- 2019). Ha recibido diversas distinciones a la calidad de la innovación docente de la Generalitat de Catalunya. Desde 2019 es Rector de la Universitat de Vic - Universitat Central de Catalunya.</p>