VNIVERSITAT DE VALÈNCIA

Course Guide
34073 Documentation and Scientific Methodology

COURSE DATA

Data Subject	
Code	34073
Name	Documentation and Scientific Methodology
Cycle	Grade
ECTS Credits	4.5
Academic year	2020 - 2021

Study (s)

Degree	Center	Acad. year	Period
1201 - Grado de Farmacia	Faculty of Pharmacy	1	First term
1211 - PDG Farmacia-Nutrición Humana y Dietética	Faculty of Pharmacy	1	First term

Subject-matter

Degree	Subject-matter	Character
1201 - Grado de Farmacia	36 - Scientific methodology and documentation	Obligatory
1211 - PDG Farmacia-Nutrición Humana y Dietética	1 - Asignaturas obligatorias del PDG Farmacia-Nutrición Humana y Dietética	Obligatory

Coordination

Name	Department
VIDAL INFER, ANTONIO MARTÍN	225 - History of Science and Documentation

SUMMARY

What is usually called "scientific method" is a set of theoretical and experimental practices very diverse characteristics vary over time and space and across disciplines and various fields of science. Even within a single scientific discipline, there are diverse views on the best ways to get sufficiently used to produce new knowledge. Therefore, in this block use the expression "scientific methodology" to refer to the heterogeneous set of strategies, procedures, reasoning, experimental practices, observational methods, etc. following scientists in their investigations, which are developed in a variety of places (observatories, laboratories, geological sites, hospitals, factories, etc..), often with the help of scientific instruments of very different characteristics. And all this in the context of certain societies and cultures very variable condition of the development of scientific activity over time.

In parallel to the great development and has taken on dimensions that modern science during the twentieth century, the discipline of information science has developed a range instruments for recording scientific production and facilitate rapid access to accurate information. Likewise, the large expansion that has seen the Internet as a communication and dissemination of information made available to researchers and users a lot of resources and information sources, regardless of spatial boundaries and intermediaries, so is essential from the field of training to introduce students to the knowledge and use of these tools and resources to be able to develop the skills to locate and manage the information they need or may be of interest to the exercise in their professional and research activities.

The aim of the course is to provide basic concepts and schemes to address the issue through various special cases (seminars). First, we discuss several specific topics, closely related to the pharmacy: anatomical dissection, animal experimentation and clinical trials. It is also dedicated to a specific scientific terminology along with a brief introduction to the various types of scientific instruments.

PREVIOUS KNOWLEDGE

Relationship to other subjects of the same degree

There are no specified enrollment restrictions with other subjects of the curriculum.

Other requirements

Previous requirements or recommendations

Being an introductory course, no prerequisites are required apart from skills and knowledge provided by high school studies. However, it should be noted that the theoretical and practical seminars involve the use of a great deal of abstract thinking, adoption of a diachronic analysis and dealing with various societies and cultures.

OUTCOMES

1201 - Grado de Farmacia

- Development of skills to update their knowledge and undertake further studies, including pharmaceutical specialization, scientific research and technological development, and teaching.
- Ability to collect and transmit information in English with a level of competence similar to the B1 of the Council of Europe.
- Module: Legislation and Social Pharmacy to master information retrieval techniques related to primary and secondary information sources (including databases by using computers) and computerized.
- Module: Legislation and Social Pharmacy - Know the techniques of oral and written communication by acquiring skills that allow informing users of pharmaceutical establishments in terms intelligible and appropriate to various cultural levels and social environments.

LEARNING OUTCOMES

We want students to think of science as a highly complex activity, related to society and the culture in which it is developed. Therefore, some aspects of the relationships between science, technology and society will be discussed, in order to offer keys that allow reflection on the working methods of science and its role in society. It aims to promote humanistic and interdisciplinary training, so that the student can favor the integration of their knowledge in a critical and autonomous way and address the analysis of situations in which knowledge of various disciplines are required.
A broad and multi-faceted vision of the different aspects that constitute the scientific methodology will be offered, as well as a discussion of a great variety of topics associated with this methodology in biomedical subjects. That is why we have articulated the agenda in four blocks: a general approach to what science is and how it works; an anthropological approach from the perspective of medicine and pharmacy; a sociological and historical approach, particularly to the pharmaceutical profession over time, as well as mechanisms for dissemination and communication of knowledge among different audiences; and, finally, a perspective from the technical particularities that intervene: scientific instruments, animal experimentation and clinical trials.
In this subject an introduction to the sources of scientific information will be made, defining the main documentary typologies, characterizing their informative usefulness and the forms of access to them. The procedures to identify and select the desired information in the systems for the provision of scientific information, identifying the main existing databases in the health sciences, and the search strategies and interrogation techniques most appropriate to identify the documents will be presented. that allow to satisfy the informative needs of the user. In addition, some of the existing tools and procedures for managing and evaluating selected documents of interest will be presented.

DESCRIPTION OF CONTENTS

1. Introducing Documentation and Scientific Methodology

2. The methods of Science

3. Science in movement: scientific revolutions

4. Science frontiers and the other ways of knowledge

5. The social construction of illness

6. The social life of medicines

7. The language of Science

8. The Scientific communication

9. Discipline and profession

10. Health Sciences and Gender

11. The consciousness of Science: Bioethics

12. A necessary evil: experimenting on animals

13. Testing therapies in humans: clinical trials

14. Evidence-Based Medicine

15. Science, Medicine, and Technology

16. The pharmaceutical industry

17. Intellectual property: patents

18. Needs and uses of information in Pharmacy

19. Primary sources of scientific information in Pharmacy

20. Bibliographic searches in Pharmacy

-Design of search strategies
-Searches in Health Sciences specific databases: Pubmed and Embase
-Searches in multidisciplinary databases: Web of Science and Scopus

21. Secondary sources of scientific information in Pharmacy: databases

22. Citations, impact and how to manage information in Pharmacy

WORKLOAD

ACTIVITY	Hours	% To be attended
Theory classes	25.00	100
Seminars	10.00	100
Computer classroom practice	5.00	100
Tutorials	2.00	100
Development of group work	30.00	0
Study and independent work	8.00	0
Readings supplementary material	2.50	0
Preparation of evaluation activities	25.00	0
Preparation of practical classes and problem	2.00	0
TOTAL	**109.50**	

TEACHING METHODOLOGY

Theoretical classes

We consider that the theoretical classes should not assume in any case passivity on the part of the students. For this we opted for an operation of the class based on the so-called flipped classroom. This implies previous work of the student to prepare the contents and readings proposed in advance by the teacher.During the face-to-face session, debates and complementary explanations will be organized. Additionally, the teacher can propose, explain and develop specific activities during the session.
To prepare the theoretical sessions, develop the practices and be able to study the subject, the following manual is necessary:
Carmel Ferragud and Antonio Vidal (coords), Ruth Lucas and José Ramón Bertomeu, Documentation and methodology in Health Sciences, Valencia, Nau Llibres, 2017.

This book can be consulted in different libraries of the UV, and can be purchased at https://naullibres.com/libro/documentacion-y-metodologia-ciencias-la-salud

Power point presentations that teachers use will not be accessible in the Virtual Classroom. Any information that students consider appropriate to pick up should be taken during the classes or obtained through the manual, other materials shared by the teachers or the recommended bibliography.
During the theoretical sessions, 5 activities will be proposed for the whole subject that will be carried out during the session and will be delivered at the end of the session, without prior notice of when they will be carried out.
Practical classes
The practical sessions, of compulsory attendance, consist of 5 seminars and 2 practical sessions of computer science.
The seminars will be the following:

Seminar 1 UV Library

Seminar 2 Searches

Seminar 3 Scientific article

Seminar 4 Impact and visibility of research

Seminar 5 Manage information

The computer practices will be:

Session 1: Search in specific databases in health sciences: Pubmed and Embase

Session 2: Search in multidisciplinary databases: Web of Science and Scopus.

The realization of the exercises will take place in computer rooms where the students will work with computers individually or in pairs, according to the availability of equipment. The faculty of the subject will indicate in advance the contents that the students must have consulted or read in order to perform the corresponding exercise.
The content worked during the sessions will be sent at the end of the sessions through the Virtual Classroom. Exceptionally, the faculty may extend the deadline if the situation so requires.
During the semester the students will develop a monographic work, in groups of 4 or 5 components, on a topic related to the subject. The subjects under study will be the following:

1. The world of anxiolytics: benzodiazepines.
2. Analgesics and antipyretics.
3. Anti-inflammatories: ibuprofen and dexketoprofen.
4. Antibiotics: amoxicillin.
5. Vaccines: the case of HPV.
6. The treatment of chronic pain: opioids.
7. Attention deficit hyperactivity disorder: methylphenidate.
8. The treatment of obesity.
9. Degenerative diseases: Alzheimer's, ERA.
10. The pharmacological approach to drug addiction.

Both the composition of these groups and the assignment of the subject will be done randomly by the faculty of the subject from the beginning of the same, without the possibility of changes.A connection should be made between the topics studied in the theoretical sessions and the topic of analysis. For this purpose, information searches should be carried out in the appropriate databases and following the instructions given by the teachers in the documentation part. In this way, for example, it is necessary to analyze how the pharmaceutical industry has been present in the research and development process of a drug or group of medicines; how they have handled animals and conducted clinical trials; what social and economic repercussions this medicine has had; its accessibility; how it has been received among the public, its success or failure, etc. For this it is also possible to manage other sources of information beyond the scientific journal, such as newspapers, blogs, or other media. In short, it is about making an approach as deep and plural as possible to the world of medicine. In addition, we intend to have a critical view of the set of information handled.

The objectives of this work are:

- encourage cooperation among students

- develop an investigation that simulates as closely as possible the different phases of a research process in the world of biomedicine

- foster a critical spirit, with as broad a view as possible towards the subject that has been proposed as the thematic axis

- offer the results of this work following the most common vehicle in science: the journal article

This work will have the following formal characteristics:

- a scientific article structure, with the following sections: Introduction, Material and method, Results and Discussion, Conclusions.

- The bibliography should be done following the Vancouver style of citation.

- a maximum of 30 pages in doc, docx or rtf format (Times News Roman 12, interlinear 1,5).

- the work may have figures or images duly described and cited.

- a conceptual map with the basic information handled will be presented.

- IMPORTANT: the teaching staff can reject those works that do not meet the minimum conditions of formal correction (spelling, grammar, etc ...)

In order to develop this work conveniently, the group members should be in contact with certain frequency. It is suggested to use possibilities such as videoconferencing to maintain contact and resolve situations that are not possible directly in the faculty.
The two tutoring sessions will be dedicated to keeping track of the work by the teachers. During these sessions the groups can take advantage to advance and resolve any doubts that may arise. We also suggest using individual tutoring sessions.

EVALUATION

It will be necessary to obtain a minimum grade of 5 out of 10 in order to pass the subject.

Theoretical evaluation:

a final written exam will be carried out, which will mean 60% of the grade. It will be necessary to obtain a minimum grade of 4 out of 10 in the exam to be able to average with the practical part. It will consist of 4 short questions [half page maximum], 1 essay question and 2 practical cases about bibliographic searches.

Practical evaluation:

-Monographic

A monographic work in group will be presented, which will represent 20% of the grade, in the terms explained above. The deadline for delivery of the work, through the Virtual Classroom, will be determined by the faculty and notified on the first day of class. The non-presentation of the monographic work will imply a grade of Not presented in the subject. A grade lower than 4 out of 10 in the monographic work will suppose a fail in the subject.

-Works delivered in class

After the conclusion of the practical sessions, those activities proposed by the teaching staff will be delivered. The joint qualification of these activities may reach 20%.

REFERENCES

Basic

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- Ferran Ferrer N, Pérez-Montoro Gutiérrez M. Búsqueda y recuperación de la información. 1ª en lengua castellana ed. Barcelona: Editorial UOC; 2009
- Fara P. Breve historia de la ciencia. Barcelona: Ariel; 2009.
- Bowler P, Morus I. Panorama general de la ciencia moderna. Barcelona: Crítica; 2007
- Collins H et al. El gólem: lo que todos deberíamos saber acerca de la ciencia. Barcelona: Crítica; 1996
- Cordón García JA. Las nuevas fuentes de información: información y búsqueda documental en el contexto de la web 2.0. Madrid: Pirámide; 2010.

Additional

- Informe APEI sobre acceso abierto | E-LIS. E-prints in Library and Information Science Disponible en: http://eprints.rclis.org/handle/10760/12507. Fecha de acceso 5/31/2011, 2011.
- Cordón García JA, López Lucas J, Vaquero Pulido JR. Manual de investigación bibliográfica y documental: teoría y práctica. Madrid: Pirámide; 2001.
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- Hernández Sampieri R, Fernández Collado C, Baptista Lucio P. Metodología de la investigación. 5a ed. Madrid: McGraw-Hill; 2010
- Jiménez Villa J, Argimón Pallás JM, Martín Zurro A. Publicación científica biomédica: cómo escribir y publicar un artículo de investigación. Barcelona: Elsevier Science; 2010
- Pinto Molina M, Mitre M, Doucet A, Sánchez MJ. Aprendiendo a resumir: prontuario y resolución de casos. Gijón: Trea; 2005

ADDENDUM COVID-19

Teaching methodology

The theoretical content of the subject, more related to the topics of Scientific Methodology, will be taught during the theoretical sessions established in the schedule.
Master class sessions: Teaching will be in person until the first week of November (provided that the current pandemic situation allows it). From this moment on, the theoretical classes will continue to be taught via synchronous videoconference. The materials for each topic will be previously posted in the Virtual Classroom (slides and readings of interest). During the work session in the classroom, and then with Blackboard, various participatory strategies will be presented. Discussion forums will be opened where students are invited to participate with questions about the session. Other activities will be questionnaires, comments on video clips, pictures or short articles. These activities will be uploaded in the Virtual Classroom at a certain time within the session and will form part of the continuous evaluation.
These activities will alternate with the teachers' comments and master explanations supported by power point.
Students must prepare five essays based on the theoretical content that the teachers will indicate. In these, they should capture what they have learned through the readings and previous works carried out, the contributions of the classmates in the forum and personal reflection. Direct copying of any material will be penalized. Students will receive individualized comments and the essays will show a student evolution, thus reinforcing the idea of continuous evaluation.
Practical teaching (Individual and collaborative work)
The theory related to Documentation will be integrated into the development of practical sessions and seminars, directly in the computer room.
Compilation through the "Task" option of the virtual classroom of the practical activities at the stipulated time. The practical sessions and seminars may be replaced by a combination of videoconferences, locutions within the explanations, forums and resolution of activities through the virtual classroom.
Group tutoring
The main objective is to offer a working technique, the conceptual map, and end up configuring one of the theme that has been developed, and which will also be a part of the final grade. The face-to-face tutorial sessions may be replaced by a combination of videoconferences, locutions within the explanations, forums and resolution of activities through the virtual classroom.
On the other hand, the virtual tutoring program is maintained (consultations by email or through the virtual classroom tutoring forum).

Evaluation

-Continuous Assessment Itinerary: Students' learning will be assessed around the two types of teaching modalities described:

1) Evaluation by the teacher: modality of evaluation that implies a process by which the professor by means of some questionnaires or on-line essays and the realization of practices by part of the student will value the knowledges acquired by the students.

2) Student self-assessment: assessment modality that involves a process by which the student analyzes and evaluates their own activities by completing the online questionnaires.
Evaluable activities: 5 essays referring to theoretical teaching (40%); 2 Computer practices (20%); 5 computer room seminars (20%); Conceptual maps (10%); Forum participation (10%).

-Final exam itinerary: Theoretical exam (60%); Computer practices and seminars (40%).

Documentation and Scientific Methodology
Course Syllabus 2020-2021

1. Introduction

I. WHAT IS SCIENCE?

2. The methods of science (2 sessions)
3. Science in movement: scientific revolutions

II. ANTHROPOLOGY OF HEALTH AND DRUGS

4. The social construction of illness
5. The social life of medicines

III. SOCIOLOGY AND HISTORY OF PHARMACY

6. The language of science (2 sessions)
7. Scientific communication (2 sessions)
8. Discipline and profession (2 sessions)
9. Health and gender sciences
10. The consciousness of science: Bioethics

IV. TECHNOLOGIES APPLIED TO DRUGS

11. A necessary evil: animal experimentation
12. Testing therapies in humans: clinical trials (2 sessions)
13. Science, medicine and technology (2 sessions)
14. The pharmaceutical industry (2 sessions)
15. Intellectual property: patents

[General review of the course. Questions and queries. Exam preparation]

V. DOCUMENTATION

16. Needs and uses of information in Pharmacy
17. Primary sources of scientific information in Pharmacy
18. Bibliographical searches in Pharmacy
19. Secondary sources of scientific information in Pharmacy: databases
20. Citations, impact and information management in Pharmacy

DOCUMENTATION AND SCIENTIFIC COMMUNICATION

ACADEMIC YEAR 2020-2021

The essays

If you have chosen the evaluation track consisting of five essays, you must upload your essays by the deadlines stipulated.

These essays must:

- be submitted in Word or ODT format (if in doubt, use PDF).

- contain a maximum of 1,500 words (please adhere as closely as possible to this guideline).

- comprise an original title and your composition (which must be related to the topic).

They must not:

- have any subsections.

- contain misspellings or inaccurate wording.

To write your essays you can draw on the following materials: the PowerPoint for this subject, the manual, any explanations (annotations), any comments made in the forums, and the specialised bibliography.

My correction of your first essay will be personalised and exhaustive. For the next essays, I will make comments in general to the group. Any personal questions you may have will be resolved via online tutorials.

After you have received my evaluation of your first essay, you must decide whether to choose this assessment route or, alternatively, whether you prefer to take the final examination.

Any student who submits copied work will receive a grade of zero for that work and risks being sanctioned. Remember that the University has a plagiarism detector program.

Participation in forums

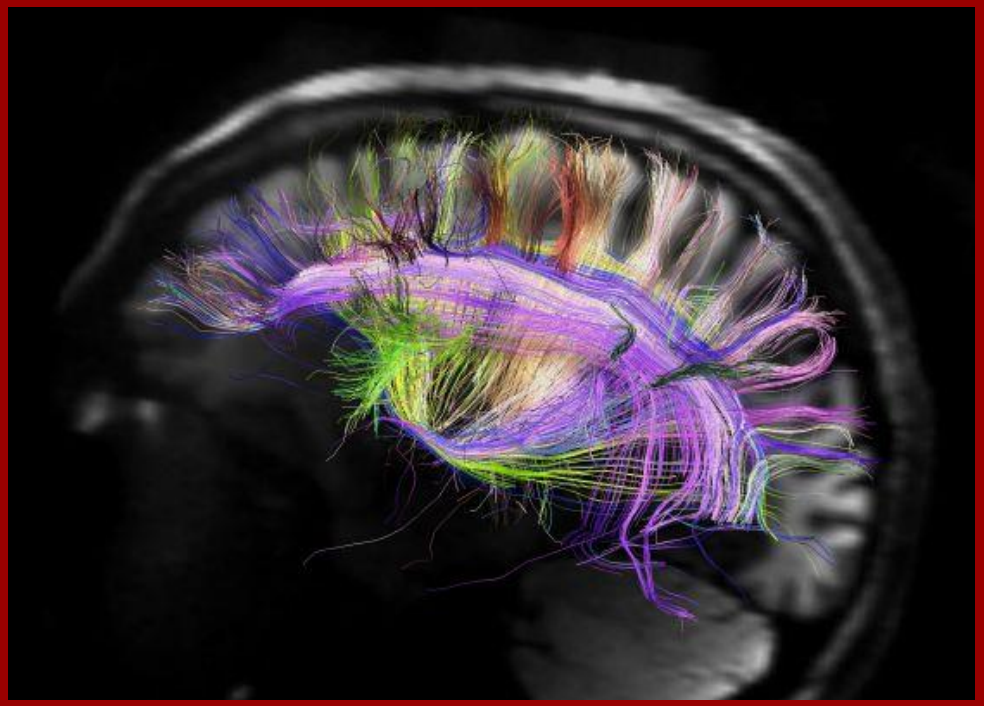
At the beginning of each topic you will find an activity in the student guide. You must answer the questions set in that activity 48 hours before the class begins. This means that if the class is held on Wednesday, you must answer the questions before 12 pm on Monday.

You must answer the questions with your own personal reasoning. A simple ‘yes’ or ‘no’ is not permitted. Nor must you answer in relation to comments from other students unless you are also adding something new.

ESSAYS

RUBRIC

1. The essay contains numerous misspellings.
2. The written expression is unsuitable or inaccurate. Some sentences are difficult to understand.
3. Punctuation is insufficient and/or there are no paragraphs.
4. Not enough ideas are presented about the topic.
5. The structure (title, introduction, development, and conclusion) is not coherent.
6. The text is either too long or too short.



Documentation and Scientific Methodology: Introduction

VNIVERSITAT DE VALÈNCIA

Carmel Ferragud, Mar Cuenca, Rut Lucas, Antonio Vidal-Infer, Juan Carlos Valderrama

Documentation and Scientific Methodology
Degree in Pharmacy

General remarks

- This subject combines several areas of knowledge, including Scientific Documentation, the History of Science, Anthropology, Sociology, and Epistemology.
- It is designed from the perspective of the Bolonia process.
- It is based on a new innovative teaching project.
- It takes into account the construction of knowledge by students.
- It involves continuous in-class participation and discussion.

General remarks

- Read the COVID-19 addendum (page 9 of the teaching guide).
- Face-to-face classes will take place until the first week of November. Theoretical classes will then continue to be taught via synchronous videoconferences (using Blackboard Collaborate).
- Practical sessions will always take place in face-to-face mode.

Structure

Theoretical sessions

- Scientific Methodology: Introduction and 14 lessons.
- Documentation: Introduction and 5 lessons.

Practical sessions

- Attendance is compulsory.
- 5 seminars and 2 practical IT sessions (you are advised to bring a USB).

Tutorials

- Attendance is compulsory.
- Two sessions.

Assessment

1. **Continuous Assessment itinerary.** Learning will be assessed by:

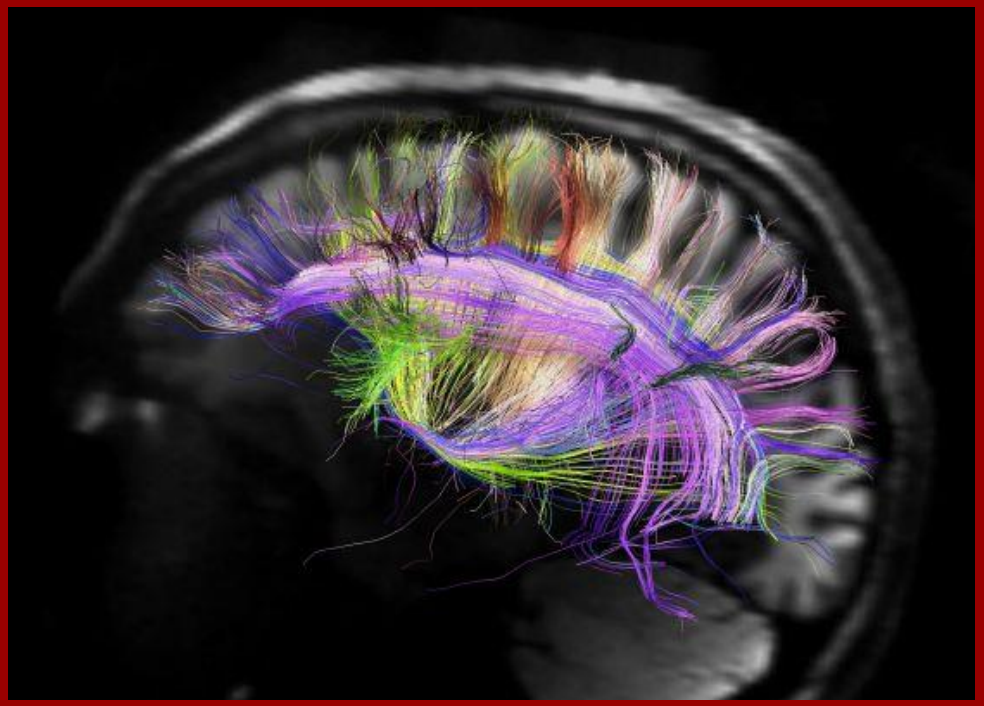
- 5 essays based on theoretical content (40%).* Check the document in the Virtual Classroom.
- 2 Computer practice sessions (20%).
- 5 Computer room seminars (20%).
- Conceptual maps (10%).
- Participation in the forum (10%). * Check the document in the Virtual Classroom.

Assessment

2. Theoretical assessment (60%):

You will be required to take a final written examination. You will need to obtain a minimum score of 4 on this exam for your practical work to be taken into consideration. This exam will comprise:

- One long question. You will need to choose from one of two options.
- Four short questions (answers of less than half a page) on specific parts of the syllabus. Your ability to connect ideas and concepts will be evaluated.
- Two practical cases relating to bibliographic searches.



Scientific Methodology: Introduction

Carmel Ferragud, Mar Cuenca, Rafaela Domínguez **Documentation and Scientific Methodology**
History of Science knowledge area Degree in Pharmacy

The Three Greats

- SCIENCE IN HISTORY
- SCIENCE IN ACTION
- SCIENCE IN SOCIETY

What can history do for us?

- There is an undeniable need for a historical perspective.
- History has its place in referential frameworks and the values of the profession.
- It presents a global (holistic) vision against increasing specialisation in the Health Sciences.
- It provides an ethical and intellectual stimulus.

Science in action

- A perspective that can question conventional and idealised images of science:
  - How do we obtain valid data; how do we construct explanations and theoretical models, etc.?
  - How should we use tools and what is the role of experimentation (including on animals)? How do we estimate and control error margins, etc.?
  - How can we study the efficiency of a drug? How do we write a scientific article?
  - How does scientific change happen? How do great revolutions occur?

Science in society

- Pharmacy is not developed in a laboratory alone but especially in industry, shops, hospitals and homes.
- Medical and pharmaceutical knowledge does not exist independently from social, political, cultural and economic contexts.
- This knowledge is socially constructed and in constant interaction with other forms of knowledge.

Unknown, Pharmacy (c. 1508)

Aims of the subject

1. To study the **fundamentals of Scientific Methodology** and learn how to apply scientific method in **practice.**
2. To critically examine the **social implications of technology and scientific change in the health sciences.**
3. To analyse the basic features of how **health worker terminology** is formed.
4. To become **reflectively aware** of what health, illness and death have always meant to people.
5. To become aware of the excessive **medicalisation** and **expropriation of health** in our society.

Aims of Documentation

The **sources of scientific information** will be introduced. The main documentary typologies will be defined, their informational utility will be described, and how they can be accessed will be explained.

Procedures for identifying and selecting the desired information in scientific information delivery systems will be described.

- The **main health science databases** will be identified.
- The most suitable **search strategies and interrogation techniques** for identifying documents that meet the user's information needs will also be identified.

DOCUMENTATION: Practical sessions and seminars

VPN

- ✓ **Seminar 1**: The UV Library
- ✓ **Seminar 2**: Searches
- ✓ **Seminar 3**: Scientific articles
- ✓ **Seminar 4**: The impact and visibility of research
- ✓ **Seminar 5**: Information management
- ✓ **Computer practice 1**: Search in specific Health Science databases: PubMed and Embase
- ✓ **Computer practice 2**: Search in multidisciplinary databases: Web of Science and Scopus

Materials for this subject

Syllabus

Chapter guides, available in the Virtual Classroom

PowerPoint

Handbook: Carmel Ferragud y Antonio Vidal (coords), Rut Lucas i José Ramón Bertomeu, *Documentació i metodologia en Ciències de la Salut,* Valencia, Nau Llibres, 2017. https://naullibres.com/libro/documentacion-y-metodologia-ciencias-la-salud

Notes or articles needed to complete the tasks

Tutorials

- Virtual tutorials (videoconference)
- Virtual tutorials (by e-mail)

maria.mar.cuenca@uv.es

Answers will be provided within 48 hours (Monday to Friday)

Theme 2. Scientific Methods

Introduction

In this theme our aim is to offer a view of "scientific methodology" as a mixed bag of strategies, procedures, reasoning, experimental practices, observational methods, and so on, that the people who work in science follow during their research. This is carried out in a great variety of places (astronomical observatories, laboratories, geological deposits, hospitals, industry, etc.), often with the help of scientific instruments whose characteristics are very varied. All this takes place in the context of particular societies and cultures that over time condition the development of scientific activity very variably.

Contents

Objectives

- Learning about the mixed bag of strategies, procedures, techniques and reasoning that people who work in science adopt during their research
- Understanding how the production of scientific facts is constructed, by observation and by experimentation, as well as by the different types of hypotheses and explanations
- Understanding particularity and the relationship between data and explanations
- Reflecting on the *ethos* and the characteristics typical of modern science based on Merton's sociology
- Reflecting on the processes of self-regulation of science and having a critical view with respect to the limitations
- Learning and correctly explaining the different forms of scientific reasoning
- Analysing how scientific knowledge is produced and its circulation
- Understanding the role of scientific instruments and the problem of their acceptance and use
- Knowing the importance of the systems of units in instrumental measurements, their variety and complexity and importance in standardization processes

- Approaching the reality of science through the criticism made of radical inductivism by different researchers: Popper's "falsationism", Kuhn's "paradigms", and Pestre's "regime of knowledge"
- Being able to explain complex theoretical concepts
- Adopting a more mature view of science in accordance with what the history and sociology of science have shown us

Previous activity

Reading: Text by Pablo Jensen, "La ciencia", *Le Monde Diplomatique* (in Spanish), 177 (July 2010, pp. 20-21

La ciencia*
por Pablo Jensen **

* El título, en la edición francesa original (junio de 2010), era "L'histoire des sciences n'est pas un long fleuve tranquille" (La historia de las ciencias no es un largo río tranquilo).
** Pablo Jensen es investigador del Centro Nacional de Investigación Científica (CNRS) en la Escuela Normal Superior de Lyon; autor de *Des atomes dans mon café crème: la physique peut-elle tout expliquer?* (Átomos en mi café con crema: ¿la física puede explicar todo?), París, Seuil, 2004.

La creencia en que la ciencia avanza sin cesar en el conocimiento de una realidad estable, limitada y siempre igual a sí misma es de un candor insostenible, heredero del optimismo del siglo XIX.

La ciencia, tal como se enseña hoy, parece producirse de forma lógica, basándose cada investigador en las teorías precedentes para elaborar las suyas. Pero esta imagen de un flujo lineal que conduce de una forma natural a la verdad científica queda rota por lo estudios sociales sobre la investigación.

Las ciencias experimentan dificultades para encontrar su lugar en la sociedad. El ejemplo de las actuales controversias sobre las biotecnologías lo ilustra bien: los biólogos se encuentran entre dos fuegos; desde ambos lados les cuestionan su aislamiento en la torre de marfil de la investigación "fundamental". Por un lado, el poder económico privilegia, a través de algunos financiamientos, la investigación con objetivos de aplicación, y exige el secreto y la inscripción en patentes. Por el otro, el público rechaza el papel de espectador pasivo que durante mucho tiempo se le ha asignado, y se rebela contra algunas ignorancias científicas, por ejemplo sobre los efectos de los organismos genéticamente modificados (OGM) en pleno campo. Todos los ámbitos científicos se encuentran presos de esta contradicción, que remite al viejo ideal de la ciencia pura, rechazando las "deformaciones inherentes a las contingencias económicas y sociales" (1).
En estos últimos años, los estudios de historia social de la ciencia, que iniciaron con gran vigor Alexandre Koyré y luego Thomas Kuhn (2), renovaron totalmente el enfoque de estas cuestiones y, más ampliamente, la manera de concebir el lugar de la ciencia en la sociedad. Estos trabajos se refieren en primer lugar a la Revolución Científica, que está en el origen de las ciencias modernas, con frecuencia presentada como la victoria de la razón frente, especialmente, a una iglesia oscurantista. Un error. La mayor parte de los sabios como, por ejemplo, Isaac Newton, eran profundamente creyentes y pensaban que "descubrir las leyes de la Naturaleza gracias a la física es descubrir las obras de una providencia soberanamente inteligente, es convencerse de que la organización del mundo no es producto del azar" (3). Mucho más que en el surgimiento repentino de la

Luz, es en la declinación de las antiguas jerarquías –gracias a la difusión de las ideas por la imprenta– y en la agitación suscitada por el descubrimiento del Nuevo Mundo donde hay que buscar la fuente de esta Revolución. Entonces, las nuevas ciencias abandonaron la concepción de la Naturaleza como una maravilla gobernada por principios ocultos, para imaginarla parecida a una gigantesca máquina. Una máquina que sigue leyes regulares y necesarias, susceptibles de ser traducidas a un lenguaje matemático, y cuyo conocimiento hace posible la previsión y, por lo tanto, acciones racionalmente fundadas.

Lo que no impidió que la visión mecanicista de la Naturaleza se mantuviera durante mucho tiempo… como un acto de fe (4), incapaz de explicar fenómenos tan familiares como la cohesión de los materiales, la caída de los cuerpos o las mareas.

El pensamiento mecanicista, inspirado tanto en la tecnología como en la religión, permitió construir un saber eficaz, dirigido al control del mundo, precisamente en el momento en que se producían la expansión colonial y la primera Revolución Industrial.

Los universos científicos, técnicos y el de los poderes económicos o políticos estuvieron entonces profundamente imbricados, ya que las ciencias contribuían al control ejercido por los Estados, a las actividades de producción y a las operaciones militares. El desarrollo de las ciencias, como lo han demostrado los estudios empíricos (5), está asociado a lugares de poder muy diversos, desde un ducado florentino hasta una revista internacional. Algunos ejemplos permiten abandonar la imagen etérea del sabio razonando por sí mismo y libre de cualquier contexto. Porque se insertó en el espacio de libertad que representaba la Corte, Galileo pudo "armar" un nuevo papel social y cultural, el del filósofo matemático del gran duque de Toscana, y así legitimar la utilización de las matemáticas, dando vuelta las jerarquías aceptadas hasta entonces (en la Universidad legada por Aristóteles, a los matemáticos se les pagaba siete veces menos que a los filósofos). Dentro de la RAND Corporation –institución de investigación típica de la ciencia estadounidense de la posguerra, dirigida por los militares– la colaboración entre físicos, matemáticos, ingenieros y economistas fue determinante para la implementación de la economía matemática moderna y su fetichismo del mercado racional. Los editores de la revista *Nature*, al seleccionar los "buenos" artículos antes de cualquier examen por los pares, influyeron con su prestigio en la política científica a nivel mundial.

La evolución de las ciencias no resulta de un proyecto coherente concebido en un determinado lugar, sino de cambios globales, producidos tanto por los productores de saber como por las potencias temporales y espirituales. Cada actor persigue sus propios intereses y trata de aprovechar lo que se modifica en su entorno. Así, surgen nuevas visiones científicas del mundo, aprovechando conjunciones singulares, algunas de las cuales "prenden" cuando, por razones complejas, logran reclutar a numerosos actores, tanto sociales como naturales. La historia de las ciencias se parece a la del lecho de un curso de agua, construido por innumerables conjunciones geológicas. Con muchos accidentes, obstáculos y desvíos. Una visión muy diferente de la propuesta por la historia habitual (6), que describe los adelantos de las ciencias como el descubrimiento progresivo de una Naturaleza fija. Como si el río "descubriera" su lecho actual, corriendo inevitablemente desde su fuente a la desembocadura. Pero el río Loire, por más sorprendente que pueda parecer, pasaba antes por lo que mucho más tarde se llamaría París. La historia realista de las ciencias está llena de suspenso, de sorpresas y de sobresaltos.

A veces, estos estudios sociales de las ciencias y de sus consecuencias políticas son acusados de no ser más que anecdóticos, porque no abordan lo que puede considerarse como el corazón de las ciencias: los objetos que ellas "descubren", átomos o microbios.

Esta objeción requiere varias respuestas. En primer lugar, la práctica efectiva de las ciencias no apunta sólo a describir el mundo tal como es, sino a crear, gracias a los

laboratorios, un mundo tecno-artificial donde sus conceptos son operacionales. Esta tendencia, dominante hoy en día, caracteriza a la ciencia moderna desde sus comienzos. Galileo privilegia el estudio del movimiento en un mundo idealizado donde las fricciones no existen, desencadenando las protestas de los aristotélicos, para quienes la física debía ocuparse del mundo real y no de un mundo artificial, aunque resultara práctico para los matemáticos. Además, la noción de "descubrimiento" es ingenua. No extrae las consecuencias de un hecho ya bien establecido: en el fondo, la realidad" siempre se nos escapa, porque lo que conocemos mezcla indisociablemente la realidad y nuestros instrumentos de conocimiento, ellos mismos ligados a la sociedad que los ha puesto de manifiesto. Reconocer estos límites conduce a una verdadera historicidad de los hechos científicos, interpretados como dispositivos que mezclan esos tres elementos. Así, los microbios de Pasteur no son los nuestros: tamizados por aparatos y teorías diferentes, son mucho más diferenciados, y algunos se convierten en virus. En cuanto a los átomos, constituyen una visión de la materia que sigue pegada a los materiales purificados producidos por los laboratorios modernos. Esto no significa de ninguna manera, contrariamente a lo que algunos teóricos han anticipado, que esas entidades sean ilusorias: se comportan bien en los laboratorios y siguen siendo un elemento esencial en la construcción de los "hechos" científicos. Pero las características que les conocemos no agotan su realidad: de cierta manera, estas entidades se expresan bien por sí mismas,pero nunca dicen todo lo que saben…

Siguiendo a los investigadores en sus gestos cotidianos, mirándolos fabricar objetos y sentidos en universos sociales y políticos diversos, esos trabajos, que se desarrollan desde hace una treintena de años, muestran que la ciencia no descubre "el" mundo, sino que construye mundos que mantiene juntos a humanos, máquinas y objetos naturales. En cuanto a las ciencias puras, nunca siguen siéndolo durante mucho tiempo. El ideal de un saber neutro, autónomo de los demás universos sociales, fue resaltado por los propios sabios en el siglo XIX para colocarse por encima de la pelea, precisamente en el momento en que su inserción en el mundo socioeconómico se intensificaba (7).

Una vez parcialmente disipadas estas múltiples ilusiones, fue posible tratar de integrar mejor las ciencias al debate democrático. Las grandes controversias científicas ya no se resumen en confrontaciones entre sabios racionales y un público oscurantista. Corresponden más bien a debates políticos entre partidarios de los diferentes mundos posibles. Ya se trate de terapias genéticas, de nanotecnologías o de OGM, ahora resulta más evidente que nunca que esos adelantos científicos no deben ser juzgados separadamente del sistema social en el cual están insertos (8). ¿Cómo asociar a los investigadores a una sociedad civil que ya no acepta el papel de espectador pasivo, pero que a veces es muy influenciable y versátil, como lo han mostrado los cambios de opinión sobre el calentamiento climático, al mismo tiempo que se salvaguarda la autonomía con relación a las presiones económicas? Para Isabelle Stengers, una solución posible consiste en centrar la definición de las ciencias en la construcción de pruebas fiables (9). Los industriales amenazan la fiabilidad con una exigencia más fuerte, la de la competitividad; mientras el público demanda la extensión de este tipo de pruebas hacia el exterior del laboratorio. Aunque ya existen varias pistas, como las conferencias ciudadanas o la separación de los poderes sugerida por Bruno Latour (10), las formas concretas que puede revestir tal implicación del público están por inventarse.

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1 Informe de síntesis del movimiento "Sauvons la recherche" (**http://cip-etatsgeneraux.apinc.org/IMG/pdf/** synthese-finale-EG.pdf).

2 Véase Alexandre Koyré, *Du monde clos à l'univers infini*, Gallimard, París, 2005; Thomas Kuhn, *La structure des révolutions scientifiques*, Flammarion, París, 2008.

3 Simone Mazauric, *Histoire des sciences à l'époque moderne*, Armand Colin, París, 2009.

4 Mary Midgley, *Science As Salvation: A Modern Myth and Its Meaning*, Routledge, Oxford, 1992.

5 Dominique Pestre, *Introduction aux sciences studies*, La Découverte, París, 2006.
6 Puede encontrarse un ejemplo caricaturesco en la obra dirigida por Georges Barthélémy, *Histoires des sciences*, Ellipses, París, 2009.
7 Dominique Pestre, op. cit.
8 Christophe Bonneuil y colaboradores, "Innover autrement? La recherche face à l'avènement d'un nouveau régime de production et de régulation des savoirs en génétique végétale", en *Dossier de l'environnement de l'INRA*, Nº 30, Editions Quae, Versailles, 2005 (**www.inra.fr/dpenv/pdf/BonneuilD30.pdf**).
9 Isabelle Stengers, *La Vierge et le neutrino: Les scientifiques dans la tourmente*, Empêcheurs de Penser en Rond, París, 2006.
10 Bruno Latour, *Politiques de la Nature*, La Découverte, 1999.

Points for consideration

- Identify important ideas that you find particularly surprising or debatable in the text.
- To what extent does this text condition the image you had of science?

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2 The Methods of Science

Carmel Ferragud, Rafaela Domínguez, Mar Cuenca
History of Science

Documentation and Scientific Methodology
Degree in Pharmacy

Introduction

1. Scientific activity
   - Areas
   - Meritocracy
   - Communication of results
   - Organised scepticism

2. Data and explanations
   - Obtaining data: observation and experimentation
   - Scientific reasoning: deductive and inductive
   - Explanations: hypotheses, laws, theories, models

3. Scientific instruments and unitary systems

4. Critique of naive inductivism

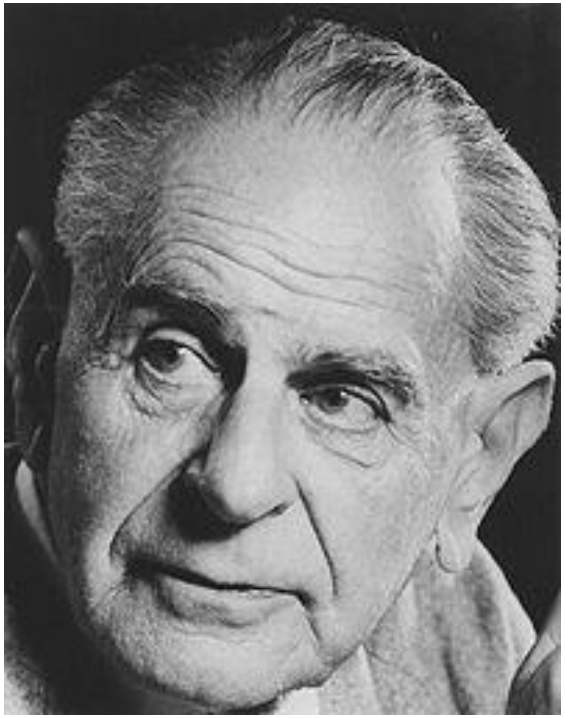
5. Answers to the the problem of induction

Final considerations

Introduction

What is science?

"I'm a teacher of scientific method, but there's a problem: there is no such thing"



Karl Popper (1902-1994)

1. Scientific activity

- There are two **areas** in the work of a scientist:
  - The private area ('private science')
    - ✓ In libraries or offices, gathering and processing information established by other scientists.
    - ✓ In laboratories, conducting experiments or fieldwork and noting down results in laboratory notebooks/diaries or computer files.
  - The public area ('public science')
    - ✓ Publishing results (generally, in journals).
    - ✓ Assessment by colleagues.

Meritocracy

- Scientists try to be recognised among their colleagues by:
  - The relevance of their inquiries (research lines).
  - The relevance of the questions posed.
  - The accuracy of the methodology used.
  - The precision of the results obtained.

Robert K. Merton (1910-2003)

Communicating results

- The scientific community (i.e. scientists) is constantly immersed in a continuous cycle of production and consumption of publications (usually journal articles):
  - Scientists should base their studies on previous work by colleagues.
  - Scientists systematically recover literature on the subject they are interested in.
  - Scientists read (analyse and recreate) the studies they recover.
  - With the results of their research, scientists are obliged to record their own work and to publish.

Organised scepticism

- The results obtained (their own or those of others) are normally called into question.
- Scientific knowledge is considered provisional, with new developments always pending.
- At the end of the process, public recognition and social consensus are obtained.
- According to the logic of scientific communication, knowledge obtained in this way is ‘re-flexive’ or ‘retro-active’ (the production-consumption cycle).
- Much scientific work aims to differentiate between acceptable and unacceptable results.

- Scientific impostures (falsifications) are usually detected immediately.
- However, when it comes to evaluating the results of a study, previous knowledge of the subject and the behaviour of the scientific community are paramount.
- Results that do not question the theory are more easily accepted (and vice versa).
- Results presented by prestigious scientists are questioned less, and vice versa (unequal recognition: Matthew effect/ Matilda effect).
- Much of the information generated (especially at the periphery of the scientific community) never becomes part of general scientific knowledge.

Hwang Woo-Suk and cloning human embryos (2004-2006)

Louis Pasteur's laboratory at *l'École Normale Supérieure* in Paris (19th century)

2. Data and explanations

- A common distinction in traditional epistemology:
  - Data is information about the world.
  - Explanations are theories based on data.
- Data come from sensorial perception and reveal information about nature (observable facts).
  - Requirements: repeatable, inter-subjective, exchangeable observers (although not just anybody).
- Systematic use of the third person (singular or plural) due to the impersonal nature of the data.

- Qualitative data indicate, for example, the presence of a substance in a sample (detection of glucose in urine through a reagent). It is a primary way of demonstrating a reality, properties or levels, without measurement.

- Data are usually expressed via numeric values (quantitative data).

- Standardising the units of measurement has always been one of the most important challenges faced by the international scientific community:

  Circa. 1965: definition of the six basic units: metre (m), kilogramme (kg), seconds (s), ampere (A), degrees Kelvin (K), and candela (cd).

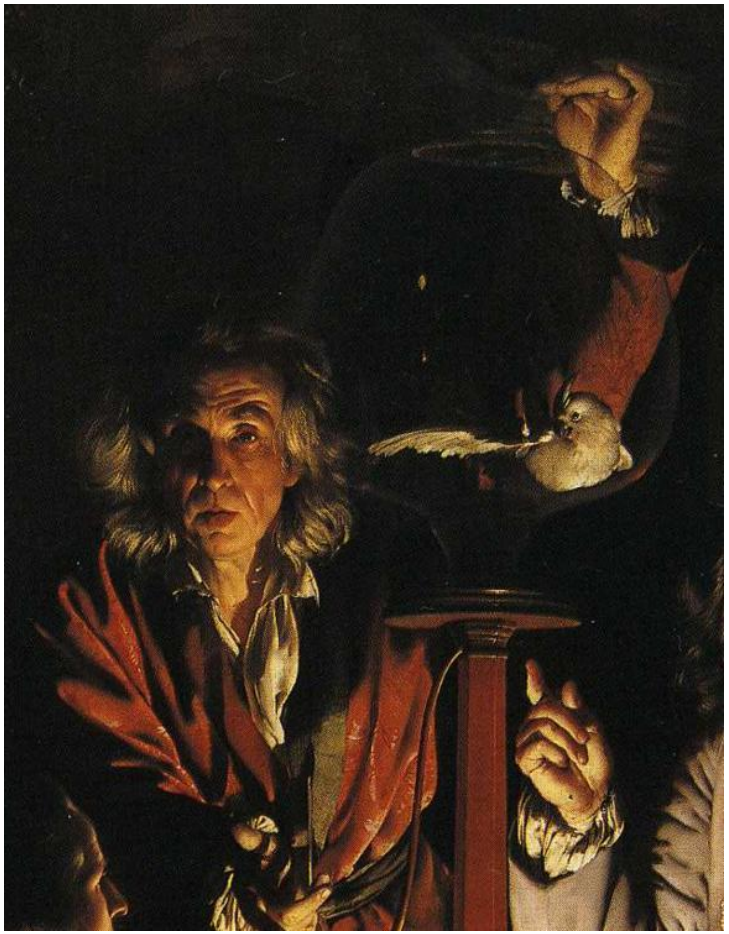
Obtaining data: observing nature

- Naked observation: entomologists, classical taxonomists.
- Observation through instruments.
- Supposedly passive.
- In general terms, maintaining the natural conditions for the event under study.
- Basis of **traditional inductive epistemology.**

Galileo's telescopes (History of Science Museum, Florence)

Obtaining data : Experimental research

- The researcher (actively) provokes events that are not spontaneous or usual in nature in order to observe them, measure the variables, and acquire new knowledge.
- The procedure involves the formulation of a hypothesis, experimentation, and empirical validation.
- It is a trial-and-error method.



Joseph Wright from Derby, *Experiment with a bird in an air-pump* (1768)

Scientifc reasoning

Induction

Observation →→→→→→→→→→→→→→→ Explanatory principles

(Singular observational statements) (universal statements)

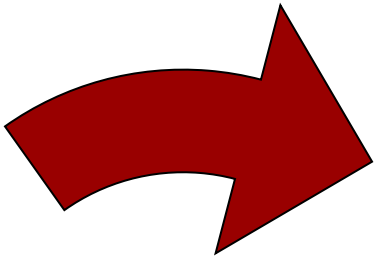
(laws and theories)

Deduction

Observation ←←←←←←←←←←←←←←← Explanatory principles

(predictions and explanations)

The conventional cycle of research

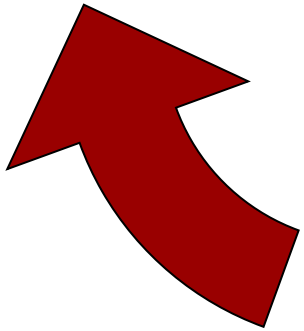


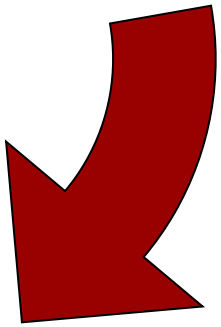
Body of available knowledge

Hypothesis and comparison

Problem

(observation and experimentation)





Verification
or
rejection

Explanations

- Hypotheses, once validated, become:
  - **Types and patterns:** the joint presentation of natural events (e.g. acids and bases).
  - **Laws**: statements that express functional relationships between variables, statistical correlations, or universal traits (e.g. Boyle-Mariotte, Newton, Maxwell).
  - **Theories:** systematic explanations that refer to a field of nature and coherently organise a set of laws (e.g. cell theory).
  - **Models or representations**: simplifications of reality based on hypotheses that are considered reasonable (e.g. atomic models, the double helix, etc.).

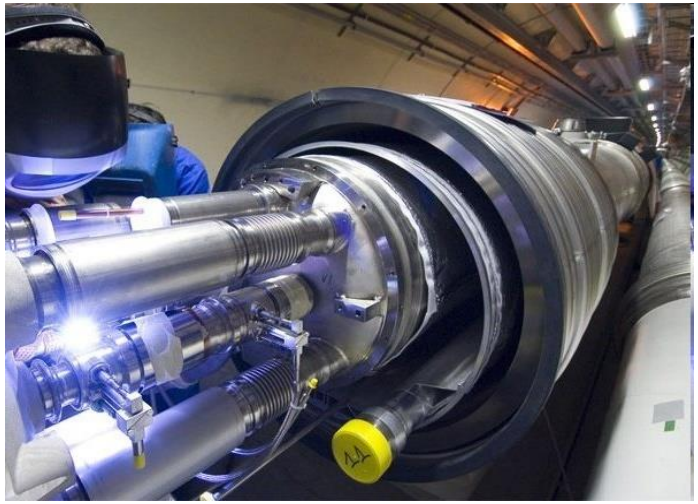
3. Scientific instruments

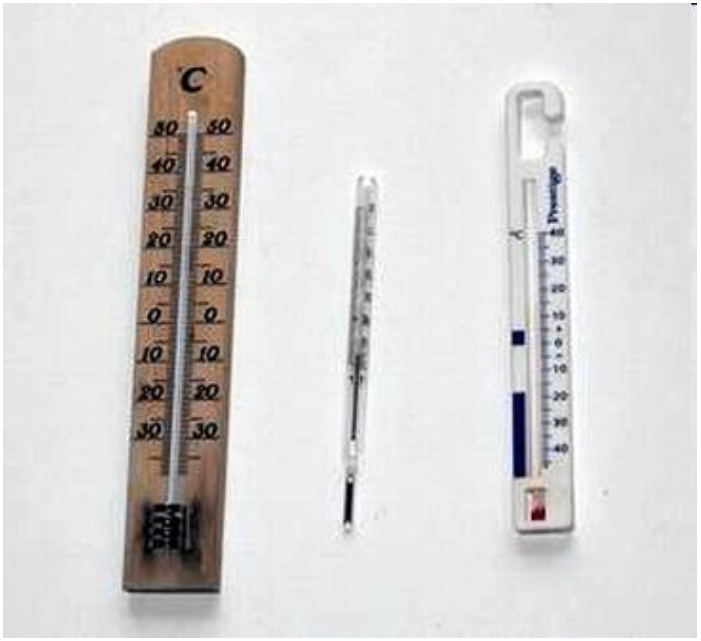
- To obtain data, it is normally necessary to use observational instruments that extend the limits of our senses and often register and measure events.
- Observers must have enough technical knowledge and skills to use them and understand the results.
- Gathering data implies accepting the laws and theories of the nature of the events observed (e.g. a spectrometric study presupposes acceptance of the laws of refracted light).

Types

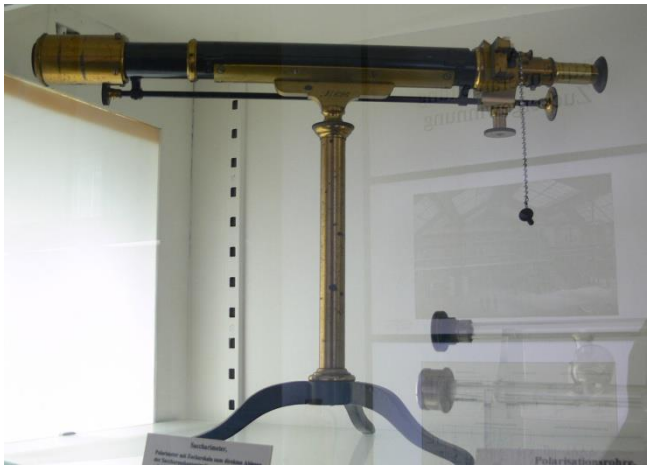
- Passive (thermometer, scales, voltmeter), to measure observations.

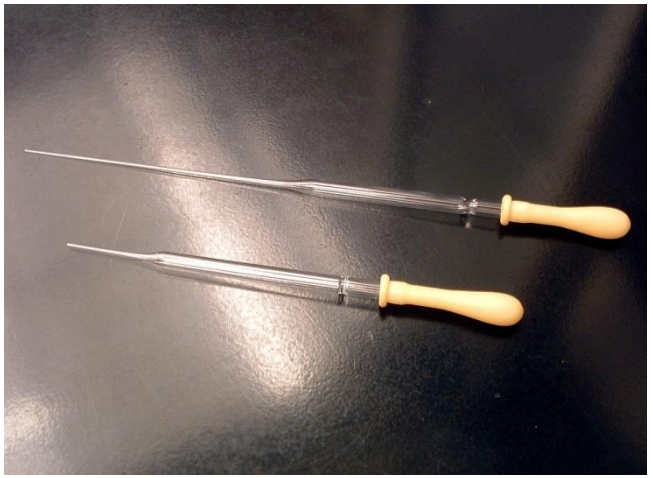
- Active (cathode ray tubes, particle accelerators, etc.), to create new events in the laboratory.





- Instruments vary depending on the type of public (consumers) they are intended for, e.g. educators, industrialists, professionals, or scientists (researchers).
- They may be very simple (e.g. test tubes or pipettes) or highly complex (e.g. astronomical telescopes or particle accelerators).





Problems associated with instruments

- **Errors** in the settings cannot be totally eliminated. These should be known and their magnitudes estimated in order to determine accuracy and precision.

- Accepting data obtained from instruments is more complicated than one might think.
- In scientific articles, instruments tend to be presented as unproblematic tools:
  - they rarely mention the theory behind their use.
  - 'transparency' is intrinsic (S. Schaffer), i.e. they are considered good transmitters of the information given, which in turn ensures that the data are trustworthy.
- Authors such as Bruno Latour and Trevor Pinch call instruments that are not well understood by the scientists who use them 'black boxes'.

- ‘Tacit knowledge’ (Collins) is knowledge on the use of instruments that does not appear explicitly in publications (‘unformalizable components of scientific knowledge’) and is only acquired through close collaboration with the creators of those instruments.
- A lack of tacit knowledge often impedes the reproduction of experiments by those who have not enjoyed prolonged contact with the work groups that created the instruments.

4. Critiques from naive inductivism

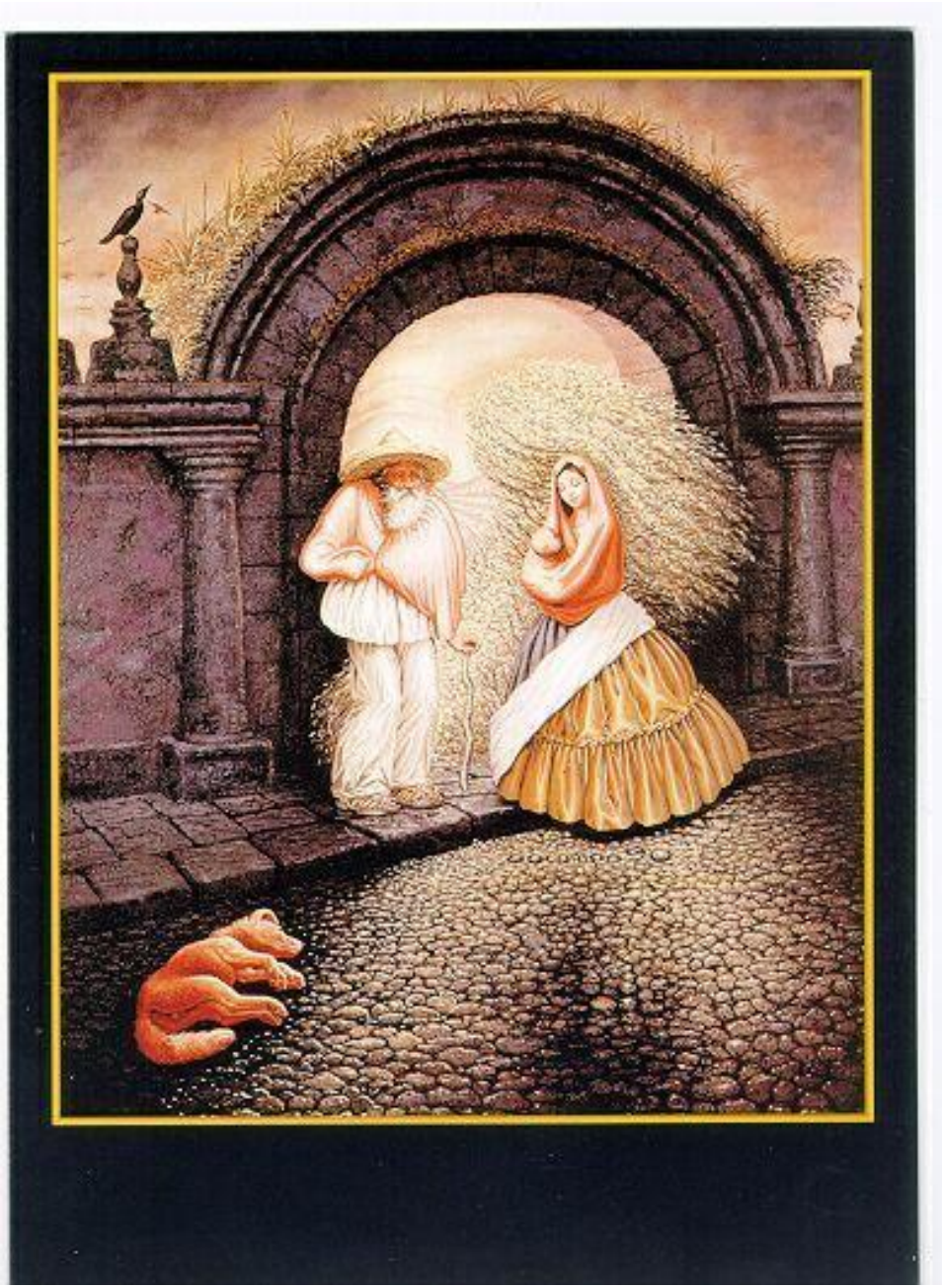
- Scientific positivism states that science produces true knowledge from objective facts that are revealed by the senses to good, non-prejudiced observers.
- True knowledge that is presupposed to science does not derive from the facts of experience even if they have been acquired by observation and experimentation (naïve inductivism).
- How one should perceive the facts has a significant social and cultural component (prior knowledge and expectations).
- Scientific knowledge is 'invented' and 'built' from observation and experimentation (practical activity network).

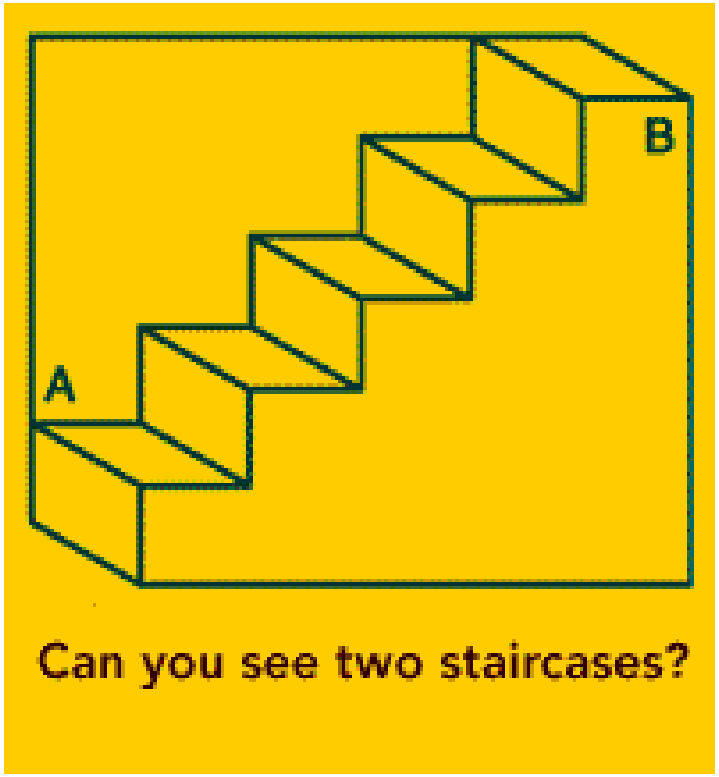
The inductive method contends that:

- Science begins with observation.
- Observation offers a safe basis for scientific knowledge.
- Inductive reasoning is objective and valid.
- An explanation is verified by repeating the observation or adding new data to those already available.
- Scientific theories rigorously derive from the facts of experience acquired through observation and experimentation.
- Scientific knowledge is trustworthy because it is objectively proven.

The inductive method has several large inconsistencies:

- The **subjectivity of observations**, which, as sensorial perceptions, are conditioned by the observer's expectations (e.g. the 'staircase' drawing or magical illusions).
- **The logical impossibility of generalisation**, i.e. going from the particular to the universal (e.g. the inductive turkey).
- **The difficulty in forming observational statements**, since these can only be expressed within existing theories.



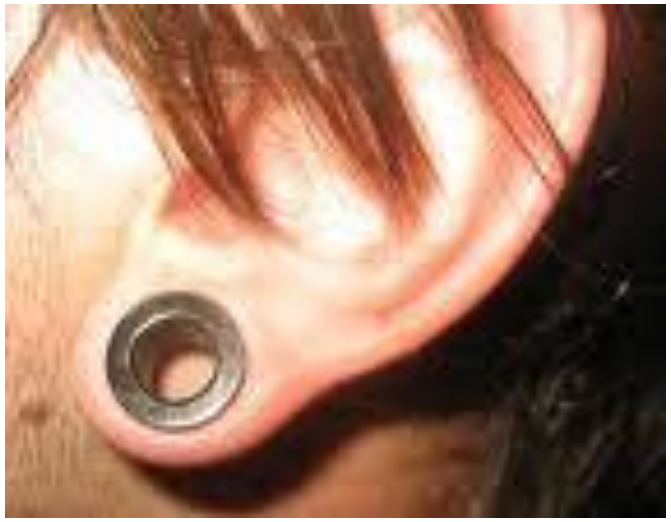

A
B
Can you see two staircases?

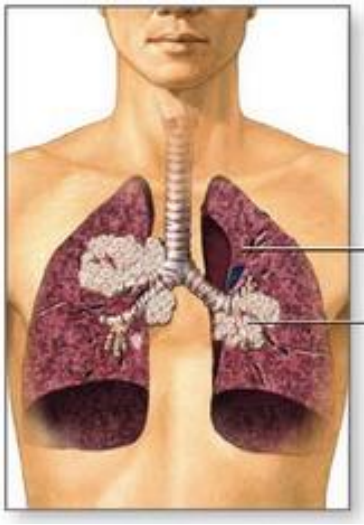
Observational statements

- Are expressed in the language of a theory; i.e. theory comes before the observation:
  - The statement: "the electron beam was repulsed by the north pole of the magnet" presupposes:
    - ✓ The atomic composition of matter.
    - ✓ The existence of subatomic particles.
    - ✓ The negative electrical charge of some particles.
    - ✓ The magnetic forces of attraction and repulsion.

- Observational statements can only be expressed through the concepts and terms of a theory.

- Theory (the theoretical framework) guides observation and experimentation:
  - Observations and experiments are carried out to validate or clarify a theory.
  - Example: it makes no sense to study the characteristics of the earlobe to establish a causal relationship with lung cancer if a relationship between the earlobe and lung cancer has not previously been established.





La persona que fuma cigarrillos corre el riesgo de contraer enfisema, cáncer del pulmón y otros problemas de salud. El humo de segunda mano (humo de un cigarrillo cercano) puede también contribuir a que se puedan contraer estas enfermedades, especialmente en los niños.

A priori inconsistent relationship

Scientific instruments

Accepting data obtained from scientific instruments is more complicated that was once thought:

- Since we are talking about a phenomenon, a margin of error must always be considered; in extreme situations, this error may be maximum (Heisenberg's uncertainty principle).

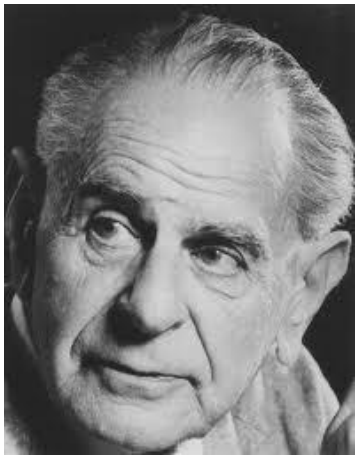
- This assumes accepting the theories involved in using the instrument.

5. Answers to the problem of induction

Falsifiability

Formulated by philosopher of science, Karl Popper (1902-1994), this concept is based on two principles:

- Observation is guided by theory.
- Verifying a law is impossible since it is logically unsustainable to claim to make infinite observations (it is impossible to establish laws based on a limited number of observations).



- Popper proposes that theories that do not overcome observational and experimental tests should be eliminated (refutation) and replaced by other more credible conjectures.
- Although we cannot affirm that a theory is true, we can say that it is the best one available.
- Researchers dedicate most of their time to refuting their colleagues' theories (and their own) by providing observational data.

Therefore, to be considered scientific, statements must be 'falsifiable'. So:

- falsifiable: "water always boils at 100° C".
- falsifiable: "the boiling point of water varies according to height".
- falsifiable (but not true): "it never rains on Wednesday".
- not falsifiable (but true):
  - ✓ "it will or will not rain next weekend".
  - ✓ "it is possible to be lucky playing bingo".

Theories as structures

Thomas Kuhn (1922-1996), *The Structure of Scientific Revolutions* (1962):

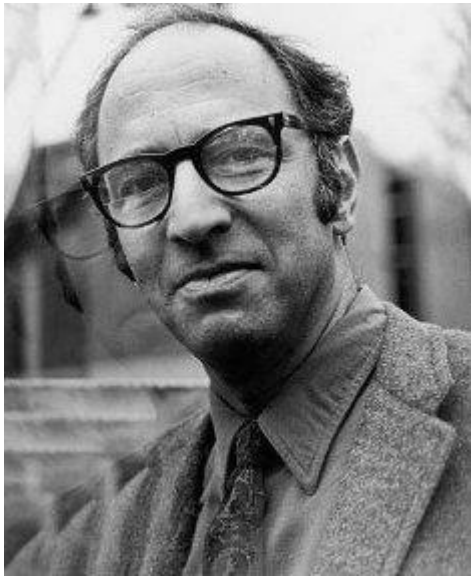
- Theories are structured totalities outside which observations make no sense.
- The concept is based on the ideas of Polish microbiologist Ludwik Fleck (1896-1961), who suggested that all theory comes within a 'thought-style' (a collection of rules, principles, concepts, and values that belong to a period that is accepted by a 'thought collective').
- Unlike Popper's falsificationism, this philosophical model is relativist and discontinuist, since the validity of an explanation is subject to a historical and social framework.

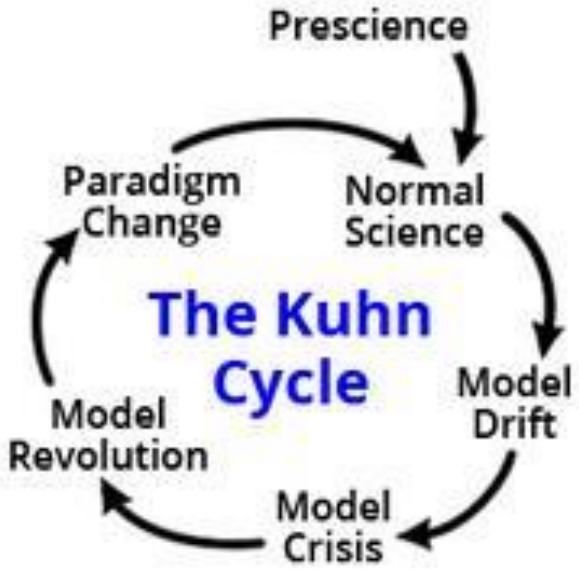
- The '**paradigm**':
  - is made up of supposed general theories of the laws and techniques adopted by members of a scientific community.
  - establishes the rules required to legitimise scientific works.

  An example is provided by cell theory, which states that the cell is a fundamental unit (form, function, origin, disease) of living material, with all its observational statements and techniques that make the paradigm possible.

- '**normal science**':
  - Normal science is made up of prevailing paradigms in the field of science.
  - Paradigms make sense at a specific historical moment.
- '**crisis**':
  - Comes from research within normal science.
  - It appears when new observations do not fit within the paradigm.
  - It involves questioning the paradigm because of the accumulation of anomalies.

- ‘**revolution**’:
  - A paradigm that weakens and that nobody trusts results in ‘revolution’.
  - This leads to a change in the paradigm.
  - The new paradigm is different and incompatible with the former.
  - In the long term, a new normal science is created and consolidated.




Prescience
Normal Science
Model Drift
Model Crisis
Model Revolution
Paradigm Change
The Kuhn Cycle

The regimes of knowledge

- Dominique Pestre (1950) (Director of Studies at the *École des Hautes Études en Sciences Sociales*).
- Science is articulated on social models, certain forms of social commitment, production techniques, and political management (diverse cultures).
- Interdependence of aspects influencing science (people, institutions, and techniques).
- Historical transformations that allow for regulation and legitimisation (good practices) with multiple rationales.

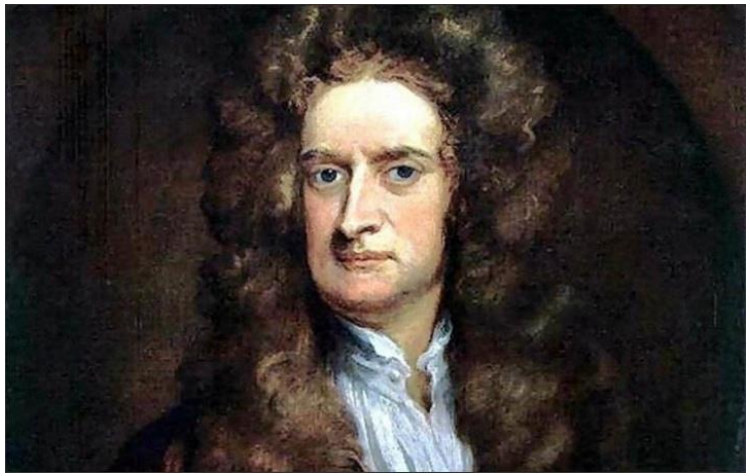
- Elements are constructed locally and routinely (methods are neither genial nor entirely rational).
- Scientific work includes persuading and achieving credibility.
- There are many ways to represent and communicate results and institutional strategies to promote science.

Final observations

- Science appears to enjoy great prestige, but its meaning has changed over time.
- Looking for antecedents is complicated and sterile. Many subjects are no longer considered scientific and are maligned (e.g. astrology and alchemy) or discarded (e.g. temperaments and phlogiston)
- Objectives change (e.g. astrolabes, observing celestial objects, or determining the timing and direction of oration).

- Self-complacency; science as the successful final product of a process of Western superiority.
- The triumphalist history of continuous progress.
- The triumph of reason and supremacy over religion; contempt for spiritual knowledge and poetic descriptions.

This most beautiful system of the sun, the planets and the comets could only proceed from the advice and dominion of an Intelligent Being. And if the fixed stars are the centre of other systems, these, formed on His wise advice, must be subject to the dominance of One. . . This Being governs all things, not as the soul of the world, but as Lord (Isaac Newton, *Principia Mathematica,* 1687*)*.



Theme 3. Science on the Move: Scientific Revolutions

Introduction

The sciences occasionally undergo changes in direction that may affect the content of knowledge, the methods used, the characteristics of the people who work in the field, the physical or institutional places, as well as society's interest in science and its public image. These scientific revolutions break with the habitual image of an accumulative continuity of scientific knowledge that appears to develop as a gradual progression towards a better and more complete understanding of the world. Although Kuhn's thinking has been questioned and is increasingly discredited nowadays, it is extremely useful for reflecting on a historical process that marked the way in which the evolution of science was interpreted.

Contents

Introduction

1. Scientific revolution
2. The paradoxical programme of the humanists
3. The Protestant Reformation and the Catholic Counter-Reformation
4. Two major transformations in knowledge: macrocosm and microcosm
5. Changes in natural philosophy
6. Institutional novelties
7. The final balance

Comentado [KPC1]: The PowerPoint says: "Concluding remarks"; both are possible but only one should be used.

Objectives

- To understand the historiographical and epistemological debate on the idea of scientific revolution.
- To learn how to use the scientific revolution (17th century) as a model and example for thinking about continuity and change in science.
- To determine the precedents that led to the development of the scientific revolution.
- To understand the main global transformations that took place during the scientific revolution involving the macrocosm and microcosm, method, the places where science was produced, communication, etc.
- To reflect on the concept of scientific revolutions.
- To hold a debate with critical arguments about a historiographical problem and relate the debate to current science.

Preliminary activity

In this activity you will view excerpts from several videos. The first is a film about Galileo Galilei, directed by Liliana Cavani in 1968, and available at: https://www.youtube.com/watch?v=dQSH2-bznno
Excerpt 1: 00:00-06:00
Excerpt 2: 34:50-39:00
Excerpt 3: 43:50-46:50

The second video is an excerpt (chapter 9 on Galileo) from the series "Érase una vez… los inventores". Watch this video from minute 16 onwards.

https://www.youtube.com/watch?v=cZI1issfSPE

(We recommend that you should watch the whole chapter and film in order to gain a better understanding of the topic)

Points to consider

- Identify important ideas you find particularly surprising or debatable in the video excerpts.
- How is the relationship between science and the Church presented?
- What factors determine the acceptance of new theories?

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Fara, P. (2009). *Breve historia de la ciencia*. Barcelona: Ariel.

Con formato: Español (España)

3. Science on the move: Scientific Revolutions

Carmel Ferragud, Rafaela Domínguez, Mar Cuenca
History of Science

Documentation and Scientific Methodology
Degree in Pharmacy

1. Scientific revolution
2. The paradoxical programme of the humanists
3. The Protestant reformation and the Catholic counter-reformation
4. Two major transformations in knowledge: macrocosm and microcosm
5. Changes in natural philosophy
6. Institutional novelties
7. The final balance

The problem of periodisation in the history of science: The debate between continuity and discontinuity

- Has Western science evolved continuously since antiquity? Or has there been a division between ancient and modern science?
- Did a quantitative change (continuity) or a qualitative change (discontinuity) take place?
- Can one properly speak of a scientific revolution in the development of European science?
- If such a revolution took place, when, how, and why did it occur?

1. The concept of scientific revolution

- The concept was formulated in 1939 by Alexandre Koyré, who defended the radical novelty of the *nuova scienza* that emerged in the 17th century (Galileo, Newton).
- After World War II, the notion of 'scientific revolution' became a widely shared historiographical category:
  - R. Hall, *The Scientific Revolution, 1500-1800* (1954)
  - T. Kuhn, *The Structure of Scientific Revolutions* (1962)
- The idea of a discontinuity coincided with the supposed crisis of European consciousness (P. Hazard) that took place in the 17th century due to the confrontation between ancients and moderns.

- The concept of ‘scientific revolution’ has recently been questioned.
- S. Shapin (*The Scientific Revolution*, 1996) asserted:
  - ✓ the existence, at the time, of multiple lines of (apparently contradictory) research and the lack of a unitary programme.
  - ✓ the existence of multiple ‘scientific revolutions’ (i.e. each era had its own revolution).

2. The programme of the humanists

- Today we know that, between 500 and 1500 AD, the philosophical and scientific legacy of antiquity was:
  - ✓ Appropriated, recreated, enriched, and expanded by the Arabs.
  - ✓ Translated into Latin in the schools of southern Europe that had contact with Islam.
  - ✓ Assimilated and reworked in the mould of Aristotelian philosophy.
  - ✓ Taught at universities (from the 13th century onwards).
  - ✓ Seen as the rational basis for later medical and biological knowledge.

Between 1450 and 1550, the humanists turned to antiquity ('Renaissance') to:

+ Draw inspiration from classic models.

+ Recover original knowledge (go back to the sources).

+ Purify the texts – which were supposedly corrupted in dark times by the Arabs – of the authors (authorities) of antiquity.

+ Disseminate knowledge (the texts of the classics) via the printing press: a single text published after the copy had been carefully selected and errors corrected.

3. Protestant Reformation and Catholic Counter-Reformation

- Renaissance Europe was an essentially Christian society.
- Medieval theology had been forged in the Aristotelian mould (the concepts of space, time, cause, substance, movement, etc.), while making compatible the concept of nature (*physis*) and the existence of an omnipotent, creative, and providential God.
- In the 16th century, Christianity broke up in the wake of Protestant Reformation (Luther, 1517) and Catholic Counter-Reformation (Trent, 1545-1563).
- Religious wars (between Catholics and Protestants) shook Europe for more than a century (in the 16th and 17th centuries).

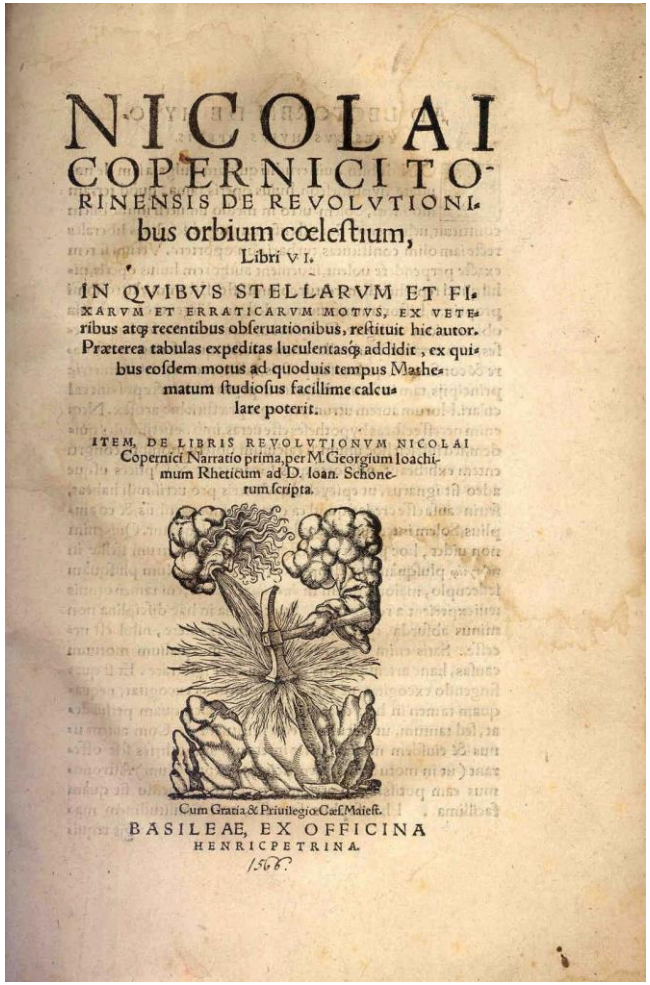
- The Christian *ethos* persisted well into the 18th century.

- Reading the book (the word) of God (the interpretation of the Bible) was substituted by 'reading' the work of God (i.e. the study of nature; the creation).

- *Scienza nuova* was considered a space for encounter (not conflict) and collaboration between philosophers and European scholars, whether Catholic or Protestant (e.g. Calvinists, Lutherans, Anglicans).

Two major transformations in knowledge: macrocosm and microcosm (1543)

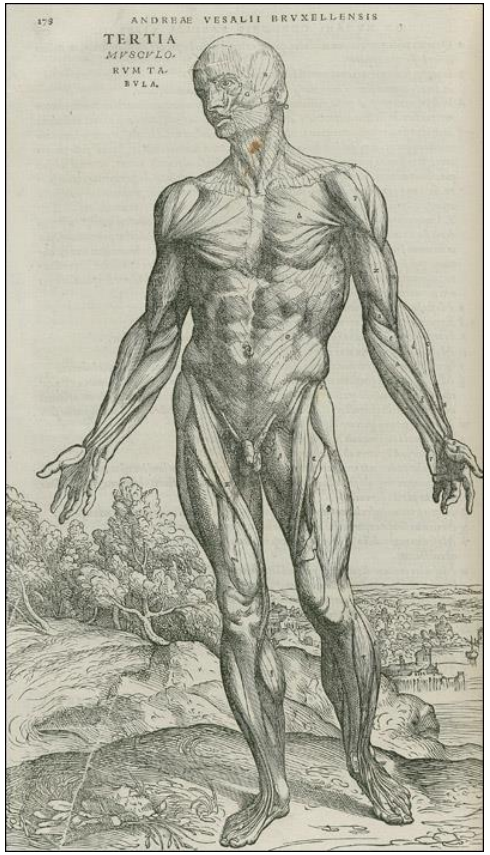
Andrea Vesalius, *De humani corporis fabrica*



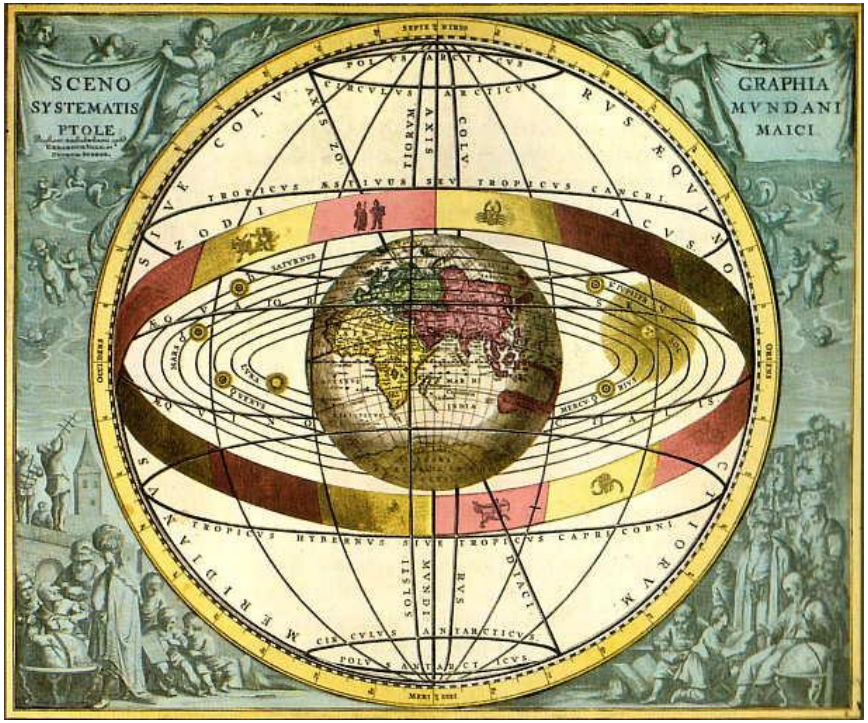
Nicolaus Corpernicus, *De revolutionibus orbium coelestium*

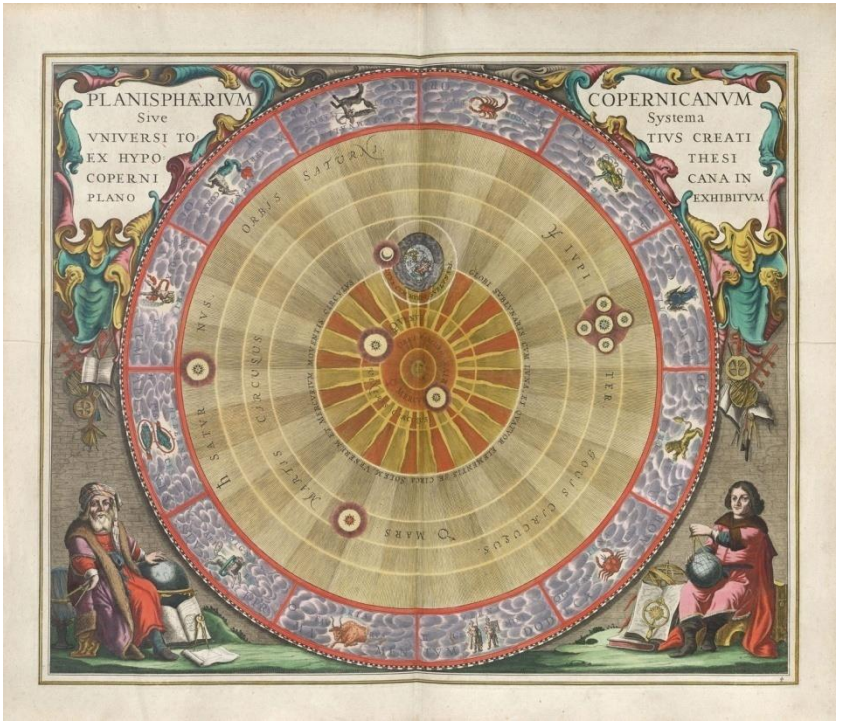
The Vesalian Revolution

- Static conception of anatomy.
- Observation of corpses.
- Solidistic and architectural vision of the human body, which was described in terms of:
  - ✓ Upper / lower
  - ✓ Medial / lateral
  - ✓ Anterior / superior
- Form (static anatomy) of the human body, isolated from function (anatomy animata).
- The beginnings of descriptive anatomy.
- The creation of chairs of anatomy.
- Anatomical theatres.
- The Vesalian movement.



The Copernican Revolution





Galileo Galilei, 1564-1642

"Then Joshua spoke to Yahweh in the day when Yahweh delivered up the Amorites before the children of Israel; and he said in the sight of Israel, "Sun, stand still on Gibeon! You, moon, stop in the valley of Aijalon!" The sun stood still, and the moon stayed, until the nation had avenged themselves of their enemies. […]The sun stayed in the midst of the sky, and didn't hurry to go down about a whole day. There was no day like that before it or after it, that Yahweh listened to the voice of a man; for Yahweh fought for Israel"
(Joshua, 10, 12-20).

Galileo ante el Santo Oficio, Joseph-Nicolas Robert-Fleury

DIALOGO
DI
GALILEO GALILEI LINCEO
MATEMATICO SOPRAORDINARIO
DELLO STVDIO DI PISA.
E Filosofo, e Matematico primario del
SERENISSIMO
GR. DVCA DI TOSCANA.

Doue ne i congressi di quattro giornate si discorre sopra i due

MASSIMI SISTEMI DEL MONDO
TOLEMAICO, E COPERNICANO;

Proponendo indeterminatamente le ragioni Filosofiche, e Naturali tanto per l'una, quanto per l'altra parte.

CON PRI VILEGI.

IN FIORENZA, Per Gio: Batista Landini MDCXXXII.

CON LICENZA DE' SVPERIORI.

SÁBADO, 31 de octubre de 1992

Juan Pablo II rehabilita hoy a Galileo, 359 años después de que fuera condenado

- La Iglesia acepta oficialmente que la Tierra gira alrededor del Sol

31 OCT 1992

Archivado en: Ciencia

Juan Pablo II pedirá hoy -359 años, 4 meses y 9 días después de la sentencia de la Inquisición- perdón por la condena injusta de Galileo Galilei y rehabilitará al filósofo y matemático de Pisa, al tiempo que presentará el libro Copérnico, Galileo y la Iglesia: fin de la controversia (1820), en el que se establece que afirmar que la Tierra gira alrededor del Sol no es blasfemia. Galileo llegó a abjurar de sus ideas y pese a ello fue condenado.

5. Changes in natural philosophy (16th–17th centuries)

1. Increasing questioning of the principle of authority, of Aristotelianism (logic and metaphysics) and of Galenism (the doctrine of the four humours).

2. Criticism of speculative knowledge (scepticism) and primacy of sensory perception as a criterion of truth (empiricism).

3. Consensus on the need for experiments (public experience) as a procedure to confirm or refute theories.

4. The usefulness of mathematics as an instrument of measurement and analysis ("the universe is written in mathematical characters").

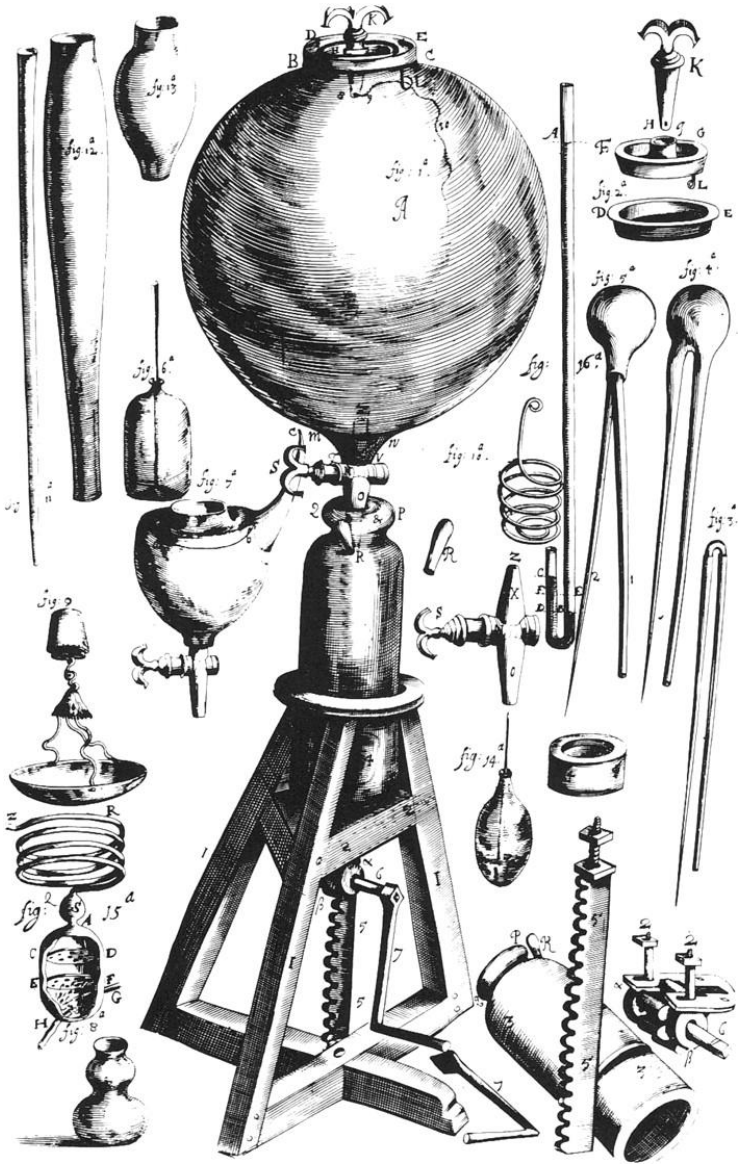
"Knowledge must be sought in the light of nature, not brought from the darkness of ancient times".

"There is only one way … to start all over again with a better plan and to begin a total reconstruction of the sciences, the arts and all human knowledge, using proper foundations".

Francis Bacon
Novum Organum (1620)

Experimental culture

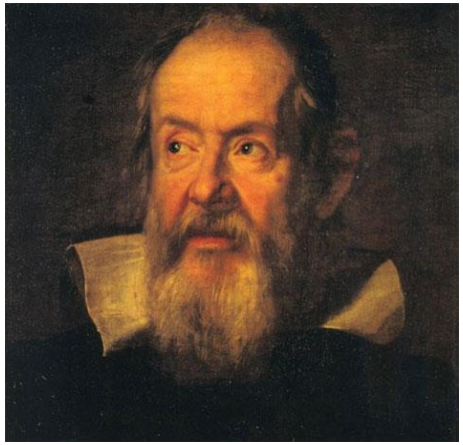
- Debates on experiments: what happens inside the machine is artificially created.
  - Is it possible to provide reliable data on how nature works?
- Testimonials, detailed reports.
  - The need for reliable mechanisms to verify, approve and authenticate knowledge.



Robert Boyle, *Experiments Physico-Mechanical* (1662)

"Philosophy [nature] is written in that great book which ever is before our eyes – I mean the universe – but we cannot understand it if we do not first learn the language and grasp the symbols in which it is written. The book is written in mathematical language, and the symbols are triangles, circles and other geometrical figures, without whose help it is impossible to comprehend a single word of it; without which one wanders in vain through a dark labyrinth".

Galileo Galilei, *Il Sagiattore* [The assayist], 1623



6. Institutional Novelties

- Republic of Letters (circa 1550-1750):
  - The mid-16th century establishment of a Europe-wide epistolary network of sages/intellectuals (philosophers, doctors, naturalists, etc.).
  - The network was based on handwritten correspondence (post).
  - Wise men worked in isolation while living under the patronage of a benefactor.
- Societies and academies (*c*.1660) under royal protection:
  - *The Royal Society* and *L'Académie Royale des Sciences.*
- New scientific spaces (e.g. observatories, anatomical theatres, botanical gardens, and cabinets of curiosities).
- The emergence of scientific journalism (1666): *Philosophical Transactions of the Royal Society, Le Journal des Sçavans.*

Louis XIV visits the *Académie des Sciences* (1671)

7. The final balance

- Did the Scientific Revolution really exist?
- We can easily observe continuities with the medieval period but we cannot observe clearly defined ruptures.
- The result of this process was not modern science as we know it today (religion, alchemy or magic).
- The protagonists believed they were experiencing an exceptional period of change.
- The role of experience vs the authority of the classics was crucial.

Theme 4. The Social Construction of Illness

Introduction

In this unit we illustrate how the way in which we perceive illness (and health) is constantly changing. Illness is 'a biological event' but the illnesses that we class as such are not 'natural' transhistorical entities, which remain in space and time. Rather, they are understood as intellectual 'constructs' developed in specific social and cultural contexts. Some authors maintain that, "in some ways, illness does not exist until it has been agreed that it exists, by perceiving it, naming it, and dealing with it". In this respect, illness as a clinical object would exist only in the historical and cultural context in which it is constituted as a specific entity and so will be fully understandable only through its interpretation in this frame of reference. However, though this may be applicable to any illness – and sufficiently conclusive examples can be found in the writings of historians (from the plague, chlorosis (green sickness) and syphilis to Aids and cancer) – it is especially relevant in the case of psychological disorders.

Contents

Introduction
1. Social aspects of medicines
2. The social construction of illness:
    - Social and cultural factors
    - The construction of illness: society and culture
3. The social construction of Aids
    - Consequences of the social image of Aids

Conclusions

Objectives

- To understand the difference between the cultural significance of illness; to know how people deal with health and illness, disease and disorder, and healthcare for both the sick and healthy.
- To understand how the social construction of illness explains how society shapes and is shaped by the ideas of healthcare professionals.
- To understand the social construction of the knowledge of healthcare professionals since this construction may reflect and reproduce inequalities of gender, class, race and ethnicity. The social constructions of Aids and breast cancer in women are provided as examples. How medical knowledge has changed significantly in just a few generations is also explained.
- To reflect on tuberculosis and cancer as illnesses and their social impact on aspects such as the social stigmatisation of those illnesses.
- To reflect on several social campaigns aimed at raising awareness of certain illnesses.
- To adopt a more mature view of illness in accordance with what the history, anthropology and sociology of science have told us.

Preliminary activity

Read an excerpt from the book by Susan Sontag, *La enfermedad y sus metáforas. El sida y sus metáforas* (Illness as Metaphor and Aids and its Metaphors), pp. 1-2 (accessible online): http://ceiphistorica.com/wp-content/uploads/2016/04/Susan-Sontag-La-enfermedad-y-sus-met%C3%A1foras.-El-sida-y-sus-met%C3%A1foras.pdf

Alternative reading: https://thinkbeforeyoupink.org/past-campaigns/buckets-for-the-cure-2/
Think Before You Pink®, a project for Breast Cancer Action launched in 2002 in response to growing concern about the number of pink ribbon products available on the market. The campaign advocates greater transparency and responsibility from companies taking part in fundraising activities for breast cancer and encourages consumers to ask themselves questions about pink ribbon promotions.
In 2010 a commercial campaign in the USA named "Buckets for the Cure" run by the KFC fast-food chain pledged to donate 50 cents to the Susan G. Komen Breast Cancer Foundation for every purchase at its restaurants (https://ww5.komen.org/). You can see the advertisement for this campaign (Hailey McCann's 2010 KFC Buckets For The Cure Commercial) at https://www.youtube.com/watch?v=dDfqIgXTlf0. This campaign soon received criticism from the public. Especially harsh were criticisms from Marion Nestle, a food and public health expert, who asked whether KFC really could help to prevent breast cancer (https://www.foodpolitics.com/2010/04/can-kfc-help-prevent-breast-cancer/), and Breast Cancer Action: https://thinkbeforeyoupink.org/past-campaigns/buckets-for-the-cure-2/.

Código de campo cambiado
Código de campo cambiado
Código de campo cambiado
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Código de campo cambiado
Código de campo cambiado

La enfermedad y sus metáforas
por Susan Sontag

La enfermedad es el lado nocturno de la vida, una ciudadanía más cara. A todos, al nacer, nos otorgan una doble ciudadanía, la del reino de los sanos y la del reino de los enfermos. Y aunque preferimos usar el pasaporte bueno, tarde o temprano cada uno de nosotros se ve obligado a identificarse, al menos por un tiempo, como ciudadano de aquel otro lugar. No quiero describir aquí cómo es en realidad emigrar al reino de los enfermos y vivir en él, sino referirme a las fantasías punitivas o sentimentales que se maquinan sobre ese estado: no a una geografía real, sino a los estereotipos del carácter nacional. Mi tema no es la enfermedad física en sí, sino el uso que de ella se hace como figura o metáfora. Lo que quiero demostrar es que **la enfermedad no es una metáfora**, **y que el modo más auténtico de encarar la enfermedad —y el modo más sano de estar enfermo— es el que menos se presta y mejor resiste al pensamiento metafórico**. **Sin embargo, es casi imposible residir en el reino de los enfermos sin dejarse influenciar por las siniestras metáforas con que han pintado su paisaje**. Aclarar estas metáforas y liberarnos de ellas es la finalidad a la que consagro este trabajo.

Dos enfermedades conllevan, por igual y con la misma aparatosidad, el peso agobiador de la metáfora: la tuberculosis y el cáncer.

Las fantasías inspiradas por la tuberculosis en el siglo XIX, y por el cáncer hoy, son reacciones ante enfermedades consideradas intratables y caprichosas —es decir, enfermedades incomprendidas— precisamente en una época en que la premisa básica de la medicina es que todas las enfermedades pueden curarse. Las enfermedades de ese tipo son, por definición, misteriosas. Porque mientras no se comprendieron las causas de la tuberculosis y las atenciones médicas fueron tan ineficaces, esta enfermedad se presentaba como el robo insidioso e implacable de una vida. Ahora es el cáncer la enfermedad que entra sin llamar, la enfermedad vivida como invasión despiadada y secreta, papel que hará hasta el día en que se aclare su etiología y su tratamiento sea tan eficaz como ha llegado a serlo el de la tuberculosis.

Aunque la mixtificación de una enfermedad siempre tiene lugar en un marco de esperanzas renovadas, la enfermedad en sí (ayer la tuberculosis, hoy el cáncer) infunde un terror totalmente pasado de moda. Basta ver una enfermedad cualquiera como un misterio, y temerla intensamente, para que se vuelva moralmente, si no literalmente, contagiosa. Así, sorprende el número de enfermos de cáncer cuyos amigos y parientes los evitan, y cuyas familias les aplican medidas de descontaminación, como si el cáncer, al igual que la tuberculosis, fuera una enfermedad infecciosa. El contacto con quien sufre una enfermedad supuestamente misteriosa tiene inevitablemente algo de infracción; o peor, algo de violación de un tabú. Los nombres mismos de estas enfermedades tienen algo así como un poder mágico. En *Armance*, de Stendhal (1827), la madre del héroe rehúsa decir «tuberculosis», no vaya a ser que con solo pronunciar la palabra acelere el curso de la enfermedad de su hijo. Y Karl Menninger, en *The Vital Balance*, ha observado que «la misma palabra "cáncer" dicen que ha llegado a matar a ciertos pacientes que no habrían sucumbido (tan rápidamente) a la enfermedad que los aquejaba». Esta observación la hace en apoyo de las beaterías antiintelectuales y esa compasión fácil tan ampliamente difundidas en la medicina y la psiquiatría contemporáneas. «Los pacientes que vienen a vernos con sus sufrimientos, sus miserias y su invalidez», sigue diciendo, «tienen todo el derecho a ofenderse si se les pone una etiqueta condenatoria». El doctor Menninger aconseja a los médicos que no usen «nombres» ni «etiquetas» («nuestra función es la de ayudar a la gente, no la de contribuir a afligirla»), lo cual, concretamente, es decir a los médicos que aumenten su reserva y su paternalismo. No es el hecho de nombrar, de por sí, lo peyorativo o condenatorio, sino específicamente la palabra «cáncer». Hasta tanto tratemos a una enfermedad dada como a un animal de rapiña, perverso e invencible, y no como a una mera enfermedad, la mayoría de enfermos de cáncer, efectivamente, se desmoralizarán al enterarse de qué padecen. **La solución no está en no decirles la verdad sino en rectificar la idea que tienen de ella, desmitificándola**.

Hace pocas décadas, cuando saber que se tenía tuberculosis equivalía a una sentencia de muerte —tal como hoy, para la imaginación popular, el cáncer es sinónimo de muerte —, era corriente esconder el nombre de la enfermedad a los pacientes y, una vez muertos, esconderlo a sus hijos. Aun a los pacientes que sí sabían qué tenían, médicos y familiares se resistían a hablarles libremente. «Verbalmente, no me entero de nada concreto»; escribía Kafka a un amigo, en abril de 1924 desde el sanatorio en que moriría dos meses más tarde, «cuando se discute de tuberculosis… todos se expresan de manera tímida, evasiva, mortecina». Las convenciones con que se esconde el cáncer son aún más acérrimas. Como regla general, los médicos de Francia e Italia solo comunican un diagnóstico de cáncer a la familia, no al paciente; consideran que la verdad no sería tolerable más que para los pacientes excepcionalmente maduros e inteligentes. (Un eminente oncólogo francés me dijo que menos del diez por ciento de sus pacientes sabía que tenía cáncer). En Estados Unidos, en parte a causa del miedo ante las posibles consecuencias legales, los médicos son hoy mucho más sinceros con los pacientes; sin embargo, el hospital de cáncer más grande del país envía la correspondencia y las facturas a sus pacientes externos en sobres sin membrete, suponiendo que la enfermedad puede ser un secreto para las familias. Dado que un cáncer puede ser un escándalo que comprometa la vida sentimental, las posibilidades de carrera y hasta el propio empleo del enfermo, los pacientes que saben qué tienen tienden a ser extremadamente remilgados acerca de su enfermedad, cuando no francamente reservados. Y hay una ley federal, la Ley sobre la Libertad de Información, de 1966, que cita «el tratamiento de cáncer» en una cláusula que autoriza a ocultar asuntos cuya revelación «sería una inexcusable invasión de la vida privada». No se menciona otra dolencia. Que se mienta tanto a los pacientes de cáncer, y que estos mismos mientan, da la pauta de lo difícil que se ha vuelto en las sociedades industriales avanzadas el convivir con la muerte. Tal como la muerte es ahora un hecho ofensivamente falto de significado, así una enfermedad comúnmente considerada como sinónimo de muerte es algo que hay que esconder. La política de tratar ambiguamente con los cancerosos no depende más que de una convicción: a los moribundos es mejor ahorrarles la noticia de que se están muriendo, y la buena muerte es la muerte repentina, mejor aun cuando estamos inconscientes o durmiendo. Sin embargo, la negación de la muerte no explica por qué se miente tanto ni por qué uno desea que le mientan; no se toca el pavor más hondo. Quien ya ha tenido un infarto, tiene por lo menos la misma probabilidad de sucumbir de otro infarto a los pocos años que la de un canceroso de morir de cáncer. Pero a nadie se le ocurre ocultarle la verdad a un

cardíaco: un ataque al corazón no tiene nada de vergonzoso. A los pacientes de cáncer se les miente no simplemente porque la enfermedad es (o se piensa que sea) una condena a muerte, sino porque se la considera obscena, en el sentido original de la palabra, es decir: de mal augurio, abominable, repugnante para los sentidos. La enfermedad cardíaca implica un problema, un fallo mecánico; no implica escándalo ni tiene nada de aquel tabú que rodeaba a los tuberculosos y que rodea hoy a los cancerosos.

Las metáforas ligadas a la tuberculosis y al cáncer suponen que unos procesos vitales de tipo particularmente resonante y horrible están teniendo lugar.

A lo largo de casi toda su historia, los usos metafóricos de la tuberculosis y el cáncer se entrecruzan y superponen. El Oxford English Dictionary (OED) señala que «consunción» era sinónimo de tuberculosis ya en 1398 (John of Trevisa: «Cuando se fluidifica la sangre siguen entonces la consunción y el agotamiento». Pero también el cáncer solía comprenderse en términos de consunción. El OED da, como una vieja definición figurada del cáncer: «Todo lo que desgasta, corroe, corrompe o consume lenta y secretamente». (Thomas Paynell, en 1528: «Un cáncer es un tumor melancólico que come partes del cuerpo»). La definición literal más antigua del cáncer es la de una excrecencia, bulto o protuberancia; y el nombre de la enfermedad —del griego *karkínos* y el latín *cancer*, que significan cangrejo— fue inspirado, según Galeno, por el parecido entre las venas hinchadas de un tumor externo y las patas de un cangrejo; y no, como muchos creen, porque una enfermedad metastásica se arrastre o se desplace como un cangrejo. Pero la etimología indica que no ya el cáncer, sino también la tuberculosis era considerada en otra época como un tipo anormal de excrecencia: la palabra tuberculosis —del latín *tuberculum*, diminutivo de *tuber*, bulto, hinchazón— significa una hinchazón, protuberancia, proyección o excrecencia. Rudolf Wirchov, que fundó la patología celular hacia 1850, pensaba que el tubérculo era un tumor.

De manera que, casi desde la antigüedad hasta hace relativamente poco, tipológicamente tuberculosis era cáncer. Y al cáncer se lo describía, al igual que a la tuberculosis, como un proceso en el que el cuerpo se consumía. La concepción moderna de ambas enfermedades no pudo quedar sentada hasta la aparición de la patología celular.

El rasgo distintivo del cáncer, un tipo de actividad celular, y el hecho de que no siempre asuma la forma de un tumor externo y ni siquiera palpable, pudo comprenderse solo con el perfeccionamiento del microscopio. (Hasta mediado el siglo XIX, nadie habría podido identificar la leucemia como una forma de cáncer). Y no fue posible separar definitivamente cáncer de tuberculosis hasta 1882, cuando se descubrió que esta última era una infección bacteriana. Estos procesos de la medicina fueron los que permitieron que las metáforas principales de estas dos enfermedades se diferenciaran realmente, volviéndose casi siempre opuestas. Entonces pudo empezar a tomar forma la imagen moderna del cáncer —una imagen que de los años veinte en adelante iría heredando casi toda la problemática planteada por la imaginería de la tuberculosis—, aunque ambas enfermedades y sus respectivos síntomas se concibieran de modos diferentes y casi contrarios.

Points to consider

- Identify important ideas you find particularly surprising or debatable in the text.
- Do you think the image of cancer has changed since the 1970s? If you think it has, what has contributed to this change?
- To what extent does this text condition the image you had of incurable illnesses and the way in which society deals with them?

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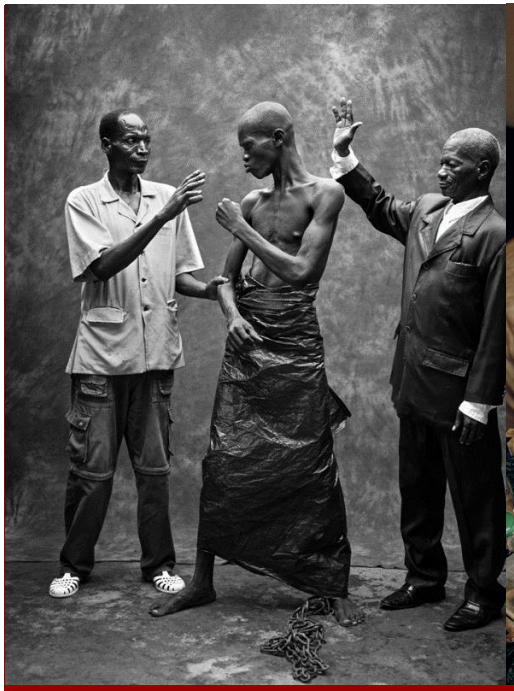

Theme 5. The social construction of illness

Carmel Ferragud, Rafaela Domínguez, Mar Cuenca **Documentation and Scientific Methodology**
History of Science Degree in Pharmacy

Contents

Introduction

1. Social aspects of medicines
2. The social construction of illness:
    - 2.1. Social and cultural factors
    - 2.2. The construction of illness: society and culture
3. The social construction of Aids:
    - 3.1. Consequences of the social image of Aids

Conclusions

Introduction

What does it mean to be healthy or ill?

Who or what does it depend on?

1. Social aspects of medicines

- Illness may have social causes.
- Illness has social consequences.
- Medicine is a social act and product.
- Illness is constructed socially, e.g. dementia as a culturally determined phenomenon and fear of ageing.

Characteristics

1. Health and illness cannot be defined merely in anatomical or physiological terms or by psychological characteristics.
2. Their true measure are the individual's ability to function acceptably **on their own** and the group to which they belong.

Different concepts of health and illness

2. The social construction of illness

ILLNESS
AS A
SOCIAL CONSTRUCT

BIOCULTURAL SYSTEMS IN RELATION TO ILLNESS

UNDERLYING BIOLOGICAL REALITY?

2.1. Sociocultural factors

- Forms of behaviour (lifestyles, sexuality, etc.)
- Language
- Diet
- Rituals practised
- Family structure
- Social networks
- Dress
- Beliefs and values

2.1. Sociocultural factors

- 'Individual' factors (age, sex, personality)
- 'Educational' factors (formal and informal education, professional cultures)
- Socioeconomic factors (social class, socioeconomic status, social support networks)
- Environmental factors
- Political factors
- Ideological factors (politics, religion, environmental awareness)

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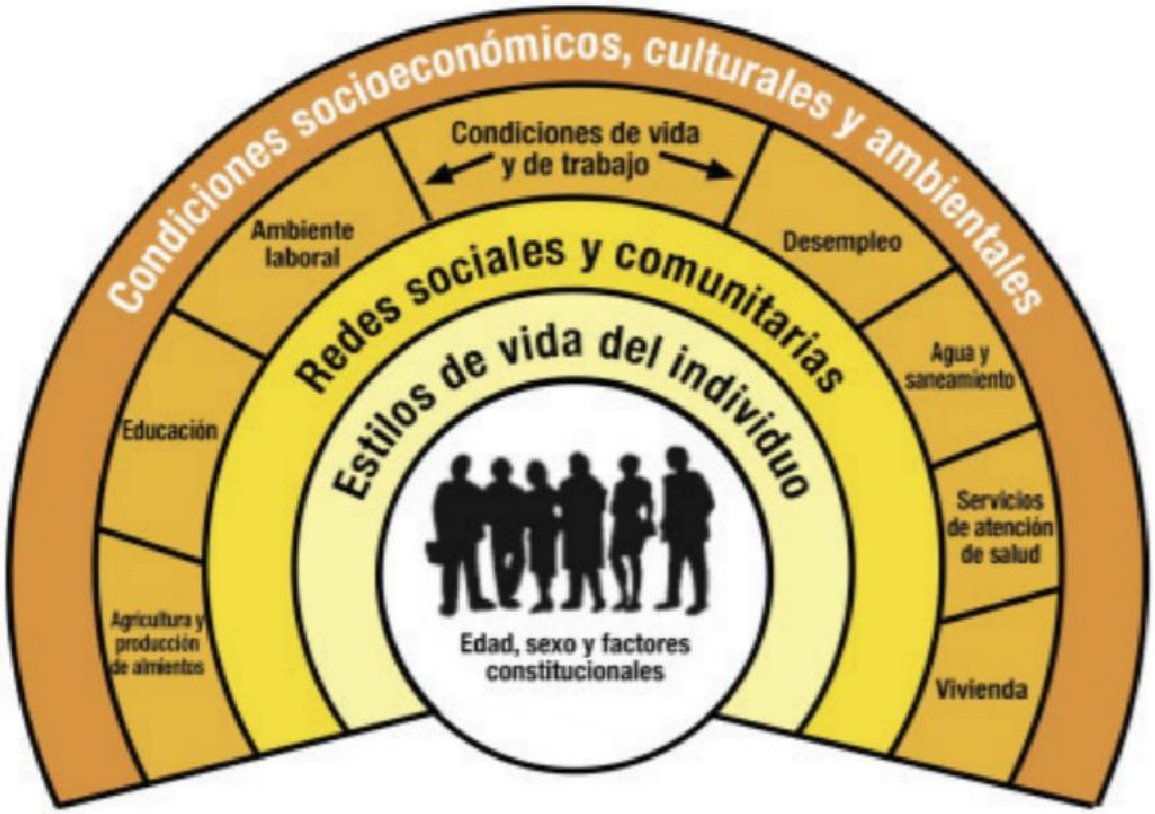


2.1. Sociocultural factors

How these factors influence:

- representations and symbolic values of illness.
- imagined ideas concerning an illness.
- the subjective experience of illness.
- how suffering is expressed (illness narratives).
- expectations in relationships with healthcare mechanisms.

2.2. The construction of illness : society and culture

- Society and culture define and typify what is health and what is illness.

Cultural relativity of the **concept of biological alteration**:

- examples from other periods in history.

- examples from other present-day cultures.

- examples from the present day.

Cultural relativity of the **concept of mental alteration.**

Louis Wain (1860-1939)

2.2. The construction of illness: society and culture

Society and culture give illness **different meanings**:

- Natural cause / random event
- Divine punishment
- Transgression of a moral law
- Imperfection of nature
- Man's destiny given his nature
- Divine gift for achieving salvation

2.2. The construction of illness: society and culture

Every society and its culture create **their own therapeutic context**.

What the population does for itself to solve its health problems.

- What each society considers '**official medicine**', from which it seeks legal protection.

- **Other forms of 'unofficial' healing** that are available in every society (healthcare pluralism).

3. The social construction of Aids

- Aids, globalisation and the media

- *NYT* 3 July 1981: "The strange cancer of homosexuals"

- *El País* 21 August 1982: "200 deaths in the United States due to an unknown disease"

- *La Vanguardia* 16 January 1983: "Aids: a puzzling new illness"

3. The social construction of Aids

- The four ‘H’s: Homosexuals, Heroine addicts, Haitians and Haemophiliacs.
- The mechanisms of transmission.
- The moral construction of illness.

  - Sodom and Gomorrah. The prophesy fulfilled (demonisation of ‘unnatural’ sex and promiscuity).

  - Infection and death.

  - The panic over contagion. The new outcasts.

* Consequences of the social image of Aids

- Stigmatisation of HIV positives.

  * Discrimination in all areas.

  * Its appearance among heterosexuals changed the characterisation of the stigma (poor, promiscuous, foreign).

- The spread of contagion.

  * There is no prevention outside high-risk groups.

  * Concealment of the disease (conscious contagion).

HIV-Aids

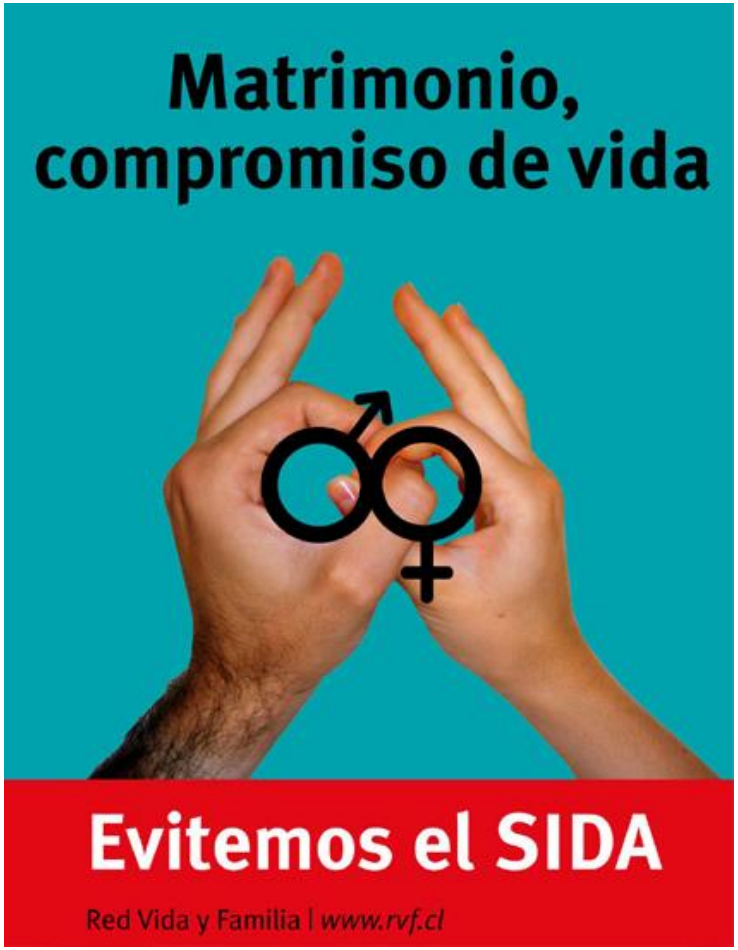
(The surface areas of the countries are modified in accordance with relevant data).

Ideologies and Aids

Federación AntiSida de España

American Life League
Fundación SINSIDA

Social images of Aids



Alehop!!

plataforma gay-lesbiana
coordinadora gai-lesbiana
colectivo Lambda del País Valencià
colectivo de lesbianas y gays de Andalucía

gl coordinadora gai-lesbiana
Les carolines, 13 08312 BCN
Tf (93) 237 70 70

¿Cuántas veces te han hecho sentir así de pequeño por ser gay?
¿Cuántas veces más un seropositivo tendrá que sentirse así?

La solidaridad empieza por ti.

Aids and Culture

Aids and Culture

Aids and Culture


ACT
AGAINST
AIDS
THERE IS STILL
NO CURE FOR AIDS.
PROTECT YOURSELF.

Conclusions

- Illness may have social causes, has social consequences, and is constructed socially.
- Medicine is a social act and product.
- Health and illness cannot be defined merely in biological terms or by psychological characteristics. Their true measure are the individual's ability to function acceptably on their own and the group to which they belong.
- Every society and culture creates its own therapeutic context in a historical context.
- The social image of illness has consequences and causes both stigmatisation and concealment.

Theme 5. The Social Life of Medicines

Introduction

In biomedicine, medicines are the basis of treatment – as they have been in many other medical traditions. As material elements, they have both a social and a pharmacological life since they coexist with people. They are elements for providing cures and for giving hope. They are also valuable merchandise. From an anthropological perspective, this view enables the exploration of numerous problems of interactions between people and medicines – including social effectiveness, the control of use, scepticism and political culture, the commercialisation of health, the attraction for technology, and the marketing of associated images and values.

Contents

Introduction
1. Medicines and their characteristics
2. Medicines as a social and cultural phenomenon
3. Between popularity and scepticism
4. Long live the medicines
Conclusions

Objectives

- To examine the social reality of medicines beyond their pharmacological and chemical aspects.
- To understand the interactions between humans and medicines at every stage: producers, suppliers and consumers.
- To consider more broadly the role medicines play in our society and in other societies around the world.

Preliminary activity

Watch up to minute 19 of the TV programme entitled 'Sobremedicados' from the *Salvados* series presented by Jordi Évole on La Sexta TV, which you can find at:
https://www.youtube.com/watch?v=TJoULVdTyzM

In this excerpt we see the introduction to the programme and interviews with family doctor Enrique Gavilán and pharmacologist Joan Ramon Laporte.

Points to consider

- What are the main ideas in the interviews about the production, distribution and consumption of medicines?
- What role do medicines play in people's lives today? Have our lives been over-medicalised?

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Theme 5. The social life of medicines

VNIVERSITAT DE VALÈNCIA

Carmel Ferragud, Rafaela Domínguez, Mar Cuenca **Documentation and Scientific Methodology**
History of Science
Degree in Pharmacy

Contents

1. Introduction: Medicines and their characteristics

- A medicine is a substance that has the power to transform bodies.
- Medicines are closely linked to the history of humanity.

Characteristics:

1. **Substances**. They are products with economic significance and resources with political connotations. They are powerful symbols that give hope to afflicted people.

1. **Transformative power**. Their effectiveness is assumed.
2. They have diverse transformative powers, e.g. **they cure, prevent, strengthen, and treat risk**.
3. They are **beneficial or harmful** (they can kill or cure): *Pharmakon* = medicine and poison or toxin
4. They are used intentionally to create an effect on the body and have great **power over minds**.

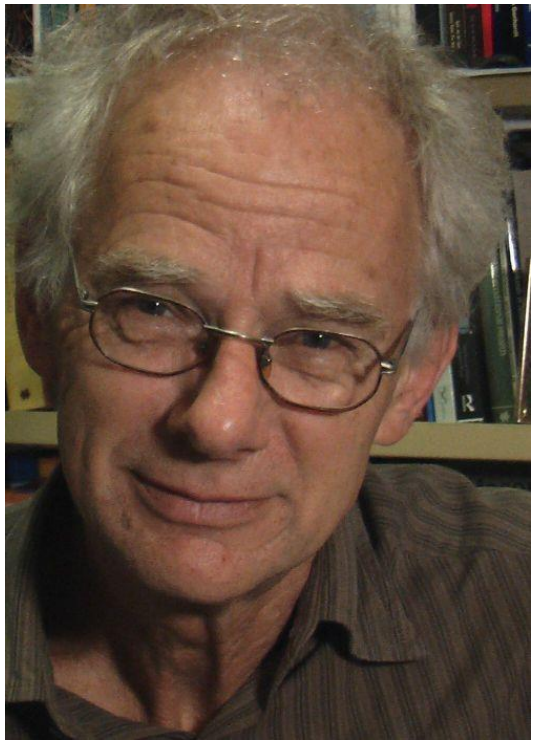
2. Medicine as a social and cultural phenomenon

- A distinction must be made between their chemical and pharmacological properties and their **social and cultural interpretations**.
- Taking a medicine is both a social and a medical act.
- Ritually-, symbolically- and culturally-structured responses show how people use medicines and experiment and cure with them (**extra-pharmacological social effectiveness**).
- Substances become **significant within a cultural context**, so people use them for their own purposes.
- The spread of industrial medicines is a good example of **globalisation**.

2. Medicine as a social and cultural phenomenon

- The social effectiveness of medicines is related to what they offer people and take from them and the social relationships of those involved.

- Pharmaceutical anthropology is the study of the connections between social and cultural processes. This includes **scientific knowledge**, **symbols**, **beliefs**, **politics**, **profit**, **trust and conflict**.



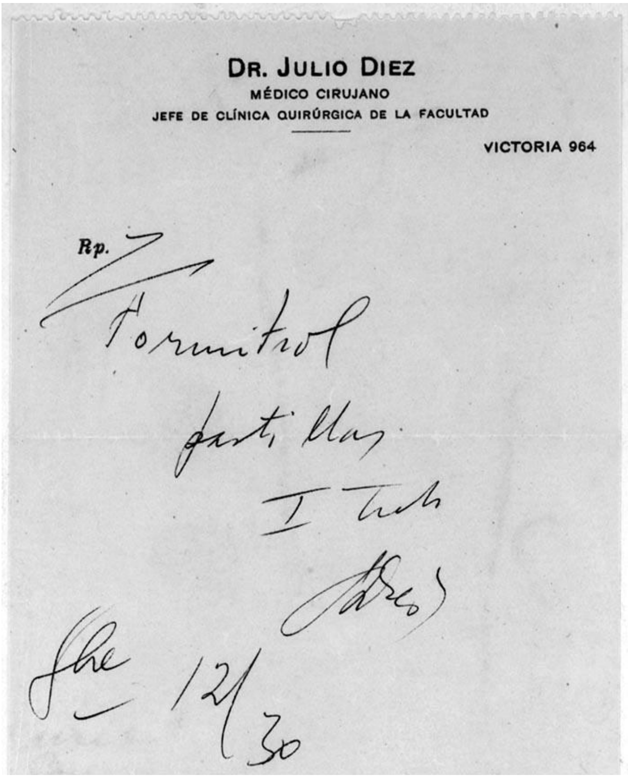
Sjaak Van der Geest

3. Between popularity and scepticism

- Pharmaceutical medicines are found everywhere.
- Popularity and scepticism seem to be dialectically united.
- Popularity: producers and sellers (lucrative); doctors (the good doctor); consumers.
- It is impossible to separate these levels: everyone benefits and devises strategies for gaining popularity.
- Practical experience that medicines work: magic bullets (e.g. antibiotics in Africa, Asia and Latin America).

3. Between popularity and scepticism

- (Symbolic) medicine helps to explain a subjective experience and make it objective (pain).
- Medicines help patients (and their close circles) to understand illness and its causes intellectually; to deduce the illness on the basis of the treatment.
- Legitimation: a prescription confirms the illness and justifies the patient's behaviour.
- Medicinal technology is the heart of the treatment.

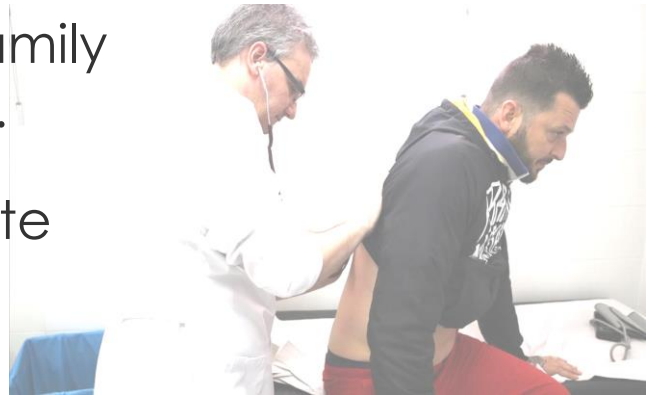


3. Between popularity and scepticism

- Medicines have an intrinsic curative quality; they attract patients and healers (they have a special charm).
- The metonymy of medicines: they have a high-tech appearance (injections, capsules); they have potential and power.
- They have positive effects depending on the prescriber; there is a mediatory mechanism (they are good because they come from a good hand) – the medicine includes a dose of the doctor.
- Medicines lie at the very heart of medical practice, so their prescription is what everyone expects.

2. Between popularity and scepticism

- Illness is a period that favours dependence and social control (by therapists, psychiatrists, family doctors, neighbours, religious leaders, etc.).
- Notions of obligations and morality gravitate around illness (family, confession, sacrifice, rituality, group prayers, etc.).
- A medicine is an alternative; a factor of individualisation that makes it possible to escape from this.
- Medicines reduce dependence on the doctor, spiritual experts, etc. (i.e. they empower patients).



3. Between popularity and scepticism

- Scepticism: taking charge of one's own life (avoiding the intermediation of medicines).
- Excessive prescription; a pretext for shortening the visit. Where is the personal advice? (inoculations).
- Nonconformity: the patient's assertion versus the professional's control (finding the right solution).
- Epilepsy, psychiatry, alcoholism, etc. Medicines as hostile substances, means of oppression and weapons of rebellion.

3. Between popularity and scepticism

- **Medicalisation**: marked sensitivity due to biomedicine escaping one's control and imposing itself in numerous issues that were previously not medicated.
- An obvious example is the multiplication of medicines.
- Iatrogency (danger) and commercial abuse (profit before health).
- Medicines are artificial, chemical, unnatural; they are foreign to the body, an alien force.
- 'Natural' medical tradition versus artificial technological invasion; medicines do not correspond to the cultural perception of illness and healing.

4. Long live to medicines

The stages of social life (the biography of medicines)

Preparation (technological moment) → **wholesalers** (pharmaceutical laboratories; science and business; marketing) → **prescribers** (healthcare professionals; clinics) → **retailers** (pharmacies and various shops; the market) → **consumers** (via prescription or self-medication).

Finally, someone uses the medicine to **recover, improve or remain in good health**.

4. Long live to medicines

The regime of values in the life of medicines

The production and marketing stage: research, market interests, and commercial competition.

The clinical stage: medical professionals see medicines as indispensable in their encounters with patients who are seeking help.

The distribution stage: pharmacists and other sellers see merchandise.

Consumers, patients and relatives hope that the medicines will solve their problems.

4. Long live to medicines

- Molecules are not ‘discovered’ but constructed and reconstructed; they are fluid and associated with a context.
- The circulation of information and advertising.
- Rewriting the pharmacological action – new uses for a medicine (particularly when the patent dies); advertising and the appropriation of users.

4. Long live to medicines

- Medicines are reinterpreted as local concepts and may become different objects.
- Ethnographic studies on the uses of medicines clearly show the intersection between cultural beliefs and market tactics.
- The role of pharmaceutical companies: sell the illness before the medicine.
- The creation of literature by laboratories (the invisible writing hand).

4. Long live to medicines

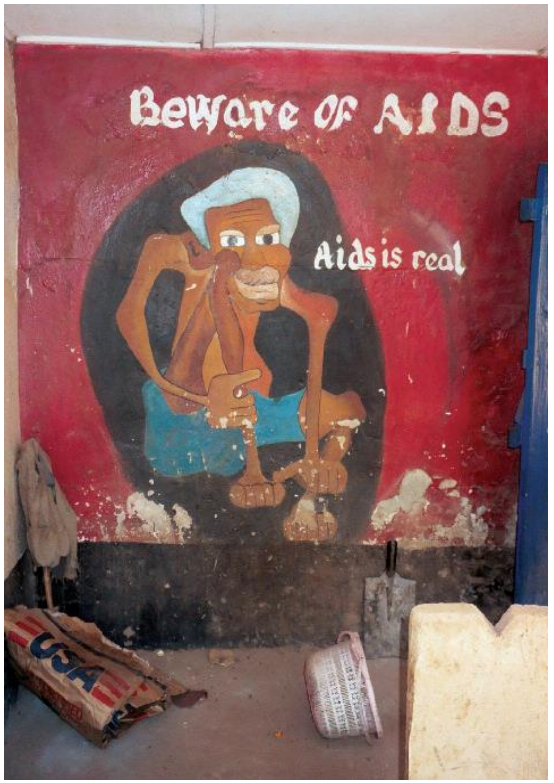
- Psychiatry in Argentina: the popularity of antidepressants such as tranquilisers (anti-panic medicines). The industry uses the political and economic crisis to offer people help in regaining control of their lives [the diagnosis matches the medicine].

- Associating medicines with attractive imagined situations (this may or may not be morally reprehensible), e.g. Viagra (gays; erectile dysfunction; advertising; couples counselling; and enjoyment).

- A multi-causal approach to pharmaceutical reality is needed to make medicines more accessible, improve their use, and promote proper consumption.

Conclusions

- High popularity versus doubt and criticism.
- Medicines are a component of global processes of attraction or rejection depending on predominant political, cultural or ideological values.
- Popularity: practical experience, tangibility, xenophilia-metonymy, symbolic exchanges, empowerment.
- Scepticism: prescriptions as a means of subjection; unsuitable for the problem; incomprehensible and complex.



Conclusions

- Sceptics in Western and non-Western societies are not the same.
- Ambiguity: a weapon of destruction and resistance.
- Doubt is caused as much by knowledge as by lack of knowledge.
- Scepticism within a type of cultural politics, a broader context (nature vs. technology; ancient tradition vs. Western modernity; freedom of the individual vs. the professional's authority; people vs. capitalism).

Theme 6. The language of science

Introduction

The circulation of scientific information, both within and outside the community of experts, is an essential element of science. Most scientists devote a considerable part of their work to locating, analysing and assimilating the many publications on their research subject. The conclusions of their investigations are generally discussed at seminars or conferences and published in books or journal articles. Even in experimental disciplines such as chemistry and pharmacy, the tasks associated with scientific communication can take up much of the time devoted to research. This information circulates across linguistic frontiers via several resources that are discussed in this topic. A huge amount of information is circulating in science and medicine. Moreover, this information is increasing rapidly, thus rendering obsolete the knowledge that has already been acquired. Scientific and medical terminology therefore includes a vast range of expressions that are in constant renewal. Controlling this vocabulary and its growth becomes an indispensable activity for ensuring the suitable transmission of information.

Contents

1. Introduction
2. Origins and basic elements
3. The construction of terms
4. Problems with using terminology
5. Nomenclatures and classifications
6. The names of medicines

Objectives

- To understand the specific nature of scientific language, especially in comparison with colloquial language.
- To analyse the origins of scientific language and its process of formation.
- To know the procedure by which neologisms are constructed.
- To become familiar with the main problems with using scientific language.
- To provide formulas for learning, understanding and using scientific and medical terminology.
- To learn some of the main scientific nomenclatures associated with pharmacy; to understand their structure and importance.
- To become familiar with the procedure for naming medicines.

Preliminary activity

Read the handbook *Documentación y metodología en ciencias de la salud*: pp. 41-43.

Points to consider

- Is the language or how science is expressed really so important?
- Why is it not advisable for everyone to express the contents of science with everyday language?

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Con formato: Español (España)

ACTIVITIES ON TERMINOLOGY

a) The c**onstruction of neologisms**

With the list of roots, prefixes and suffixes, write terms that mean the following:

1. Science that studies the heart

2. Instrument used to explore the movements of the heart

3. Heart disease

4. Fast movement of the heart

5. Heart layer, envolture

6. Chirurgical cut in the heart

7. The art of writing fast

8. The science or study of blood

9. The science or study of water

10. Method of analysis based on measuring the quantity of silver or compounds of silver

11. Instrument used to observe the ear

12. Of a material that has or contains gold

13. Instrument for measuring humidity/moisture

14. Instrument for measuring atmospheric pressure

15. Science that studies animals

Comentado [KPC1]: Do you mean "envelope"?

Comentado [KPC2]: Archaic; do you mean "Surgical incision"?

Comentado [KPC3]: Simply, "Of a material that contains gold"?

b) Analysis of terms (elements, combinations and meanings)

Identify the elements used to form these words. Show how the elements are combined and explain the meanings of the words.

Comentado [KPC4]: UK spelling applied.

1. Chromatophore

2. Astronomy/astrology

3. Biology

4. Chromatography

5. Astrocyte

6. Leucocyte/leukocyte

7. Erythrocyte

8. Nephritis

9. Haematuria

10. Leukaemia

11. Tachycardia

12. Hypoglycaemia

13. Hyperglycaemia

14. Odontology

15. Echography

c) Eponyms

Find three scientific terms that are formed from the names of the following scientists:

Louis Pasteur (1822-1895)

Alessandro Volta (1745-1827)

André M. Ampère (1775-1836)

Luigi Galvani (1737-1798)

d) Semantic phenomena

Look at the following definitions of the word 'virus' from different editions of the dictionaries of the *Real Academia Española*.

1803 Med. Cir. Podre, mal humor.

1852 Med. y Cir. Podre, humor maligno. Virus, sanies // El principio material de las enfermedades contagiosas. Tómase a veces también por el principio material que produce cualquier enfermedad, aun cuando no sea contagiosa.

1899 (Del lat. virus) m. Med. Podre, humor maligno // Med. Germen de varias enfermedades, principalmente contagiosas, que se atribuye al desarrollo de microbios especiales para cada una.

1925, 1936 Id.

1950 Med. Podre, humor maligno // Med. Germen de varias enfermedades, principalmente contagiosas, que se atribuye al desarrollo de microbios.

1956 (Del lat. virus) Med. Podre, humor maligno // Med. Cualquiera de los agentes infecciosos apenas visibles con el microscopio ordinario y que pasan a través de los filtros de porcelana. Son causa de muchas enfermedades, como la rabia, las viruelas, la glosopeda, etc.

1989 Med. Podre, humor maligno // Biol. El organismo de composición más sencilla que se conoce. Es capaz de reproducirse en el seno de las células vivas específicas, siendo sus componentes esenciales ácidos nucleicos y proteínas. Es causa de muchas enfermedades. # No varía en plural.

2003 (Del lat. virus). 1. m. Biol. Organismo de estructura muy sencilla, compuesto de proteínas y ácidos nucleicos, y capaz de reproducirse solo en el seno de células vivas específicas, utilizando su metabolismo. 2. m. Inform. Programa introducido subrepticiamente en la memoria de un ordenador que, al activarse, destruye total o parcialmente la información almacenada.

Discuss the most important semantic phenomena that have taken place.

e) Appendix

Roots

Antr	g.	man
Aur	l.	ear (auris)
Aur	l.	oro, dorado (aurum)
Argent	l.	silver
Aster / Astr-	g.	star
Bacil	l.	(in form of) stick
Bacter	g.	(in form of) stick
Bar (o)	g.	weight
Bradi	g.	slow
Bio	g.	life
Calc	g.	stone
Cardi	g.	heart
Cephal	g.	head
Cyt, cyte	g.	cell
Chlor (o)	g.	green
Cryo	g.	cold
Chrom / chromat	g.	colour
Eco	g.	environment, house (oikos)
Eco	l.	sound (echo)
Erytr	g.	reed
Etio	g.	cause
Fleb	g.	vena
Ge(o)	g.	Earth, land
Gluc, glic	g.	sweet, sugar
Graph	g.	write, describe, register
Haem/ Haemat	g.	blood
Hydr	g.	water

Comentado [KPC5]: "gold, golden (aurum)"?

Hygr	g.	moist, wet
Iatr	g.	healer, doctor
Leuc, leuk	g.	white
Log	g.	reason, study, science
Melan (o)-	g.	black
Metr	g.	measure (metrón)
Metr	g.	uterus (métra)
Mio	g.	muscle
Nephr	g.	kidney
Nom	g.	ordered knowledge, law
Pat	g.	disease
Odont	g.	tooth
Tachy	g.	quick, swift
Therm	g.	heat
Tom	g.	cut, slice
Ur	g.	urine
Zo(o)	g.	animal

Comentado [KPC6]: ???

Comentado [KPC7]: ???

Prefixes and suffixes

ecto-	g.	out of
endo-	g.	inside
exo-	g.	outside
hyper-	g.	above, beyond over
hypo-	g.	below, under, less
-itis	g.	inflammation
-ia	g.	condition, state
para-	g.	beside, near, equal

peri-	g.	around
-pher	l.	bear, carry, produce
-phore	g.	carrier
-osis	g.	abnormal condition (not inflammation)

6. The language of science

Carmel Ferragud, Rafaela Domínguez, Mar Cuenca
History of Science

Documentation and Scientific Methodology
Degree in Pharmacy

1. Introduction
2. Origins and basic elements
3. The construction of terms
4. Problems with using terminology
5. Nomenclatures and classifications
6. The names of medicines

1. Introduction

- It is necessary to express the ideas, concepts and realities of the world of science.
- It is estimated that 10,000-15,000 terms must be learned during vocational training in the Health Sciences.
- Analysing the origin, formation process, neologism construction norms and main problems involved in scientific language can aid its comprehension and use.

Why colloquial language is unsuitable:

- It lacks precision and concision.
- It lacks the universality of specific language.
- It lacks the emotional neutrality scientific terms require: problems with some terms (syphilis, tuberculosis, hysteria).
- Specific resources, e.g. abbreviations, symbols, diagrams and formulas, etc. are often required.
- New words must be incorporated for new concepts and new discoveries.
- Professional secrecy must be maintained.
- The sociological characteristics of the profession must be maintained.

General characteristics of scientific language

- Universality: it is an international language but it adapts to the spelling and syntax, etc. of each language (e.g. cardiopathy, cardiopatía, cardiopathie, kardiopathie, etc.).
- Concision: this is necessary to save time (oral) and space (writing) (e.g.haemoglobinuria, etc.).
- Accuracy: each signifier should correspond to a single meaning, and vice versa (e.g. amelia, exophthalmos, tachycardia, etc.).
- Emotional neutrality: affective components are absent and the style is objective and impersonal (3rd person).

Spanish		**hiperglucemía**	**espectroscopio**	**ecografía**	**ecología**	**Mastectomía**
Danish		hyperglykaemi	spektroskop	echografi	økologi	mastektomi
German		hyperglykämie	Spektroskop	Echographie	Ökologie	Mastektomie
Catalan		hiperglucèmia	espectroscopi	ecografia	ecologia	mastectomia
Greek		υπεργλυκαιμία	φασματοσκόπιο	Υπερηχογράφημα	οικολογία	μαστεκτομή
English		hyperglycemia	spectroscope	echography	ecology	mastectomy
French		hyperglycémie	spectroscope	échographie	écologie	mastectomie
Italian		iperglicemia	spettroscopio	ecografia	ecologia	mastectomia
Portuguese		hiperglicemia	espectroscópio	ecografia	ecologia	mastectomia
Swedish		hyperglykemi	spektroskop	Ultraljud	ekologi	mastektomi

2. Origins and basic elements

- Greece and Rome.
- Galen of Pergamus, 2nd century: spread of Byzantine Galenism; Arabised (incorporation of Arabic terms); great encyclopaedias (Canon of Avicenna); return to the West and Christianisation (translations).
- Purification of classical terms, 15th and 16th centuries; Renaissance humanism; hegemony of Latin as the *lingua franca*; foundations of current terminology.
- Growing use of vernacular languages (17th century).
- Hegemony of French (eighteenth century), German (transition from the 19th to the 20th century) and, finally, English (since the mid-20th century).

- **Traditional lexical heritage:** terms of Greco-Latin origin have been a substantial component of the process of scientific dissemination since antiquity.

- **Words from modern languages** that replaced Latin as a vehicle for scientific communication include those from: French (e.g. chancre, tic, tissue), German (e.g. Gestalt, Kernicterus), and, less frequently, Italian (e.g. pellagra, malaria), Spanish (e.g. dengue and pint), and other languages. English is currently predominant (e.g. by-pass, stress, rash, etc.).

- **Vocabulary from other origins** (e.g. ribosome, oncornavirus)
  - Changes in meaning.
  - Associations of an indirect or metaphorical nature.
  - Terms with an ambiguous or equivocal meaning or an unknown or uncertain origin.

- **Eponyms:** names of physicians, inventors, places, gods, myths (e.g. narcissism, hermaphrodite, venereal) such as Herophilos' Press, Parkinson's disease, Babinski's syndrome, Creutzfeldt-Jakob disease, Billroth's operation, Alzheimer's dementia, Wassermann's reaction, Colles' fracture, Pavlov's reflex, Gimbernat's ligament, Malpighi's glomerulus, etc.
  - Problems: several meanings; diverse attributions to a discoverer; use as root (pasteurisation, roentgenology).
- **Acronyms**: AIDS, CT, DNA, RNA / aldehyde (alcohol + dehydrogenated).
  - Problems: restricted scope, matches, order of acronyms.
- **Onomatopoeias**: borborygmus (stomach rumble), murmur.

3. The construction of terms

- One of the basic characteristics of scientific language is its **adaptability** and possibilities for **expansion.**
- New terms or **neologisms** are often created to express new concepts, methods, diagnostic tests, surgical techniques, etc.
- Types of neologisms:
  1. Neologisms of **form**: creation of a term or a new expression.
  2. Neologisms of **sense**: attribution of a new sense to an already existing term.
  3. **Syntactic** neologisms.

Neologisms of form

- Constructing neologisms from Greco-Roman morphemes:
  - Ensures **coherence** with existing terms.
  - Expresses science-related ideas and concepts **accurately** and **concisely** .
  - Ensures the **universality** of scientific language.
- Neologisms are formed by combining **roots**, **prefixes** and/or **suffixes.**
- A term may contain one or more roots and one or more prefixes and suffixes (or none).
- A thousand Greek or Latin roots are available.

Main roots

- General: soma, phren, physio, bio, let, necr (o), topo
- Anatomical parts: cervic-, brachy-
- Organic liquids or secretions: hem- (haem-), galact-
- Organic functions: -trophy, phage-, men-
- Diseases and conditions: pat-, algia
- Animals and plants: helmin-, radic-
- Chemical elements and compounds: hydro-
- Phenomena and physical agents: cryo-, term-
- Objects: acou-, burs-
- Operations and actions: -tomy

Prefixes and suffixes

- Many prefixes delimit position: within (endo- / intra- / in-); outside (ecto- / exo- / extra-); around (circum- / peri-), lower (infra- / sub-); in the middle (inter-); through (dia- / per- / trans-), beyond (meta-); on / upon (epi-); before / in front of (ante- / pre- / pro); after / behind (post- / retro-); far (tele-).
- Many indicate forms, colours, numbers, quantity, size or other qualities: poly-; oligo-; eu-
- Many suffixes indicate the type of disease: pathology (-ia); inflammation (-itis); tumour (-oma); process / condition (-osis).
- There are diminutive particles: clostr (idi) um; fontan (el) a
- Other meanings exist: absence (a-); defect (hypo-); excess (hyper- / super); equality (iso-); inequality (aniso-); equal (homo-); unequal (dis); negation (in-); repetition (re-); similarity (pseudo-).

Basic combinations

- **Determinative:** A main root is delimited and specified by other roots, prefixes, or suffixes.

Hyper (excess) + leuko (white) + cyt (célula) + haem (blood) + ia (state or condition):

Hyperleukocytaemia

- **Copulative:** Several morphemes combine to associate their meanings.

Cervico (neck) + brachi (bazo) + al (derivative suffix)

Cervicobrachial

- **Mixed:** Combining the previous.

Gastro (stomach) + enter (intestine) + estom (mouth, opening) + ia (state or condition)

Gastroenterostomy

Special combinations

- **Link:** is used when combining a morpheme that ends with a consonant with another morpheme that begins with a consonant. It involves adding a vowel:
  - If the link is between two roots of Greek origin, or a Greek and a Latin one, an **o** is usually added: gastr**o**pathy.
  - If the link is between two roots of Latin origin an **i** is usually added: papill**i**form.

Complex words or expressions

- Syntactic combination of several words to form an expression. Several words from common or specialised language are articulated:
  - In **juxtaposed** form (amyotrophic lateral sclerosis, transient ischemic attack).
  - In **coordinated** form (coffee ground vomiting).

Neologisms of sense

- **Terminologisation** means incorporating a new meaning to a word in everyday language (e.g. mouse).

- **Passing a term from one branch of knowledge to another**, where in the latter it acquires a different meaning from the meaning it had in the first (genetic code).

Syntactic neologisms

- **Changes in an element's grammatical category or function**:
  - An adjective begins to function as a noun: (drug) analgesic, (substance) anticoagulant.
  - An intransitive verb becomes transitive (e.g. enter data), or a proper noun becomes a common noun (e.g. "he has Alzheimer's").

4. Problems in using terminology

Scientific language does not always conform to logical or uniform criteria because of:

1. **Semantic phenomena characteristic of natural language.**
2. **Changes in meaning.**
3. Associations of an indirect or metaphorical nature.
4. Words with ambiguous or equivocal meanings or with an unknown or uncertain origin, e.g. eponyms, acronyms, and onomatopoeias.

Semantic phenomena

- **SYNONYMS:** two or more words with the same meaning:
  - This is a common problem.
  - A variant may be eponymous.
  - Greek / Latin roots may be used:

    nephropathy / renopathy; tetraplegia / quadriplegia
- **POLYSEMY AND HOMONYMY** occurs when a single term refers to different concepts. The difference between polysemy and homonymy is that in the former there is a common nexus between the contents of the term but there is no such nexus in the second. Example: memory, tarsus.
- **ANTONYMS:** terms of opposite meaning (hyper / hypotension).
- **GENERIC-SPECIFIC RELATIONS** (gastropathy-gastritis).

Changes in meaning

- **Transfer** is a term's simple change in meaning: rheumatism, virus, vitamin.

- **Contraction** involves a reduction in meaning. The meaning of the term is more restrictive than its original meaning: neurosis, fever.

- **Expansion:** the term takes on a broader meaning than its original meaning: nausea, cancer.

5. Nomenclatures and classifications

These aim to solve problems due to lack of logic and uniformity in terminology.

- **Nomenclature** is a list or catalogue of terms approved by a specific scientific community according to norms that determine their meanings.
- **Classification** is the establishment and characterisation of systematic groups according to the knowledge and resources available at any given moment.

International Classification of Diseases (ICD)

Main nomenclatures I

- Botanical terminology: Hindu (rice), Persian (spinach, saffron), Hebrew (cumin), Arabic (artichoke), Greek (sesame), Latin (lentil), American (potato, tomato), and others (tea).
- Zoological terminology: Greek (hippopotamus), Latin (tiger, lion), Arab (giraffe), and others (puma, reindeer, kangaroo, mammoth, chimpanzee).
- Bacteriological terminology.
- Proposed nomenclatures from Linnaeus (1707-1778): later Vienna (1906) and Brussels (1912) codes.

- Anatomical terminology (Basel 1895, *Parisiensis* 1977 (4)).
- Nomenclatures at initial stages, e.g virological, genetic, etc.

Main nomenclatures II

- Chemistry: 1787 (inorganic), 1892 (organic).
- Mineralogy:
  - Various criteria (eponyms, properties, etc.) recognised by the IMA (International Mineralogical Association) Mineral Names Commission. Roughly 3,000 species in 1990.
- Astronomy:
  - First Congress of the International Astronomical Union in Rome (1922): establishment of the number of constellations (88) and Latin nomenclature. Stars are letters of the Greek alphabet, while comets are eponymously named.
  - IAU's SIMBAD database: 3,148,048 objects in 2003.

The ICD-10 (1989) consists of 25 codes (letters) from A to Z that generate 20 groups of diseases.

2015 ICD-10-CM Codes

- A00-B99 Certain infectious and parasitic diseases
- C00-D49 Neoplasms
- D50-D89 Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
- E00-E89 Endocrine, nutritional and metabolic diseases
- F01-F99 Mental, Behavioral and Neurodevelopmental disorders
- G00-G99 Diseases of the nervous system
- H00-H59 Diseases of the eye and adnexa
- H60-H95 Diseases of the ear and mastoid process
- I00-I99 Diseases of the circulatory system
- J00-J99 Diseases of the respiratory system
- K00-K95 Diseases of the digestive system
- L00-L99 Diseases of the skin and subcutaneous tissue
- M00-M99 Diseases of the musculoskeletal system and connective tissue
- N00-N99 Diseases of the genitourinary system
- O00-O9A Pregnancy, childbirth and the puerperium
- P00-P96 Certain conditions originating in the perinatal period
- Q00-Q99 Congenital malformations, deformations and chromosomal abnormalities
- R00-R99 Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified
- S00-T88 Injury, poisoning and certain other consequences of external causes
- V00-Y99 External causes of morbidity
- Z00-Z99 Factors influencing health status and contact with health services

Diseases of the musculoskeletal system

- Arthropathies (M00-M25).
- Systemic diseases of the joints (M30-M36).
- Diseases of the spine and back (M40-M54).
- Diseases of soft tissues (M60-M79).
- Osteopathies and chondropathies (M80-M94).
- Other diseases of the musculoskeletal system and joints (M95-M99).

6. The name of medicines

- Bayer chemists believed that heroin did not produce dangerous side effects and it was used to calm coughs. After taking it, Bayer workers were said to feel 'heroic' (hence the name). In 1915, the Bayer factory produced a ton of heroin.
- It was exported as a medicine to 22 countries, including Spain.
- The (brand) name *Heroína* was requested in Spain on 22-12-1920 by Bayer's Spanish subsidiary *(Sociedad Federico Bayer & Cia*).

- Aspirin was discovered by chemist and pharmacologist, Felix Hoffmann, when helping his father with painkillers to combat rheumatism.
- Aspirin comes from **A**cetyl **Spir**säure (another form of the name Salicylsäure, i.e. salicylic acid in German) and the suffix **in** ('matter of', i.e. which treats or cures).

Brand drugs(EFE):

Aspirina®, AAS®	salicylic acid
Clamoxil®	amoxicillin
Gelocatil®, Febrectal®	paracetamol
Mercromina®	mercurochrome
Primperan®	metoclopramide
Valium®, Aneurol®	diazepam


Dorcol
Zolben
Alvedon
Eu-Med P Mono
Vips
Sinpro
Fanalgic
Malgis
Anacin-3
Reliv
Nina
Treupel mono
Panamax
Algina
Neuridal
Hedex
Dial-a-gesic
Panadol
Tempra
Ben-u-ron
Nebs
Dolofugin
Exdol
Momentum
Finimal
Gardan

International Nonproprietary Names (INNs / DCI): the active ingredients of drugs

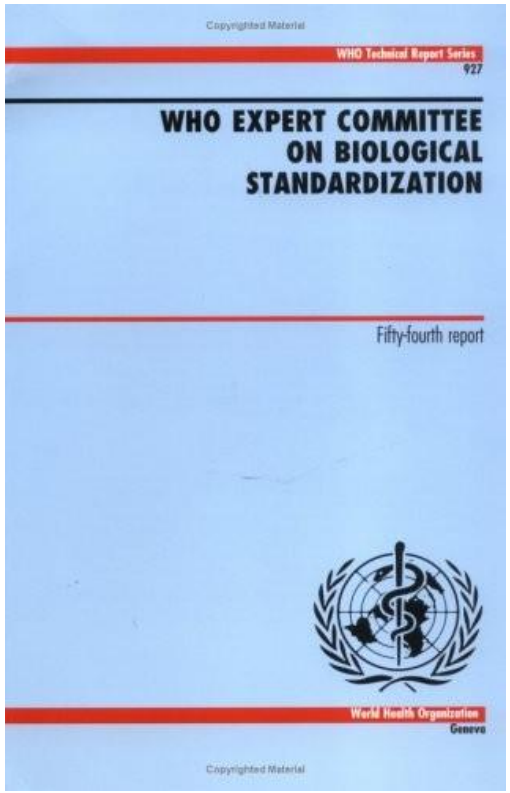
"Denomination derived from the name of a pharmacological particle or a substance (or its chemical origin or structure) which can be recognised immediately, either because it is very characteristic, or because of its place in the denomination".

WHO recommends that INNs:

- Should not refer to clinical use.
- Should not be capitalised.
- Should not lead to confusion with other denominations.
- Should not be too long (such as chemical names).
- Should not stray from solutions adopted in other languages of international communication.
- Should adapt to the spelling of each language.
- Should show kinship according to pharmacological group.

Generic drugs

International Nonproprietary Names for Pharmaceutical Substances (INN)



Fuente: http://www.who.int/medicines/publications/druginformation/innlists/RL73.pdf?ua=1

Brand names

- Agencies and advertising campaigns (short, catchy, and global).
- Letters x, y, z (Clamoxil, Zyprexa) are associated with high technology.
- Viagra: Vigor + Niagara (flow).
- Similarities and confusion force name changes (33,000 names approved each year): Almax - Atarax / Natusán – Natulán).

Theme 7. Scientific Communication

Introduction

An important aspect of scientific activity is its popularisation. This is especially true in the field of biomedicine, where people's attitudes are crucial for the success of healthcare campaigns aimed at encouraging the responsible consumption of medicines or promoting healthy practices. Scientific information is often presented in a way that most of the population finds impossible to understand. This is particularly inappropriate, for example, when a doctor has to explain to a patient a diagnosis that requires a series of operations or changes in their habits or behaviours. It is impossible to achieve those goals if those who work in the medical and healthcare professions are unable to transmit information in a way the public can understand. It is a problem, for example, if a drug's patient information leaflet (which is intended to be read by patients) contains highly specialised vocabulary or information that is too complex for most people. In addition, the leaflet may contain false or insufficiently tested information that promotes certain economic interests rather than improvements in people's health. We must be aware of this tension between healthcare and business, which lies at the heart of the pharmaceutical industry's activities.

Contents

1. The culture of scribes
2. Dissemination through print
3. Challenges facing scientific information today
4. The popularisation of medicine and pharmacy
5. Models of scientific popularisation
6. Actors, targets, media, and purposes of scientific popularisation

Objectives

- To understand the process involved in disseminating science as a fundamental feature of all cultures (albeit with their own specific characteristics).
- To discuss the idea of the circulation of knowledge as an explanation for the fusion that often imbues scientific production.
- To know that scientific communication has specific characteristics that are far removed from the traditional model of dissemination everybody usually accepts as valid.
- To understand the role played by laymen (patients' associations) in the production of scientific knowledge.

Preliminary activity

Read an extract from Puerto, J. (2004). El medicamento en el escaparate. Barcelona: Uriach; and Gabriel J. (2014). *Medical Monopoly. Intellectual Property Rights and the Origins of the Modern Pharmaceutical Industry*. Chicago: University of Chicago Press.

La historia de la publicidad farmacéutica

Los primeros pasos de la publicidad farmacéutica fueron realizados en un contexto muy diferente al actual, antes del nacimiento de la moderna industria farmacéutica en el siglo XIX. Sus autores trataban de defender ciertas terapias o popularizar determinados "remedios secretos" que habían sido sugeridos por algunos autores. En realidad, la mayor parte de la terapéutica oficial era registrada en las farmacopeas y no existían derechos de patente que hubieran podido justificar campañas de publicidad como las actuales. En muchos países, existían comisiones que se encargaban de otorgar los derechos para poder fabricar algunos de estos medicamentos secretos. Sus autores a menudo empleaban libros y folletos para darlos a conocer y alabar sus virtudes, casi siempre de forma algo exagerada. Con el desarrollo de la prensa, sobretodo en el siglo XIX, comenzaron a publicarse los primeros anuncios de productos farmacéuticos. Estos anuncios se hicieron tan frecuentes que provocaron las críticas de un médico, que escribió en 1903: "la cuarta plana de los diarios es una consulta [médica] gratuita que debería reglamentarse pues no tiene gracia, que en virtud de la sugestión escrita, se ejerza una profesión tan sagrada y difícil como la del médico". La regulación restrictiva de la publicidad farmacéutica había sido ya introducida en España por las ordenanzas de farmacia de 1860, pero la prensa cotidiana continuó publicando anuncios de este tipo de forma creciente. La llegada de los nuevos productos "específicos" fabricados por la industria química provocó nuevos debates y regulaciones durante la segunda mitad del siglo XIX. Se abrieron nuevas vías para la publicidad como las exposiciones farmacéuticas, que presentaban las novedades, e incluso se crearon revistas que incluían básicamente publicidad de remedios farmacéuticos de fabricación industrial. También se desarrollaron, sobre todo desde principios del siglo XX, toda una amplia gama de carteles, recipientes policromados y folletos con imágenes atractivas y textos publicitaros. Grandes empresas farmacéuticas como Burroughs Wellcome, se caracterizaron por su ingenio, creatividad y capacidad para comercializar sus productos y el uso amplio de nuevas técnicas publicitarias. La llegada de la radio y la televisión multiplicó las posibilidades, aunque también aumentaron las restricciones y los controles por parte de los gobiernos, especialmente en las últimas décadas del siglo XX. La publicidad farmacéutica refleja las expectativas sociales y los intereses económicos de sus productores, así como toda una serie de conexiones entre la medicina y otros rasgos de la cultura (la religión o las fiestas populares, por ejemplo). Su análisis permite también conocer las personas que se consideran como autoridades en cada momento y que son movilizadas por la publicidad para sus intereses: científicos, médicos, literatos, etc. El uso denigrante de la mujer e imágenes sexistas de todo tipo ha sido también habitual para conseguir mejores ventas, no solamente en el terreno de la farmacia. Las regulaciones más recientes tratan de evitar los abusos y limitan los efectos negativos de la publicidad en la automedicación, el consumo excesivo de medicamentos y la compra de productos patentados frente a los genéricos. En España, la ley general de sanidad de 1986 limitaba la publicidad de medicamentos, los que se regulo mediante un decreto de 1994 y otras normativas posteriores.

Points to consider

- What objective is the pharmaceutical industry pursuing with regard to drug advertising? What does it hope to achieve?
- Can advertising campaigns cause people to increase their consumption of drugs? Can they generate healthcare panics?
- Who ought to be popularising science? Why?

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7. Scientific Communication

Carmel Ferragud, Rafaela Domínguez, Mar Cuenca
History of Science

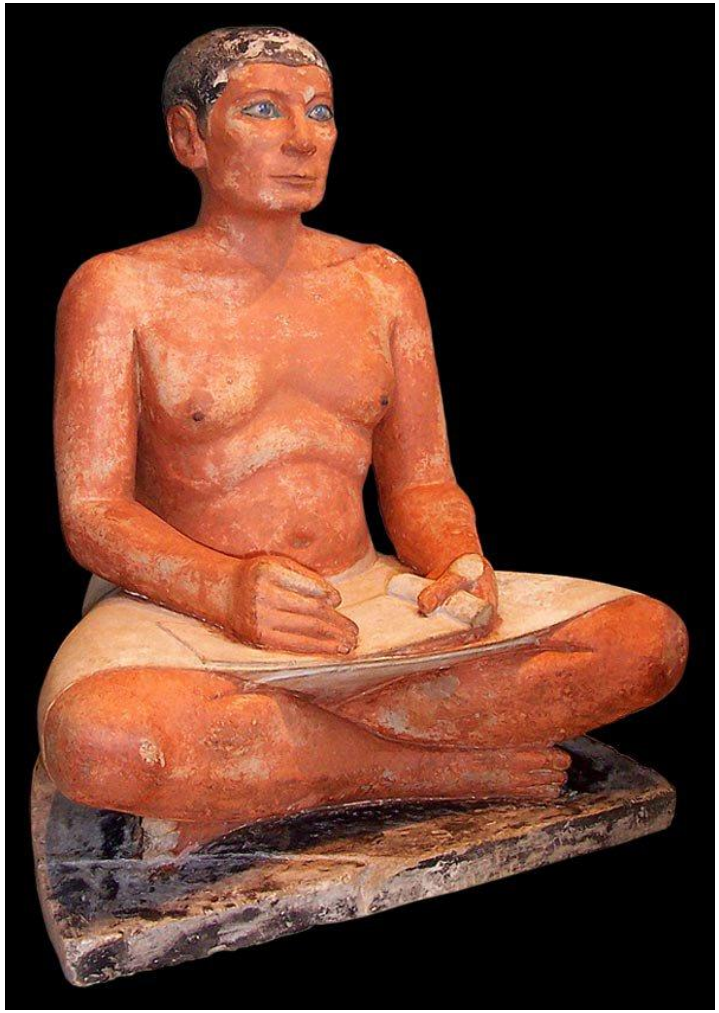
Documentation and Scientific Methodology
Degree in Pharmacy

1. The culture of scribes
2. Dissemination through print
3. Challenges facing scientific information today
4. The popularisation of medicine and pharmacy
5. Models of scientific popularisation
6. Actors, targets, media, and purposes of scientific popularisation

1. The culture of scribes

- Writing began in Egypt and Mesopotamia around 3000 BC.
- Knowledge of nature (including the stars, calculations and geometric figures) was rapidly recorded in writing.
- The materials used (e.g. clay, stone, papyrus, wax, parchment, etc.) depended on the resources available.
- The diffusion of knowledge was extremely limited despite the creation of the first libraries (such as the Library of Alexandria).

Papyrus Ebers, (30x2000 cm), c. 1500 BC
(Universitätsbibliothek, Leipzig)



The seated scribe, c. 2300 BC
(Musée du Louvre)

Library of Celsus (Ephesus, 101, c. 12000 volumes)

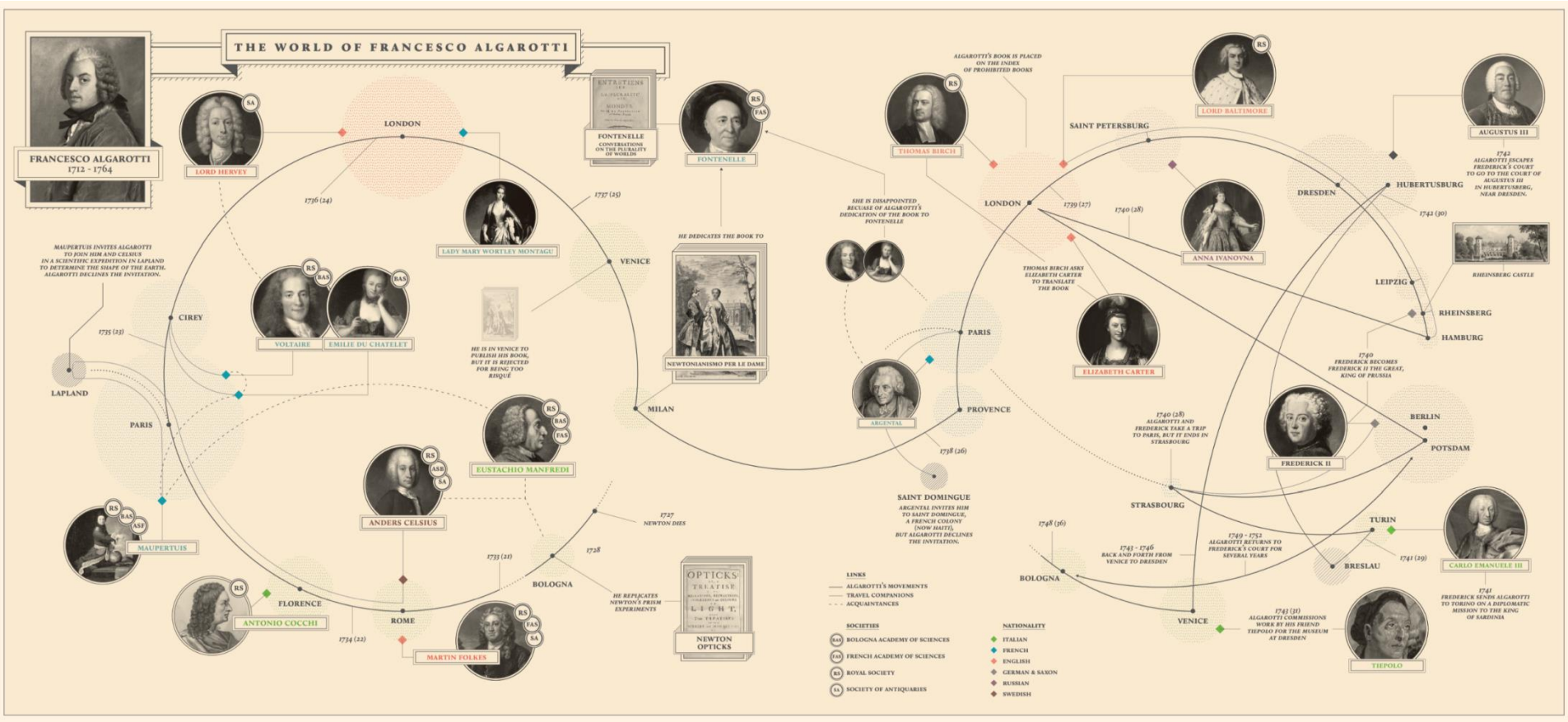
Copyists and translators

- Throughout the Middle Ages, texts inherited from Greco-Roman antiquity were collected and copied.
- These texts were also translated from:
  - Greek to Arabic (in Baghdad).
  - Arabic to Latin (in Western Europe).
- Copying was done mainly in monasteries and cathedral schools and, from the thirteenth century onwards, at universities (copyist students).
- Some medical texts were also translated into vernacular languages.

Translators at the court of King Alfonso X (1221-1284)

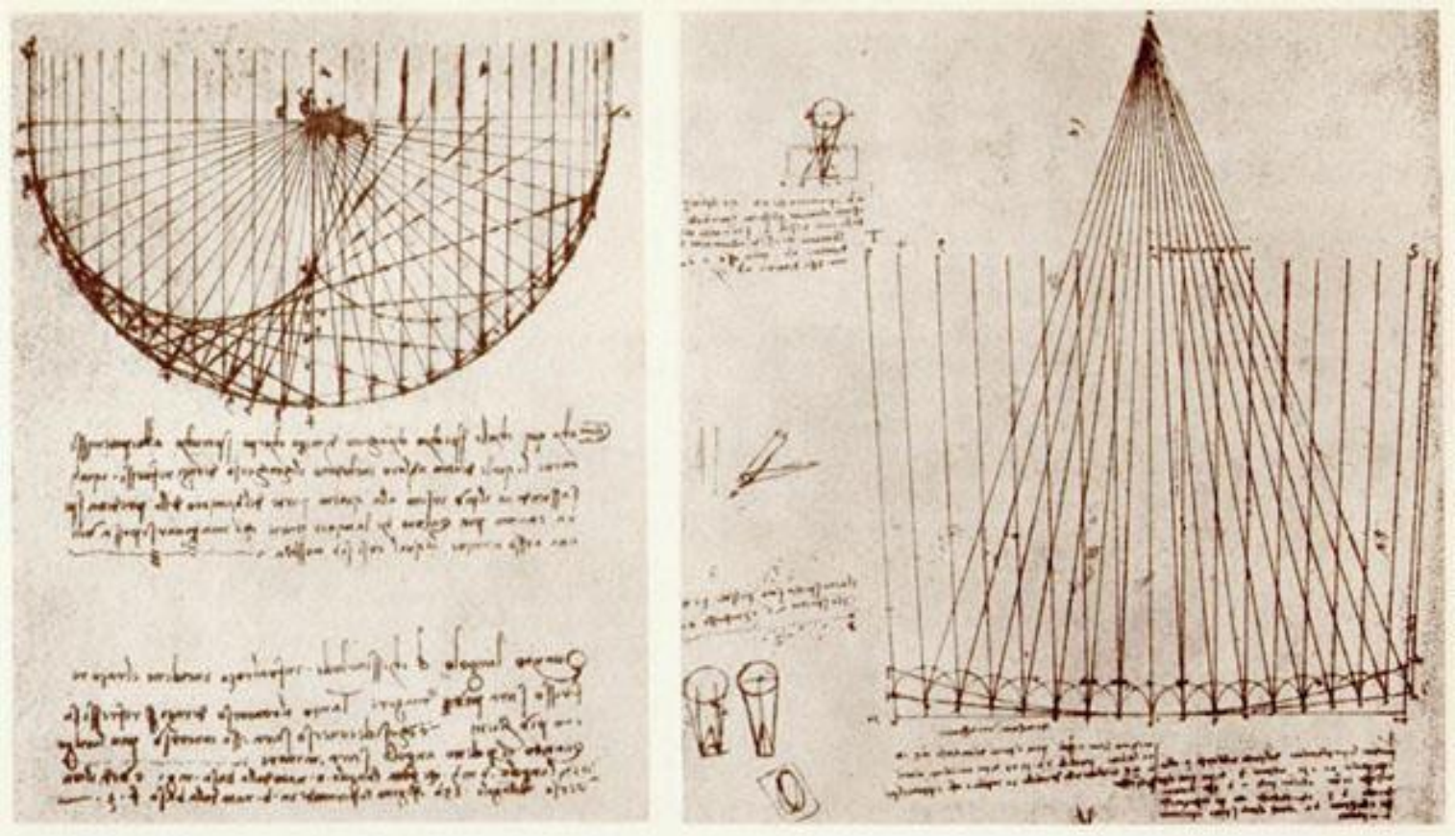
Republic of Letters

- From the Renaissance period onwards, networks of correspondence among European scientists (physicians, naturalists, geographers, mathematicians, etc.) multiplied.
- Letters often contained an observation followed by a comment on a particular phenomenon, e.g. earthquakes, eruptions, epidemics, the auroras borealis, exotic or unknown plants or animals, stars, microorganisms, etc.
- The authors were forced to copy the same letter dozens of times and to send all copies simultaneously in order to:
  - reach all correspondents.
  - demonstrate authorship/primacy.
  - avoid plagiarism.

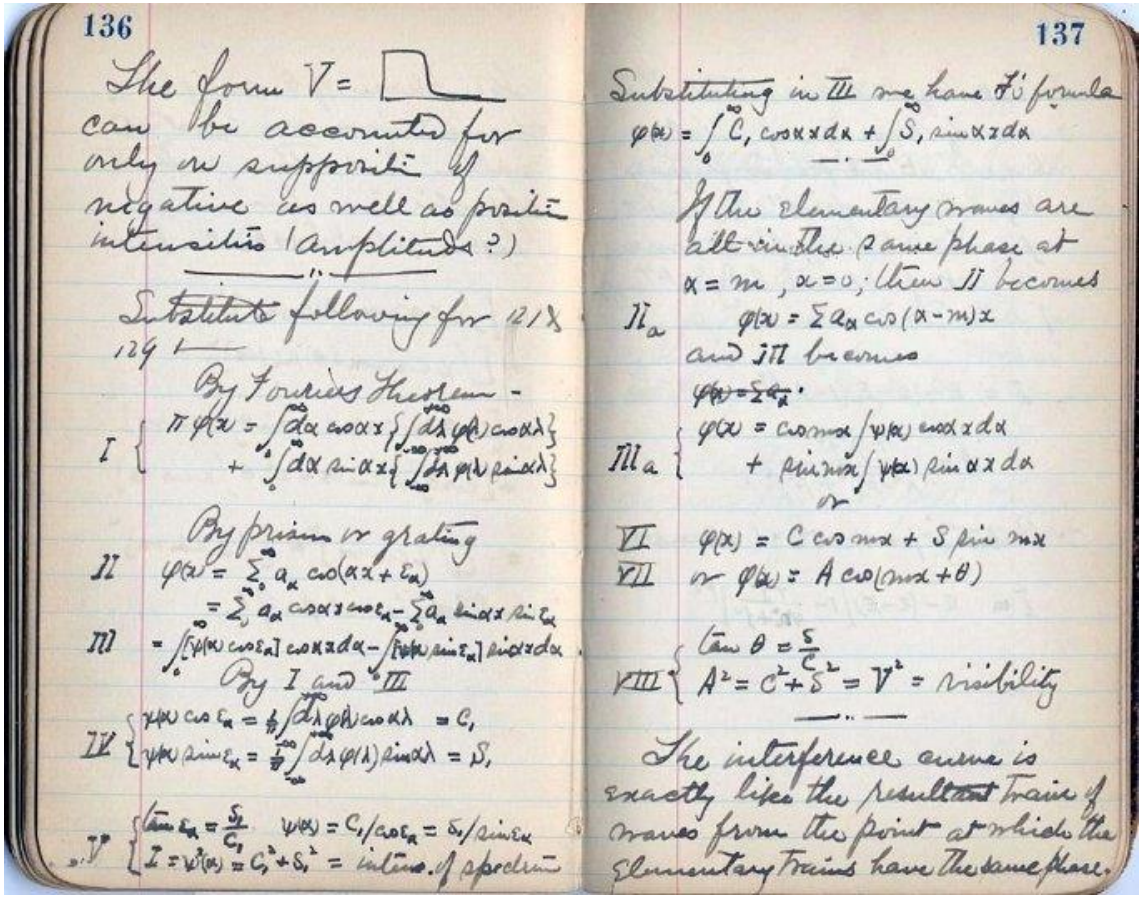

THE WORLD OF FRANCESCO ALGAROTTI
FRANCESCO ALGAROTTI
1712 - 1764
LONDON
LORD HERVEY
1736 (24)
LADY MARY WORTLEY MONTAGU
1737 (25)
VENICE
FONTENELLE
CONVERSATIONS ON THE PLURALITY OF WORLDS
FONTENELLE
HE DEDICATES THE BOOK TO
NEWTONIANISMO PER LE DAME
HE IS IN VENICE TO PUBLISH HIS BOOK, BUT IT IS REJECTED FOR BEING TOO RISQUÉ
MILAN
MAUPERTUIS INVITES ALGAROTTI TO JOIN HIM AND CELSIUS IN A SCIENTIFIC EXPEDITION IN LAPLAND TO DETERMINE THE SHAPE OF THE EARTH. ALGAROTTI DECLINES THE INVITATION.
1735 (23)
CIREY
VOLTAIRE
EMILIE DU CHATELET
LAPLAND
PARIS
MAUPERTUIS
EUSTACHIO MANFREDI
ANDERS CELSIUS
1727
NEWTON DIES
1728
1733 (21)
BOLOGNA
HE REPLICATES NEWTON'S PRISM EXPERIMENTS
OPTICKS
TREATISE
LIGHT
NEWTON OPTICKS
FLORENCE
ANTONIO COCCHI
ROME
1734 (22)
MARTIN FOLKES
SHE IS DISAPPOINTED BECUASE OF ALGAROTTI'S DEDICATION OF THE BOOK TO FONTENELLE
ALGAROTTI'S BOOK IS PLACED ON THE INDEX OF PROHIBITED BOOKS
THOMAS BIRCH
ARGENTAL
PARIS
PROVENCE
1738 (26)
SAINT DOMINGUE
ARGENTAL INVITES HIM TO SAINT DOMINGUE, A FRENCH COLONY (NOW HAITI), BUT ALGAROTTI DECLINES THE INVITATION.
LORD BALTIMORE
SAINT PETERSBURG
LONDON
1739 (27)
1740 (28)
ANNA IVANOVNA
THOMAS BIRCH ASKS ELIZABETH CARTER TO TRANSLATE THE BOOK
ELIZABETH CARTER
1740 (28) ALGAROTTI AND FREDERICK TAKE A TRIP TO PARIS, BUT IT ENDS IN STRASBOURG
STRASBOURG
1748 (36)
1743 - 1746 BACK AND FORTH FROM VENICE TO DRESDEN
1749 - 1752 ALGAROTTI RETURNS TO FREDERICK'S COURT FOR SEVERAL YEARS
BOLOGNA
VENICE
1743 (31) ALGAROTTI COMMISSIONS WORK BY HIS FRIEND TIEPOLO FOR THE MUSEUM AT DRESDEN
TIEPOLO
DRESDEN
HUBERTUSBURG
AUGUSTUS III
1742 ALGAROTTI ESCAPES FREDERICK'S COURT TO GO TO THE COURT OF AUGUSTUS III IN HUBERTUSBURG, NEAR DRESDEN.
1743 (30)
RHEINSBERG CASTLE
LEIPZIG
RHEINSBERG
HAMBURG
1740 FREDERICK BECOMES FREDERICK II THE GREAT, KING OF PRUSSIA
FREDERICK II
BERLIN
POTSDAM
TURIN
CARLO EMANUELE III
1741 (29)
BRESLAU
1741 FREDERICK SENDS ALGAROTTI TO TORINO ON A DIPLOMATIC MISSION TO THE KING OF SARDINIA
LINKS
ALGAROTTI'S MOVEMENTS
TRAVEL COMPANIONS
ACQUAINTANCES
SOCIETIES
BAS BOLOGNA ACADEMY OF SCIENCES
FAS FRENCH ACADEMY OF SCIENCES
RS ROYAL SOCIETY
SA SOCIETY OF ANTIQUARIES
NATIONALITY
ITALIAN
FRENCH
ENGLISH
GERMAN & SAXON
RUSSIAN
SWEDISH

Scientific manuscripts

- Manuscripts have lost their importance as a means of spreading scientific knowledge.
- However, they have not disappeared altogether:
  - Notebooks and laboratory diaries are used for studying how scientists think and work.
  - Medical records are an enormous mass of manuscripts still stored in the central archives of hospitals.



Leonardo da Vinci, *c*. 1510-1515, Studies on the behaviour of light



Laboratory notebook of physicist Albert A. Michelson (1852-1931), the first American Nobel Prize winner (1907)

2. Dissemination through print

- Printing, which became available in Europe in 1453, brought about a technical revolution thanks to its impact on the spread of knowledge, where it enabled greater speed and a wider distribution.

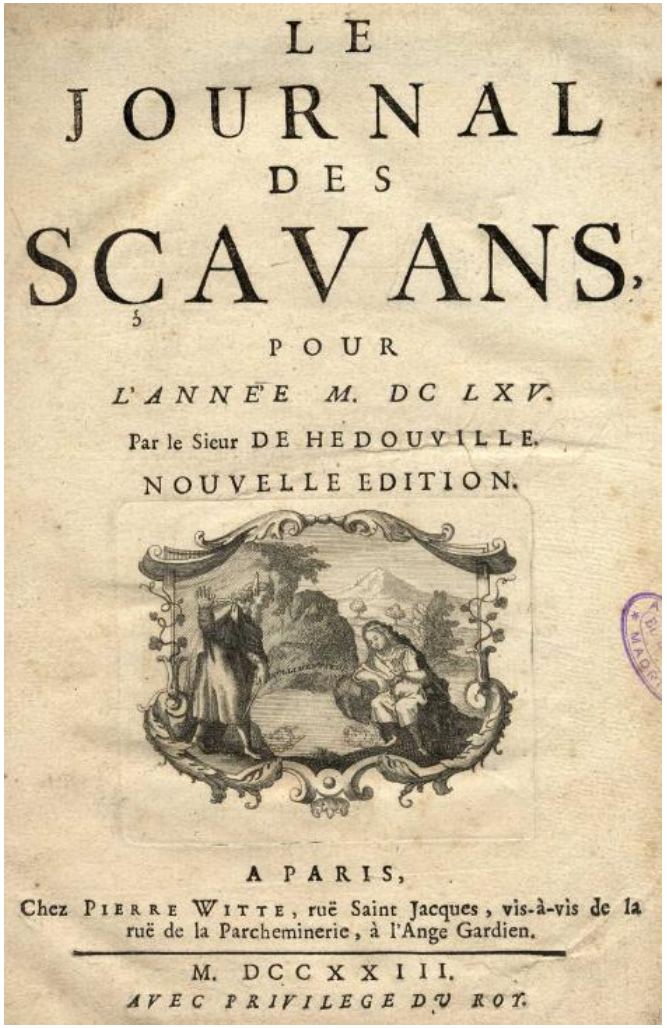
  a) From 1453 to the 17th century:
     - ✓ Printed books imitated manuscripts.
     - ✓ The science of antiquity predominated.

  b) From the 17th century to end of World War II
     - ✓ Crisis of authority.
     - ✓ Obsolescence of scientific works.
     - ✓ Scientific journals.


15th century printing towns of incunabula
1–9 incunable edition(s)
10–99 incunable editions
100–999 incunable editions
more than 1000 incunable editions
1452–1460
1461–1470
1471–1480
1481–1490
1491–1500
decade of first print
Lübeck
Gouda
Delft
Zwolle
Deventer
Magdeburg
Westminster
London
Antwerp
Leuven
Cologne
Leipzig
Erfurt
Mainz
Bamberg
Rouen
Speyer
Nuremberg
Paris
Strassburg
Reutlingen
Ulm
Augsburg
Vienna
Basel
Memmingen
Poitiers
Geneva
Lyon
Milan
Brescia
Vicenza
Treviso
Venice
Padua
Pavia
Ferrara
Bologna
Florence
Toulouse
Burgos
Salamanca
Zaragoza
Barcelona
Rome
Naples
Seville

The first scientific journals

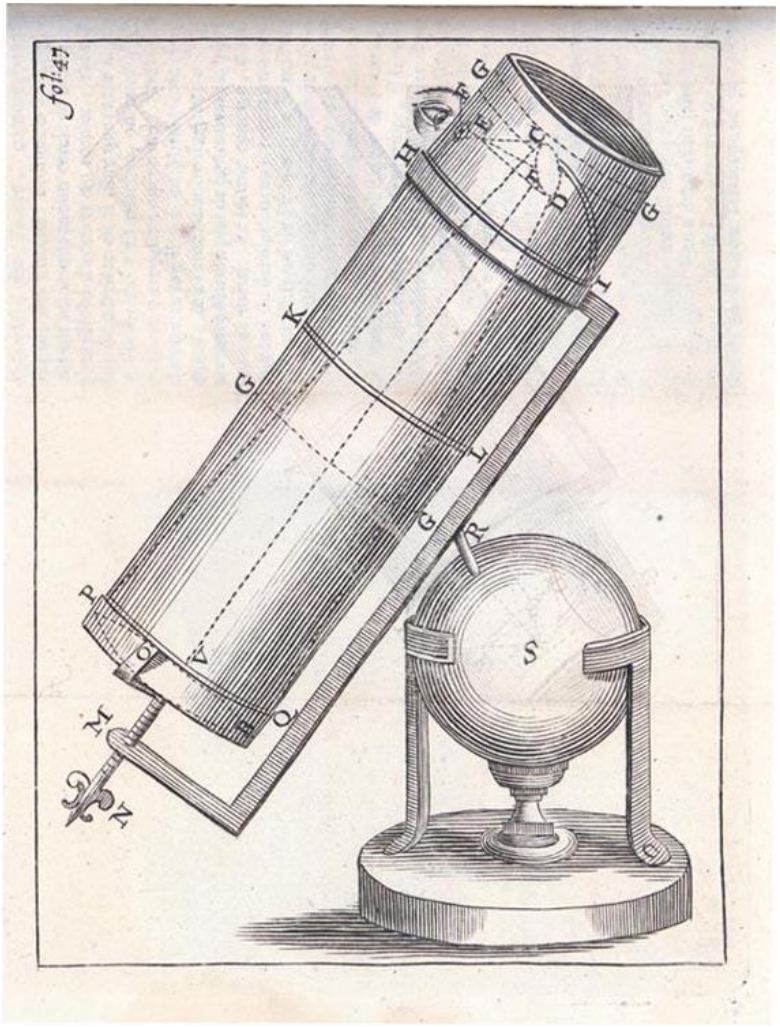
- Journals provided a greater dynamism than books for scientific communication:
  - Books involved structured knowledge and demanded slow preparation.
  - Articles required less processing time: they were much shorter and much more agile (though some of the more innovative books of the time contained just a few pages, e.g. William Harvey's *Exercitatio anatomica motu cordis et sanguinis* (London, 1628) had just 72).
  - In the context of new scientific institutions, journal articles were an instrument against plagiarism and a tacit recognition of authorship.



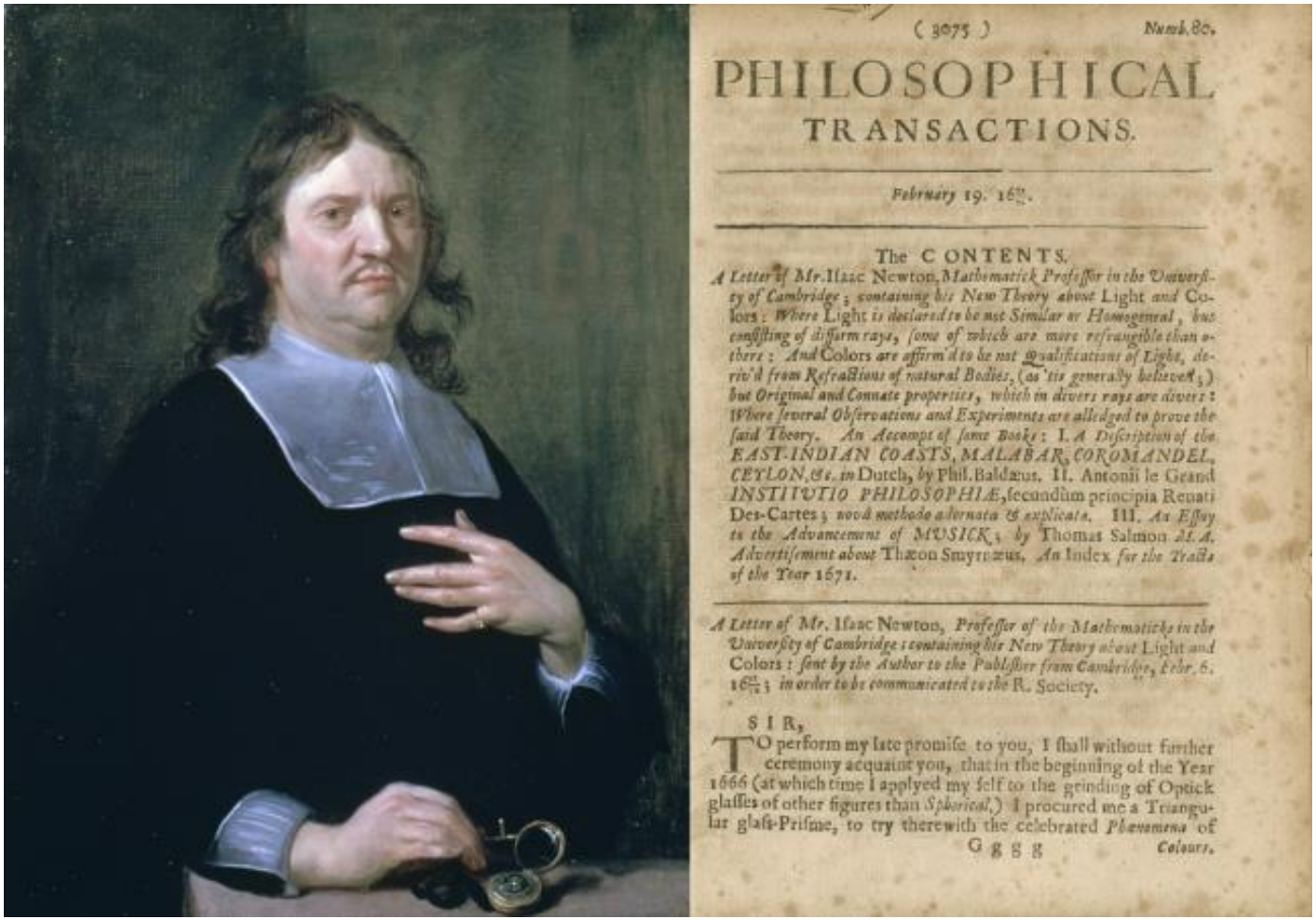
LE
JOURNAL
DES
SCAVANS,
POUR
L'ANNE'E M. DC LXV.
Par le Sieur DE HEDOUVILLE.
NOUVELLE EDITION.

A PARIS,
Chez PIERRE WITTE, ruë Saint Jacques, vis-à-vis de la ruë de la Parcheminerie, à l'Ange Gardien.

M. DCC XXIII.
AVEC PRIVILEGE DU ROY.



Founded in 1665 with the aim of disseminating "ce qui se passe de nouveau dans la République des lettres"



(3075) Numb. 80.

PHILOSOPHICAL
TRANSACTIONS.

February 19. 167⅓.

The CONTENTS.

A Letter of Mr. Isaac Newton, *Mathematick Professor in the University of Cambridge; containing his New Theory about* Light *and* Colors: *Where* Light *is declared to be not Similar or Homogeneal, but consisting of difform rays, some of which are more refrangible than others: And* Colors *are affirm'd to be not Qualifications of Light, deriv'd from Refractions of natural Bodies, (as 'tis generally believed;) but Original and Connate properties, which in divers rays are divers: Where several Observations and Experiments are alledged to prove the said Theory. An Accompt of some Books: I. A Description of the EAST-INDIAN COASTS, MALABAR, COROMANDEL, CEYLON, &c. in* Dutch, *by* Phil. Baldæus. II. Antonii le Grand *INSTITUTIO PHILOSOPHIÆ, secundùm principia* Renati Des-Cartes; *novâ methodo adornata & explicata.* III. *An Essay to the Advancement of MUSICK; by* Thomas Salmon *M. A. Advertisement about* Thæon Smyrnæus. *An* Index *for the Tracts of the Year* 1671.

A Letter of Mr. Isaac Newton, *Professor of the Mathematicks in the University of Cambridge; containing his New Theory about* Light *and* Colors: *sent by the Author to the Publisher from Cambridge, Febr.* 6. 167⅓; *in order to be communicated to the* R. Society.

SIR,

TO perform my late promise to you, I shall without further ceremony acquaint you, that in the beginning of the Year 1666 (at which time I applyed my self to the grinding of Optick glasses of other figures than *Spherical*,) I procured me a Triangular glass-Prisme, to try therewith the celebrated *Phænomena* of

Henry Oldenburg, first editor of the *Philosophical Transactions of the Royal Society of London for the Improvement of Natural Knowledge* (1665)

Boom in scientific journalism

- Specialised journals appeared (for physics, chemistry, medicine, biology, agriculture, geology, etc.) and the proportion of articles describing original experiments increased.

- There was a predominance of medical literature:
  - *New England Journal of Medicine* (1812).
  - *The Lancet* (1823).
  - *British Medical Journal* (1840).
- Bibliographic repertoires were published (collections of abstracts and bibliographical references): *Index Medicus* (1878), *Chemical Abstracts* (1908).

Scientific journalism in the 20th century

- The IMRAD structure was gradually adopted for journal articles (Introduction, Material and Methods, Results and Discussion).

- The peer review procedure became generalised as an indispensable requirement for the publication of an article:
  - It was introduced in 1731 as standard practice by *Medical Essays and Observations* (Royal Society of Edinburgh) and soon after by the Royal Society of London.
  - It consists of a report and anonymous opinion of the original text (paper) by one or more experts (peers).

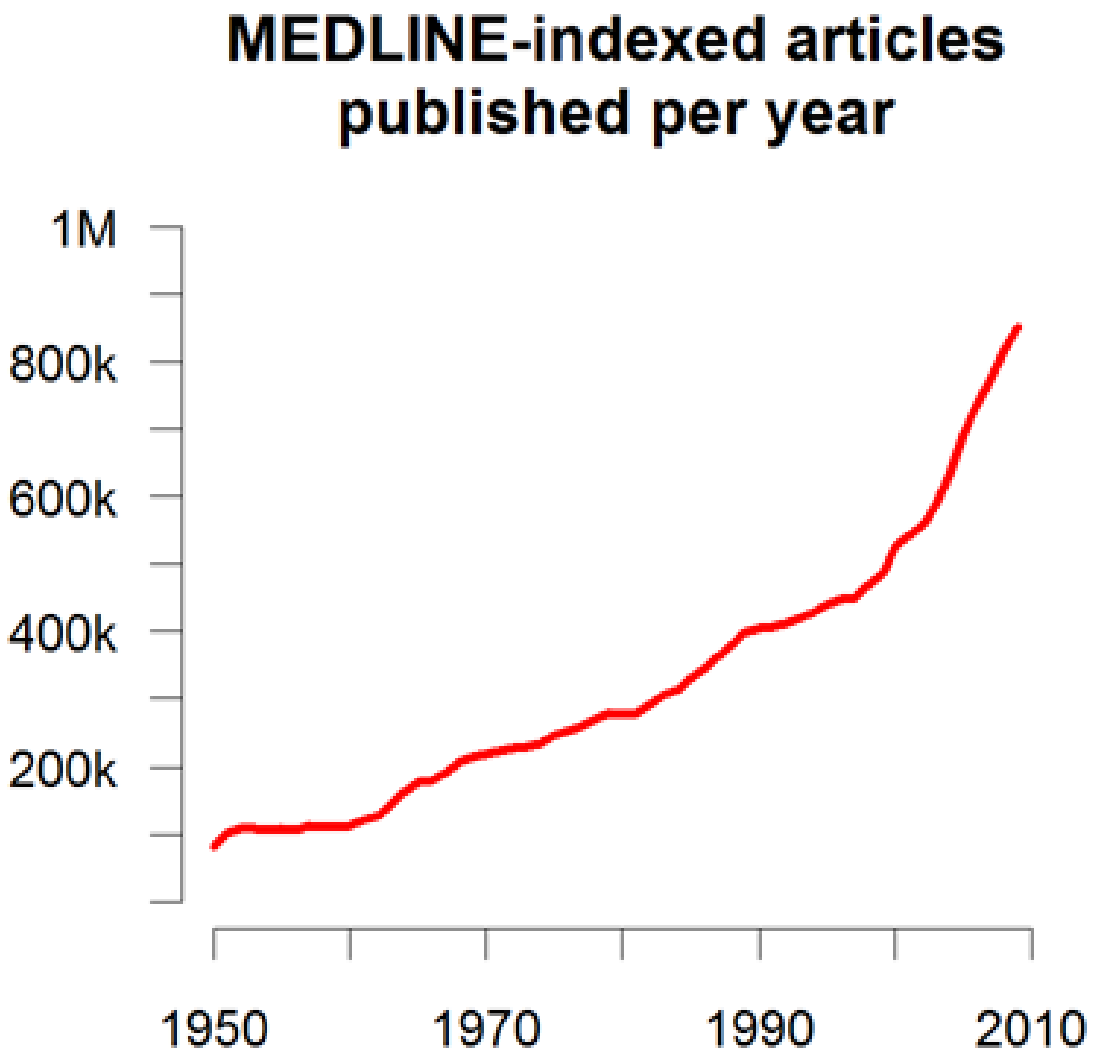
Objectives of scientific journalism

- To communicate knowledge that is being produced for the corresponding community.
- To disseminate new techniques of observation and/or experimentation.
- To update and systematise knowledge (review articles).
- To enable validation, by experts of a discipline, of observations, experiments and conclusions.
- To certify authorship and primacy.
- To avoid the duplication of experiments.

3. Challenges facing scientific information today

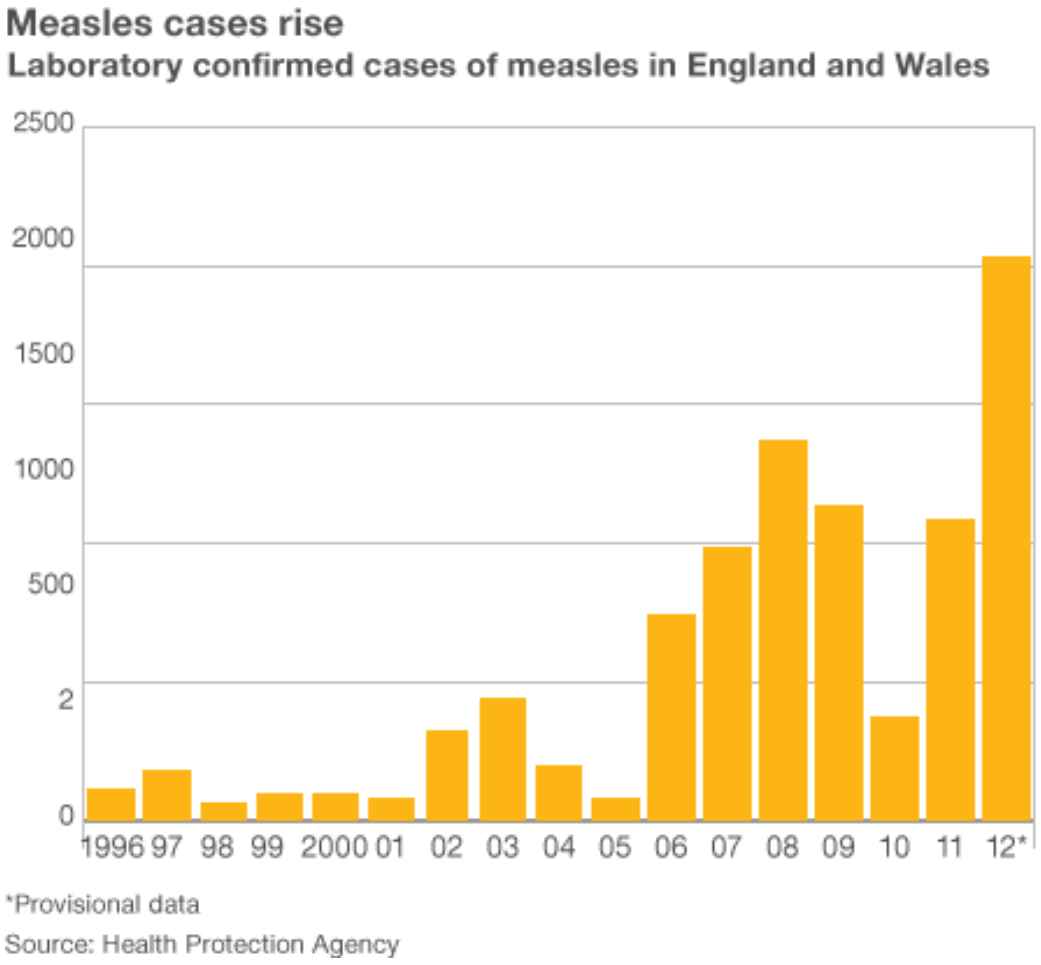
- *Little Science, Big Science* (1963):
  - Exponential growth of scientific activity until the 1960s.
  - Growing obsolescence of scientific work.
  - Inability to store scientific documents.
  - Fragmentation of scientific disciplines.
  - Need for more dynamic forms of communication.

Derek de Solla Price (1922-1983)


MEDLINE-indexed articles
published per year
1M
800k
600k
400k
200k
1950
1970
1990
2010

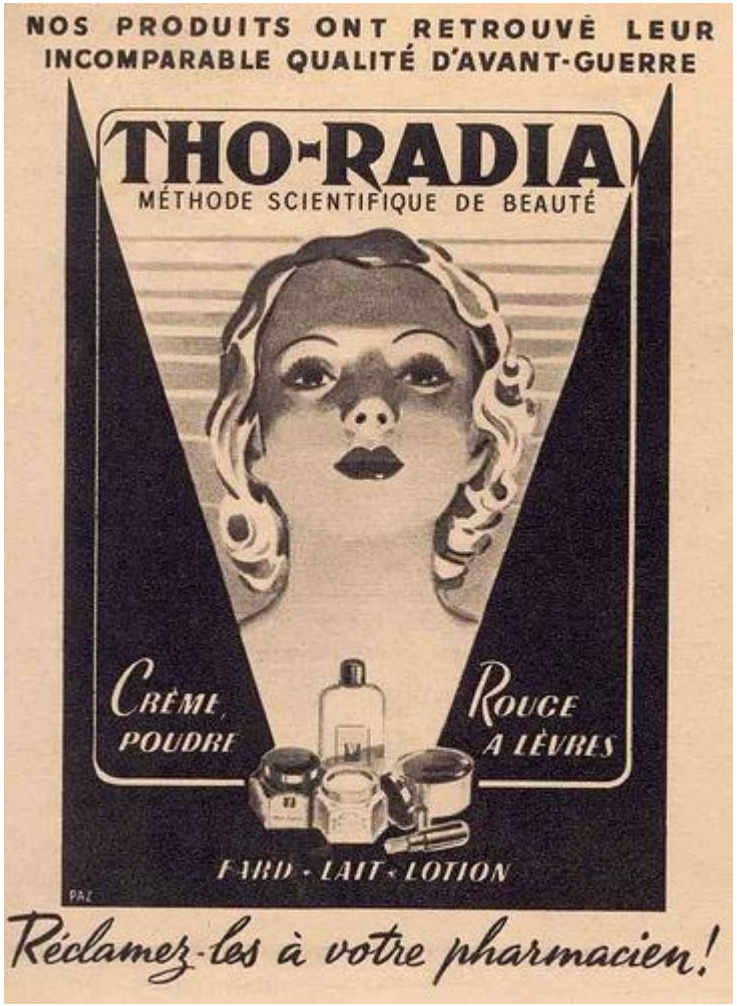
4. The popularisation of medicine and pharmacy

- The popularisation of science is not a recent activity but has been developing since the beginnings of science.
- Scientific information is often expressed in a way that is unintelligible to most people.
- The popularisation of science is an important component of scientific activity, especially in the field of biomedicine, where public attitudes are crucial for the success of health campaigns aimed at encouraging responsible drug consumption or promoting healthy practices.



Over 100,000 young people at risk of measles were given the vaccine thanks to a campaign launched after an outbreak of the disease in Swansea in spring 2013.

Popularisation or advertising?


NOS PRODUITS ONT RETROUVÉ LEUR INCOMPARABLE QUALITÉ D'AVANT-GUERRE
THO-RADIA
MÉTHODE SCIENTIFIQUE DE BEAUTÉ
CRÈME, POUDRE
ROUGE A LÈVRES
FARD - LAIT - LOTION
PAZ
Réclamez-les à votre pharmacien!


154
MÉTHODE
THO-RADIA
EMBELLISSANTE PARCE QUE CURATIVE
4°
DENTIFRICE
THO-RADIA
A BASE DE SELS DE THORIUM
FORMULE
du Docteur Alfred CURIE
Le grand tube : 6 francs
Astringent et bactéricide, il stérilise la cavité buccale, évite et combat les gingivites, prévient la carie et les pyorrhées alvéolaires. Il assainit les dents, laisse dans la bouche une délicieuse impression de fraîcheur, conserve l'éclat, la blancheur et l'intégrité de la dentition.
Pas de joli sourire sans de jolies dents
CHEZ LES PHARMACIENS EXCLUSIVEMENT

5. Models of scientific popularisation

Diffusionist model

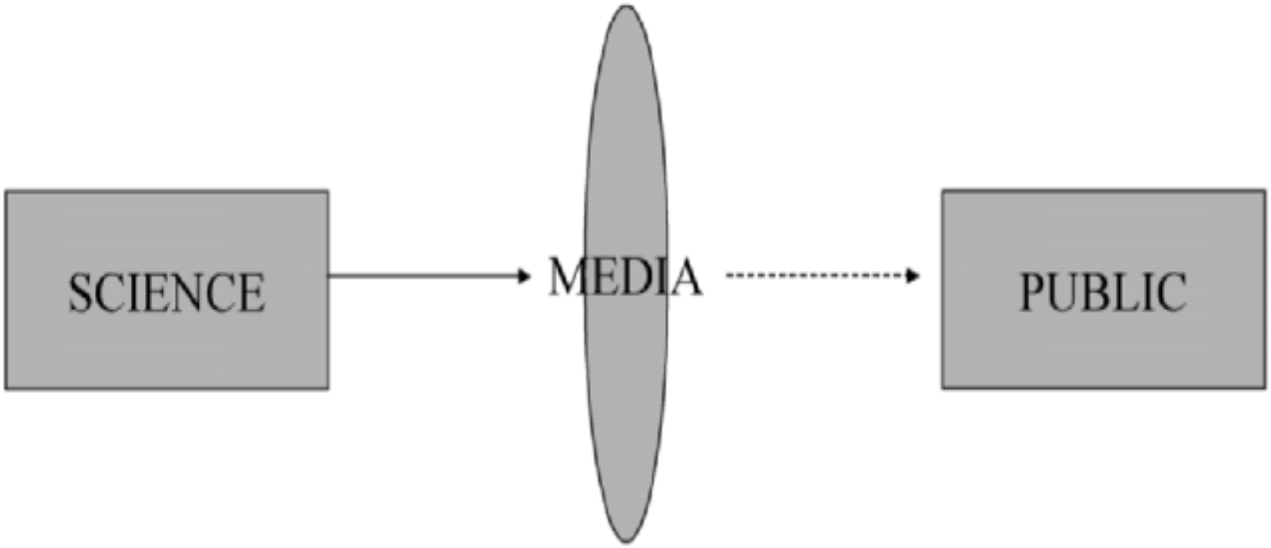


FIGURE 1. The transfer model of public communication of science.

The continuum of communication practices

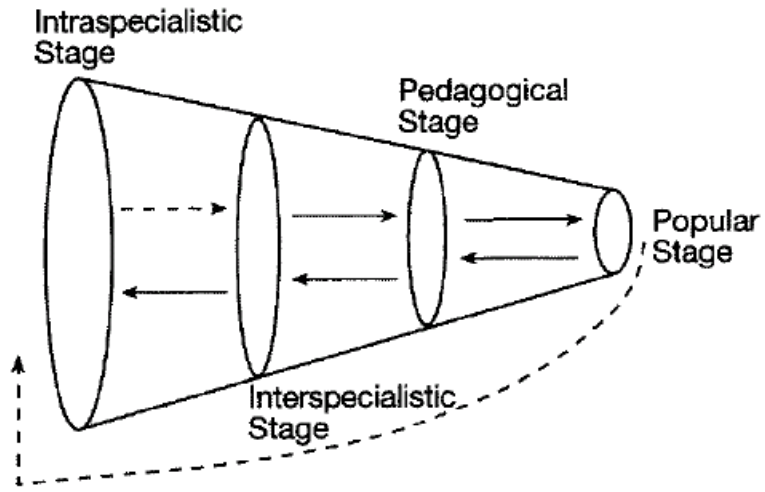


FIGURE 2. A model of science communication as a continuum.

- Different phases or stages
- Differences are a matter of degree:
  a) Many communicative activities are aimed at scientists themselves.
  b) Teaching overlaps with research and popularisation.
  c) There is a lack of well-defined limits.

- Many popularisation practices aim to maintain the authority of certain professional communities.
- Audiences are not empty boxes: knowledge is transformed and prepared according to the type of public.

1. Actors
2. Targets
3. Media
4. Purposes

Scientists *vs. popularisers*

"When I began to publish my first popularisation works thirty years ago ... my friends turned away from me, colleagues criticised me, editors of great scientific works were worried, good men reproached me for having lowered the dignity of science by making it accessible to all, and the great heads of the Academy of Sciences, Chevreul and Claude Bernard, spoke of desecration "(Louis Figuier)

(a) Precursors:

Bernard Le Bovier de Fontenelle (1657-): cosmology

Marie Meurdrac: *Chimie des dames* (1666)

Marquise de Châtelet (1706-1749): Newtonism

Voltaire: *Eléments de la philosophie de Newton* (1738)

(b) Professionals:

Louis Figuier (1819-1894): industry, chemistry, physics

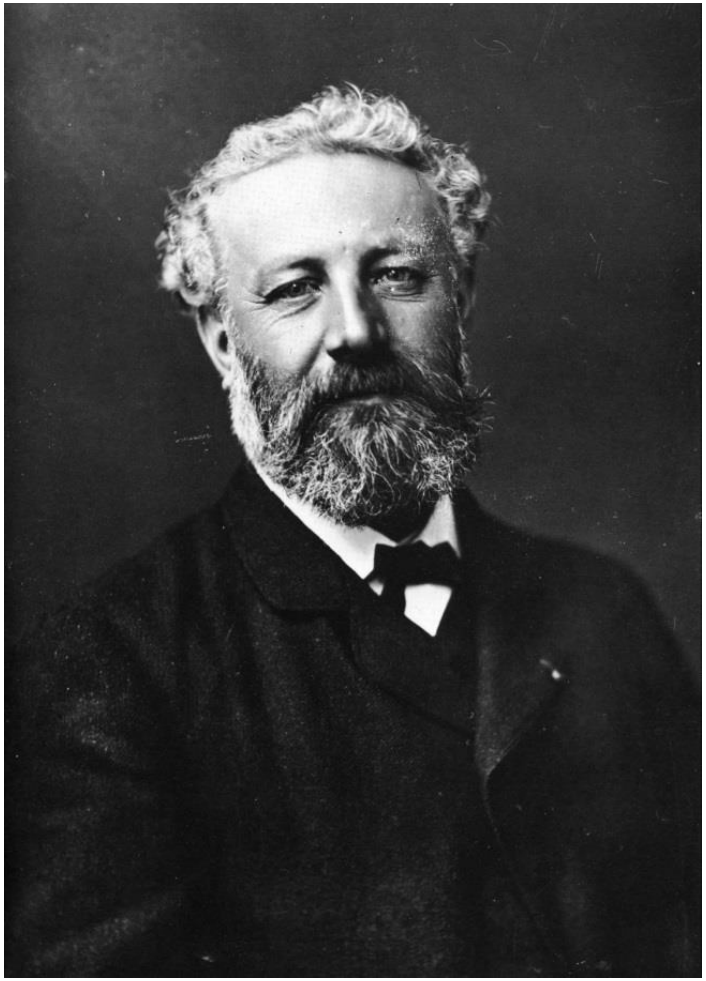
Nicolas Camille Flammarion (1842-1925): astronomy

Jean Henry Fabre (1825-1915): biology, entomology

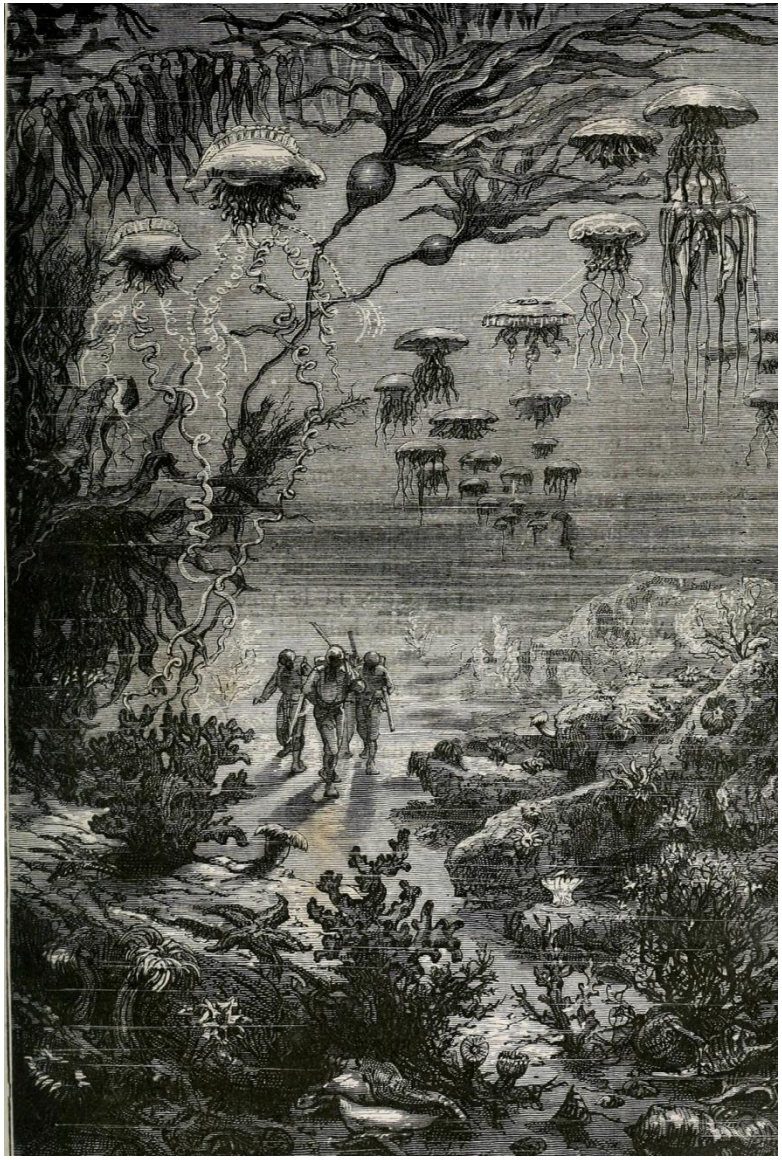
Gaston Tissandier (1843-1899): astronomy

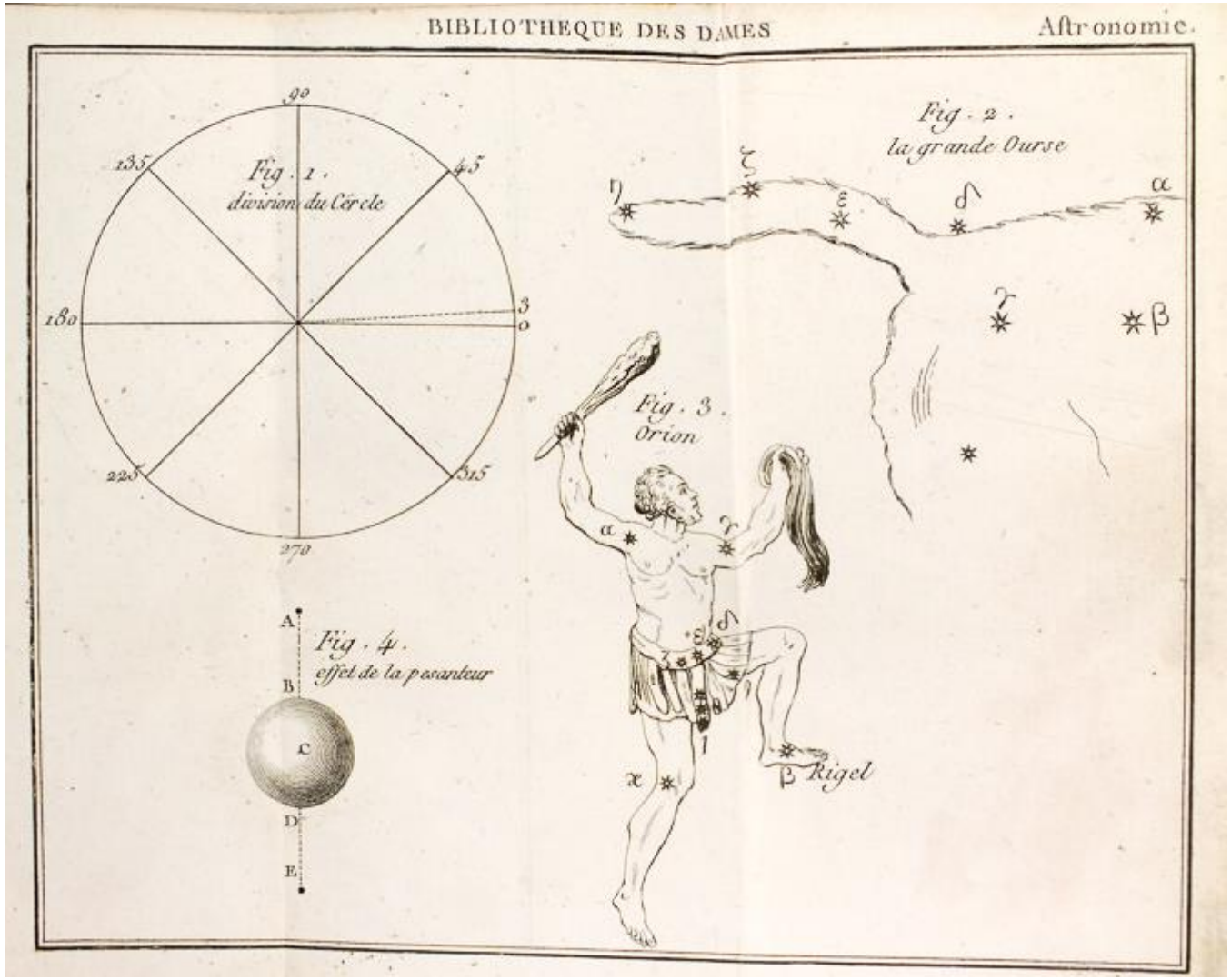
(c) Journalists: Victor Meunier (1817-1903)

(d) Jean Painlevé (1902-1989) and audiovisuals

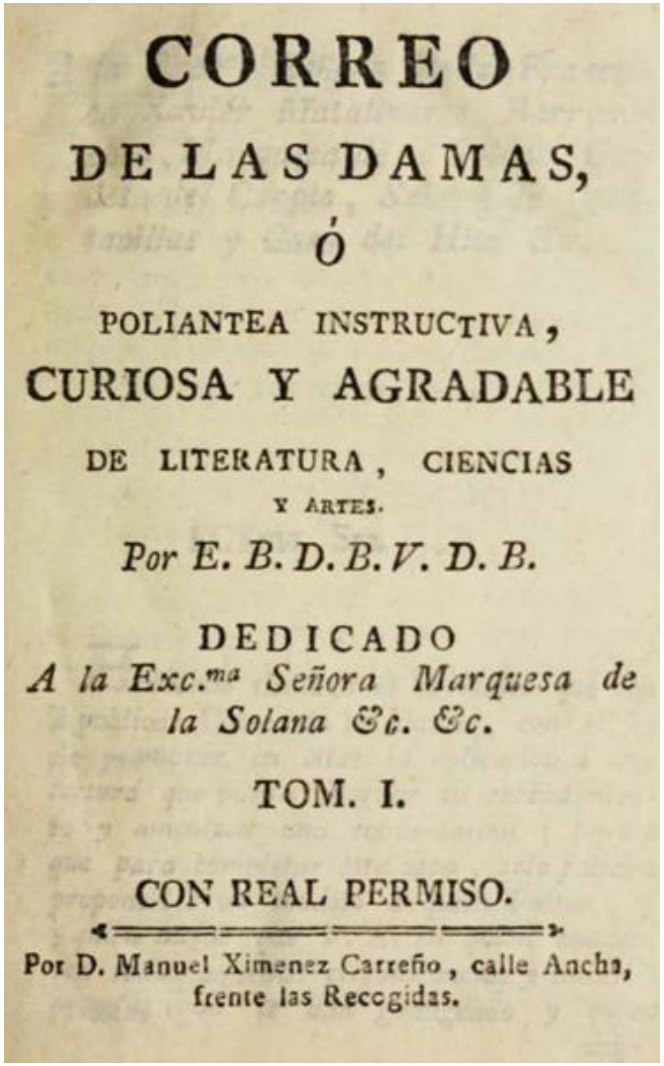


Jules Verne (1828-1905)





Joseph Jérôme Lalande, *Astronomie des dames* (1785)



CORREO

DE LAS DAMAS,

Ó

POLIANTEA INSTRUCTIVA,

CURIOSA Y AGRADABLE

DE LITERATURA, CIENCIAS

Y ARTES.

Por E. B. D. B. V. D. B.

DEDICADO

A la Exc.ma Señora Marquesa de la Solana &c. &c.

TOM. I.

CON REAL PERMISO.

Por D. Manuel Ximenez Carreño, calle Ancha, frente las Recogidas.

El Correo de las Damas, Cádiz (1804-1808)

- A. Fernández Ollero, *Breves nociones de higiene y economía domésticas*, Valencia, 1877.
- P. Pascual de San Juan, *Guía de la mujer o lecciones de economía doméstica,* Barcelona, 1881.

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THE ADVOCATE OF INDUSTRY AND JOURNAL OF SCIENTIFIC, MECHANICAL AND OTHER IMPROVEMENTS.

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☞ *See Advertisement on last page.*

POETRY

Nature's Image of Washington.

BY MARSHALL S. PIKE, OF THE HARMONEON'S

DESCRIPTIVE: Opposite Harper's Ferry,—which is situated on a pleasant elevation at the junction of the Potomac and Shenandoah rivers—a few rods north of "Pinnacle Bluff," a flighty eminence on the Blue Ridge Mountains, stands a most singular formation of rock, known as 'Washington's Face'; and which,to a casual-ist void of imaginative powers, is easily recognized if pointed out by a guide; but to a close observer, however, with common discernable perception, it presents *at first sight* a most striking and correct resemblance *of the great original*. From midway the bridge which crosses the Potomac, the countenance and contour of *the face to me*, appeared discriminatingly perfect, and constrained me to look upon it as *one* of the most wonderful, and the noblest work of revealed nature.

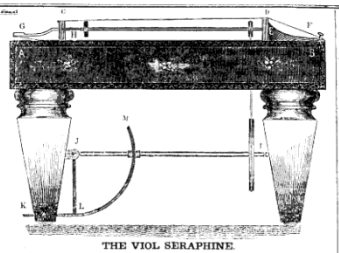
In the high barren cliffs of the Blue Mountain Ridge,
That frightfully hang o'er the trestle-built bridge,
Juts out into space a huge rocky bluff,
Which the elements rudely left broken and rough.

Near this, stands a bust so exquisitely fair,
That the chisel of art would be useless were there:
For nature wrought well till the model was done—
An impress on stone of our GREAT WASHINGTON.

The Earth born from chaos at some mighty shock,
Left the image to rest on the high mountain rock,
On a turret-like peak, in the heavens above,
As a sentinel over the country we love:
Where the sunbeam could linger till daylight had fled,
Where the bright stars of night, form a crown o'er its head;
And where, through the greenwood, the faintest breeze creeps,
To sigh for the Hero, who deathlessly sleeps.

There it stands like a giant in storm and in calm,
Like the Hero in battle, no foeman could harm!
And commandingly looks with a Patriot's pride,
On the wild mountain stream of Potomac's fast tide,
Whose waters swell on in the valley between,
Through the vast hilly regions and forests of green;
O'er a rock-bottomed track, to the blue-bosomed sea,
From its struggles to rest, like our sire of the free.

Stand up there in might, till the bright sun shall die,
Till the stars glimmer out their light in the sky,
And the moon shall no longer lend beauty or light,
But *all* shall again be dark chaos and night,—
Till then, let its base be the tall craggy steep,
Where rocks are o'er moss-grown, and ivy-vines creep;
With the Heaven's wide canopy over its head,
An immortal image of greatness that's dead.



THE VIOL SERAPHINE.

INTRODUCTION.—The clear tones of a violor bass viol are generally admitted to be more melodious than those produced by other kinds of instruments, and many have expressed a desire to see an instrument so constructed as to be played with keys, like the organ or piano forte, and give the tones of the violin. This in the character of the instrument here introduced. It is elegant in appearance; occupies less than half the space of a piano forte, and is so light and portable that a lady-performer may readily place it before her, and thus avoid the necessity,—unpleasant to all parties,—of turning her back on the company. We do not say that an instrument of this kind has been as yet constructed complete: but the principle has been proved, and it may, and probably will be soon, offered to the public, at a cost not exceeding sixty dollars.

EXPLANATION.—In the engraving, a side view elevation only is represented, showing only one string and one key of a series of twenty or more of each. The body of the machine A B, is a light hollow chest about three feet square and six inches deep, supported by four posts or legs with castors. Two bridges, C and D, extend across the breadth of the chest. The bridge D is supported by a cleat, E, in which is inserted the pin F, to which is attached one end of the string C D F. The other end of the string is simply attached to the bridge C. A key-lever, G H, passes through the bridge, and is mounted on a pivot therein. The front end of the key (G) is held in its ordinary position by a small spring thereunder, and may be easily depressed by the finger of the performer: the other end of the key serves as the bearing of the pivot of a delicate arbor, the opposite pivot of which has its bearing in the bridge D. On the front end of this arbor is a wheel three-fourths of an inch in diameter, with its periphery smooth, and polished with rosin, or rosin varnish; and so adjusted, that by the depression of the key, this wheel is brought up in contact with the string, whereby, if in motion rotarily, a full sound is produced, as if a violin bow was drawn across the string. On the other end of the arbor is a grooved pulley, over which passes a silken cord, which also passes round a delicate band-wheel, I, below, and by which, motion is communicated to the arbor and sounding wheel. The band-wheel is mounted on a shaft, I J, which has its bearings in two small level blocks which project from two crossbars: and from the block J is suspended a vertical rod, to the bottom of which is attached a treadle, K L, and from which a curved ratch, L M, extends upward and takes to a small ratchet on the shaft I J, so that, by the horizontal motion of the treadle, the motion is communicated to the wheel, &c. The teeth of the ratch and ratchet have so gentle an inclination on one side of each, that although the ratch applies force to the ratchet in the upward direction, they slide freely over in their return. It may be understood that the machine is to have two treadles and two ratches, which move forward alternately: and that twenty or more arbors, pulleys, strings and keys are arranged in series. Although only one of each is represented in the engraving. The cord applies to each pulley in the series, by passing over the first, under the second, and over the third, and so on, descending from the last of the series to the band-wheel. Each arbor is placed directly under its respective string, and it is also proposed to place moveable stops under the strings, at equal distances from the key bridge, and to regulate the tones by adjusting the stops, without depending on the pins at the ends for that purpose. We shall employ a competent mechanic to construct one or more of these instruments as soon as convenient, and give due notice accordingly.

An Eclipse in Arabia.

Casting my eyes over the bright, full moon, I perceived that an eclipse was just coming upon it. What astronomer had calculated this eclipse for Arabia? It was indeed a privilege to witness one in the bright sky that overspread the lonely mountains of Seir. Soon we were seated in a circle, with our Arabs round their watch-fire, enquiring of them their views of an eclipse, and explaining to them ours. They appeared to have no idea of its real cause, regarding it as a judgment from God, a sign of a bad season, and little camel feed. When we undertook to explain to them the theory of the earth being round, turning over every day, sometimes getting between the sun and moon, they seemed to look upon us as telling very strange tales. The eclipse was nearly total. I gazed upon it with interest, and then eyed the strange scene around me. The wild, lonely landscape of rock and sand—the camels kneeling round the bivouac—the wild faces of the Arabs, reflecting the red light of the fire round which they were seated—their wild voices and strange guttural language, all combined to produce an effect as startling, that I felt till then I had never been thoroughly sensible of our complete separation from the civilized world.

Giving Credit.

"One of our exchanges," says one of our exchanges, "came to us this week with four of our editorials *not credited*." A *frivolous* complaint. Not a week passes but we find in some of our exchanges from ten to twenty of our editorials; and instead of complaining, we are thankful for being thus complimented.

The Bowie Knife and its Inventor.

This instrument was devised by Col. James Bowie, an American, and a man of desperate valor. He considered, and apparently with justice, too, that, in close fighting, a much shorter weapon than the sword ordinarily in use, but still heavy enough to give it sufficient force, and, at the same time, contrive to cut and thrust, would be far preferable, and more advantageous to the wearer. He accordingly invented the short sword, or knife, which has since gone under his name. It is made of various sizes; but the best, I may say, is about the length of a carving knife—one perfectly straight in the first instance, but gently rounded at the end on the edge side; the upper edge at the end, for the length of about two inches, is ground into the small segment of a circle and rendered sharp; thus leaving an apparent curve of the knife, although in reality the upturned point is not higher than the line of the back. The back itself gradually increases in weight of metal as it approaches the hilt, on which a small guard is placed. The Bowie knife, therefore, has a curved, keen point; is double edged for the space of about a couple of inches of its length; and when in use, falls with the weight of a bill hook—Bowie went to Texas during the troubles which preceded the independence of that country,—and was lying sick in bed at the fortress of the Alamo, when, on the 6th of March, 1836, it was stormed by Santa Anna and taken. Bowie was murdered there upon his pillow. The hand that formed the dreadful knife could no longer wield it.

Forests and Streams.

That remarkable man, Humboldt, has reduced it almost to a demonstration, that the streams of our country fail in proportion to the destruction of its timber. And of course, if the streams fail, our seasons will be worse; it must get drier and drier in proportion. Humboldt, speaking of the Valley of Araguay in Venezuela, says that the lake receded as agriculture advanced, until the beautiful plantations of sugar-cane, banana and cotton-trees, were established on its banks, which (banks) year after year were farther from them. After the separation of that Province from Spain, and the decline of agriculture amid the desolating wars which swept over this beautiful region, the process of clearing was arrested, and old lands grew up in trees with that rapidity common to the tropics, and in a few years the inhabitants were alarmed by a rise of the waters, and an inundation of their choice plantations.

Prussian Music.

The Boston Brigade Band has been presented with a copy of the collection of the celebrated martial music of the Prussian army. Prussia has long been famous for the excellence of its military bands, and the music which they have produced is of the highest order. We hope this attempt to introduce it into our city will improve the style of martial music here.

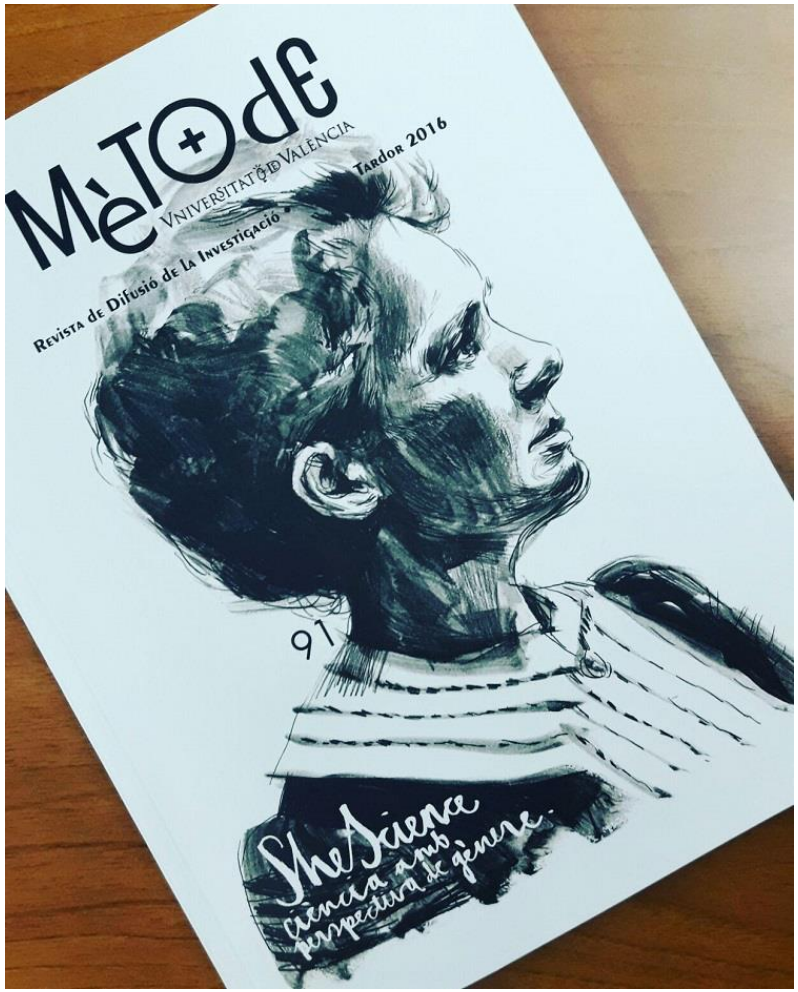
Philosophy.

"Uncle Jo," said an observing little boy, "our folks always put up the window when the room is filled with smoke, and the wind always blows in so as to prevent the smoke from going out that way: now where does the smoke go?" "It goes into the people's eyes," was uncle Jo's philosophic answer.

Polite Preaching.

A certain preacher, when treating on the subject of repentance, said, "My dear hearers, you must repent, if you do not, you will go to a place which it would be improper to mention in this polite assembly."

Mr. H. Longfellow of Cincinnati, has about one hundred acres under culture of grapes strawberries, peaches and raspberries.



La cultura científica se ve como una frivolidad en tiempos de recortes, pero es clave en el desarrollo de un país. / CARLES FRANCESC

Malos tiempos para la ciencia

La crisis se está llevando por delante los avances de los últimos años en cultura científica y divulgación ● La caída de la financiación ahoga el sistema de I+D

ALICIA RIVERA

"Un sistema de ciencia no requiere de la caridad de un estado opulento, sino de la constante inversión de uno que mira al futuro", advierte el astrofísico Javier Armentia, director del Planetario de Pamplona. ¿Era España, hace unos pocos años, un país opulento que podía permitirse el lujo de la ciencia? Muchos pensaban que era un país que miraba al futuro. Hasta que llegó la crisis. El Gobierno está ahogando la ciencia española con recortes drásticos de la financiación, parálisis de programas que hasta hace poco venían desarrollándose con normalidad, aplazamientos de convocatorias de contratos que, en realidad suponen cancelaciones, y reducción de becas y de apoyo a los jóvenes científicos que provocan la fuga de cerebros.

Malos tiempos para la ciencia en España. Y no solo para la que se desarrolla en los laboratorios, universidades y centros de investigación. También se está ahogando todo el conglomerado de actividades de divulgación, educación y difusión del conocimiento científico, esa asignatura pendiente que se había empezado a superar. "España ha tenido siempre una cultura más humanista y ahora se está desmoronando el arranque de la cultura científica que se había iniciado", señala Elías Fereres, presidente de la Real Academia de Ingeniería y ex secretario de Estado de Investigación.

"La ciencia es un artículo de primera necesidad para un pueblo, es un alimento básico de la colectividad para poder construir el futuro, para poder hacer investigación e innovación, para poder producir, y la divulgación científica es un alimento de la sociedad para construir una democracia auténtica", advierte Ramón Núñez, director del Museo Nacional de Ciencia y Tecnología (MUNCYT). En principio, todos de acuerdo, pero, cuando llegan las vacas flacas, lo que parecía una necesidad se convierte en secundario y prescindible.

Unas 300.000 personas (de ellas, 90.000 escolares) visitan cada año el museo científico Cosmocaixa en Alcobendas (Madrid). Ahora está en el aire. "La Obra Social La Caixa ha decidido reorientar su programa Ciencia en Sociedad en la Comunidad de Madrid con el objetivo de llegar a un mayor número de públicos de manera más eficiente, decisión que implicará el cierre del Museo de la Ciencia Cosmocaixa, en Alcobendas, antes de final de año", declara un portavoz de la entidad. Su museo de Barcelona recibe 800.000 visitas al año, destaca. En resumen, que recortan en ciencia las Administraciones públicas, pero también el sector privado.

Divulga es una empresa de comunicación científica que se ocupa de relaciones públicas de organismos de investigación o de empresas, edita libros, prepara exposiciones, organiza congresos o crea contenidos web para universidades, museos, instituciones de I+D, fundaciones y bancos. "Mi experiencia indica que existe un auténtico interés por el fomento de la cultura científica, pero los recortes que sufren en sus presupuestos les obligan a eliminar o minimizar las acciones que llevan a cabo, supliendo la falta de medios con imaginación y actividades de muy bajo coste", señala Ignacio Fernández Bayo, director de Divulga. La evolución de su facturación en los últimos años parece un indicador de la tendencia general: alcanzó su máximo en 2006, se redujo un poco en 2007 y se mantuvo estable durante tres años, como si todos esperasen que la depresión económica durase poco. "Desde 2011, nuestra facturación se ha reducido y ahora es una cuarta parte de la de 2006", señala Fernández Bayo.

> Derek Bok: "Si cree que la educación es cara, pruebe con la ignorancia"

> El interés popular mantiene vivas las actividades del Planetario

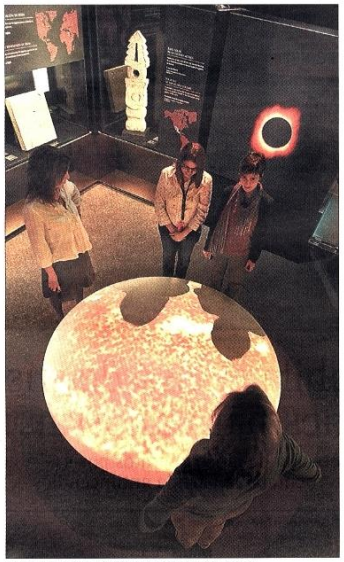
"La situación es terrible en el mundo de la divulgación de la ciencia, de desmantelamiento y cierre por derribo", se queja Armentia. "Los que trabajamos en esto sabemos que, si tenemos que sostener el sistema educativo y el de salud, el quejarnos por los museos de ciencia parece algo cosmético. Pero no es así", añade, y describe la situación: "ERE en museos, cierre de centros de ciencia, cancelación de proyectos o desaparición de un empuje que, poco a poco, comenzaba a poner la ciencia en la agenda cultural". En el Planetario de Pamplona la reducción de la financiación autonómica, explica, es este año del 97%, sobre un recorte anterior de más de un 30%. Eso sí, la respuesta del público y el interés creciente de la gente mantienen vivas las actividades del Planetario, la semana de la ciencia, los talleres o los debates. "La cultura es algo que, en tiempos de recortes, se pone en el lado de lo superfluo, y la parte de la cultura científica más aún", comenta Armentia, y recuerda aquella frase del que fue presidente de la Universidad de Harvard, Derek Bok: "Si cree que la educación es cara, pruebe con la ignorancia".

El MUNCYT nació en tiempos de bonanza económica y le ha tocado desarrollarse en tiempos de depresión. "Quizás hemos renunciado a sueños, pero no hemos renunciado a planes", dice Núñez. El museo mantiene diversas actividades con los recursos disponibles, añade, tirando de la creatividad e ilusión. Y recalca: "las pérdidas en educación y cultura científica significan daños irreparables, no ya al presente, sino al futuro de una sociedad".

La ciencia, en cualquiera de sus ámbitos y facetas, no es algo que se active cuando conviene, que se desenchufe cuando llegan las vacas flacas y se pueda volver a poner en marcha automáticamente cuando las arcas permiten retomar la inversión. "Es muy peligroso ese mensaje de 'no pasa nada, podemos parar y volver a arrancar después', porque la gente puede desentenderse, volver a esa idea de que la ciencia es algo que pasa en otros países; y sería muy difícil retomar el entusiasmo social del esfuerzo por el avance de la I+D", advierte Miguel Ángel Quintanilla, catedrático de Filosofía de la Ciencia en la Universidad de Salamanca y ex secretario de Estado de Investigación.

¿Tan negro es el panorama? Entre 2009 y 2012, la financiación de la I+D cayó más de un 31% (subvenciones), pasando de 4.174 millones de euros a 2.860. En 2013, el recorte es de un 13,9%, según datos de la Confederación de Sociedades Científicas de España (Cosce). Encima, los presupuestos se quedan en gran parte sin gastar, lo que significa que el dinero invertido es menos aún.

El efecto negativo empapa todo el sistema de I+D. En los contratos Ramón y Cajal de científicos de alto nivel se ha perdido ya un año por recortes y retrasos, y puede perderse otro por aplazamiento; la financiación de los proyectos de investigación del Plan Nacional de I+D+i está tiritando y miles de científicos siguen esperando que se abra la convocatoria este año para presentar sus proyectos. Los de la anterior no saben todavía cómo y cuándo recibirán el dinero y todos andan atientas en sus proyectos científicos ante las incertidumbres que no despeja la Secretaría de Estado de Investigación (Ministerio de Economía y Competitividad, Mineco). El CSIC sigue pendiente del rescate de 100 millones de euros que necesita para no paralizarse. El dinero no llega y el Mineco no responde a la urgencia que tiene la mayor institución científica española. España ha dejado de pagar su cuota a la Fundación Europea de la Ciencia y tiene una deuda abultada con la del Laboratorio Europeo de Física de Partículas (CERN). Ha reducido tan drásticamente su participación en los programas de la Agencia Europea del Espacio (ESA) que las empresas del sector temen un desplome de actividad y empleo. España y Portugal son los únicos países que no se han comprometido aún en el futuro telescopio gigante europeo E-ELT, cuando sus socios en el Observatorio Europeo Austral (ESO) están ya listos para empezar este gran proyecto. Decenas de arqueólogos han visto paralizados sus trabajos internacionales, ya aprobados, porque Hacienda ha denegado los pagos.



Exposición en el Cosmocaixa de Alcobendas (Madrid).

España ha pasado de ocupar el noveno lugar mundial por número de publicaciones científicas al décimo (India se ha colocado por delante) y su esfuerzo en I+D ha caído, alejándose su porcentaje de PIB de la media europea. Pese a todo, hay algún dato positivo: aumenta el número de científicos españoles que compiten por los fondos del Consejo Europeo de Investigación (ERC) y logran más proyectos (44 en 2012, frente a 31 en 2009). Pero los expertos advierten de que estos resultados positivos se deben a la inercia del sistema, que responde al esfuerzo de los años pasados.

"El sistema español de ciencia está sufriendo ya un daño estructural, aunque todavía es pronto para evaluar cuánto", explica Quintanilla. "Tenemos un retraso y habíamos iniciado el camino de la modernización de España a nivel científico y esta situación actual supone una ruptura que va a costar volver a reiniciar. Se puede perder una generación".

> Guindos: "La I+D debe buscar retorno en el ámbito del mercado"

> "Los demás países avanzan y nosotros quedamos atrás", dice Elías Fereres

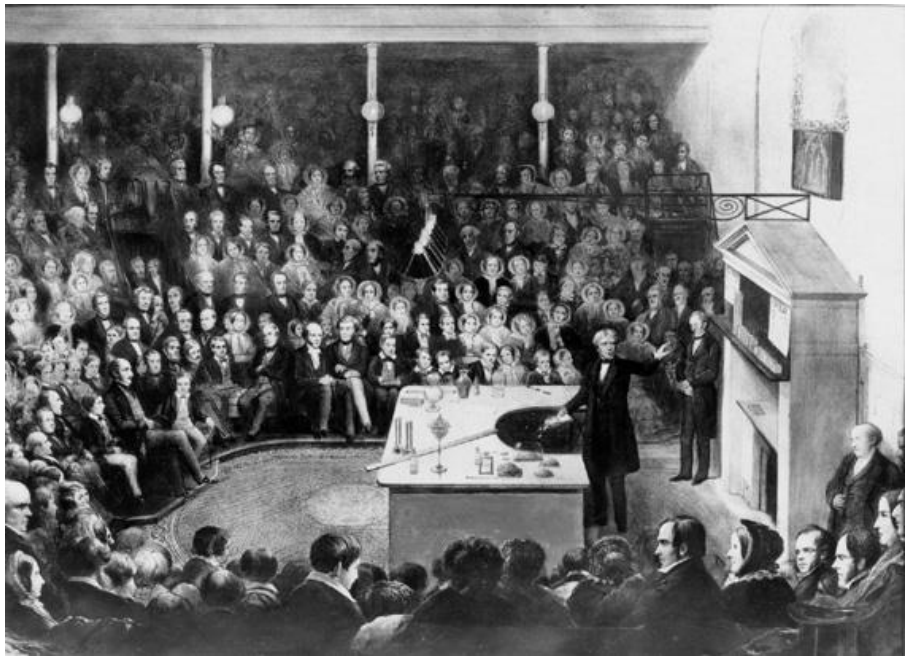
A la pregunta, hace unos días, en el foro Nueva Economía, de si corría el riesgo de pasar a la historia como el ministro que paró el progreso en España de la innovación y la I+D, Luis de Guindos respondió: "Hemos tenido que hacer un ajuste en el ámbito de I+D+i, que ha sido doloroso, por los ajustes presupuestarios". Luego declaró: "Nos tenemos que buscar la vida de otras formas". Su receta incluye priorizar en los proyectos, "buscar fuentes de financiación alternativas a la presupuestaria" e intentar maximizar los retornos de la financiación de Bruselas. Se trata dijo, "de hacer más con menos". El ministro completó su visión señalando que es fundamental "que el I+D+i se integre en la competitividad de la economía española y, para eso, es fundamental que busque retornos en el ámbito de los mercados porque eso también estará justificando gran parte del gasto que está realizando".

Pero en ciencia, aclara Quintanilla, "estamos hablando de cosas que no tiene valor mercantil, sino valor estratégico, y muy alto". Mientras tanto, los países desarrollados y varios en desarrollo piensan más en términos de inversión que de gasto en I+D y, pese a la crisis, sus Gobiernos mantienen o aumentan la financiación pública de la ciencia y la tecnología.

"El retraso que se está produciendo es bastante preocupante en el sentido de que los demás países están avanzando y nosotros nos quedamos atrás", señala Fereres. "No es que se pierda del todo el tren, pero se cambia de vagón a uno de más atrás". Y las dificultades no se limitan a la investigación científica, señala este ingeniero que fue presidente del CSIC. "También el desarrollo tecnológico se resiente porque las dificultades de las empresas para conseguir financiación tienen efectos muy negativos incluso a largo plazo; la limitada tendencia que se estaba creando, se frena". La máquina se va parando porque no se alimenta, apunta Armentia y recuerda que cuesta más empujar un coche que está parado que hacer que se mueva más rápido uno que anda, aunque sea lentamente.

El bloguero Daniel Díaz lanzó hace poco un tuit: "Como sigan recortando en ciencia, la Tierra volverá a ser plana".

Michael Faraday, *The Chemical History of a Candle*, 1861



A

COURSE OF SIX LECTURES

ON THE

CHEMICAL HISTORY OF A CANDLE:

TO WHICH IS ADDED

A LECTURE ON PLATINUM.

BY

MICHAEL FARADAY, D.C.L., F.R.S.,

FULLERIAN PROFESSOR OF CHEMISTRY, ROYAL INSTITUTION; FOREIGN ASSOCIATE OF THE ACADEMY OF SCIENCES, ETC.

Delivered before a JUVENILE AUDITORY *at the* ROYAL INSTITUTION *of* GREAT BRITAIN *during the Christmas Holidays of* 1860-1.

EDITED BY WILLIAM CROOKES, F.C.S.

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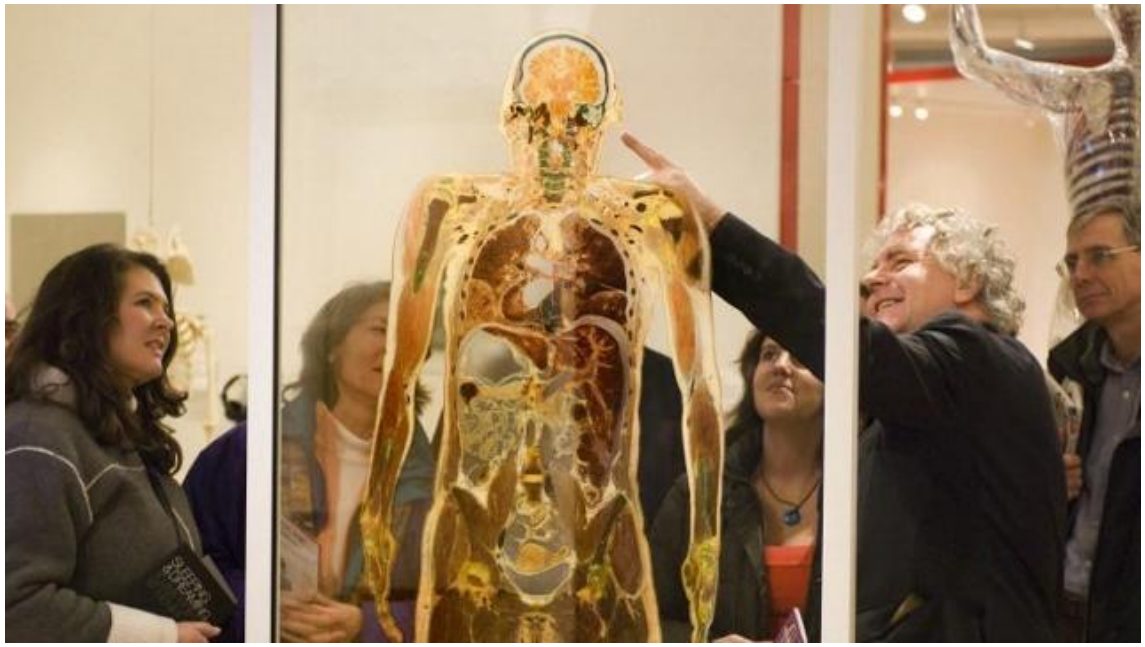

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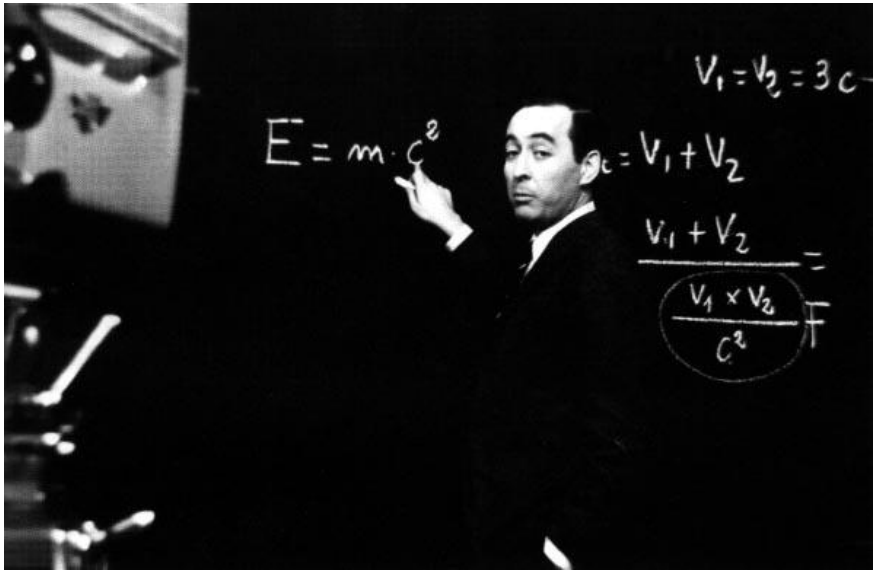
Col.lecció Científico-Mèdica de la Universitat de València (Institut d'Història de la Medicina i de la Ciència López Piñero i Facultat de Medicina)

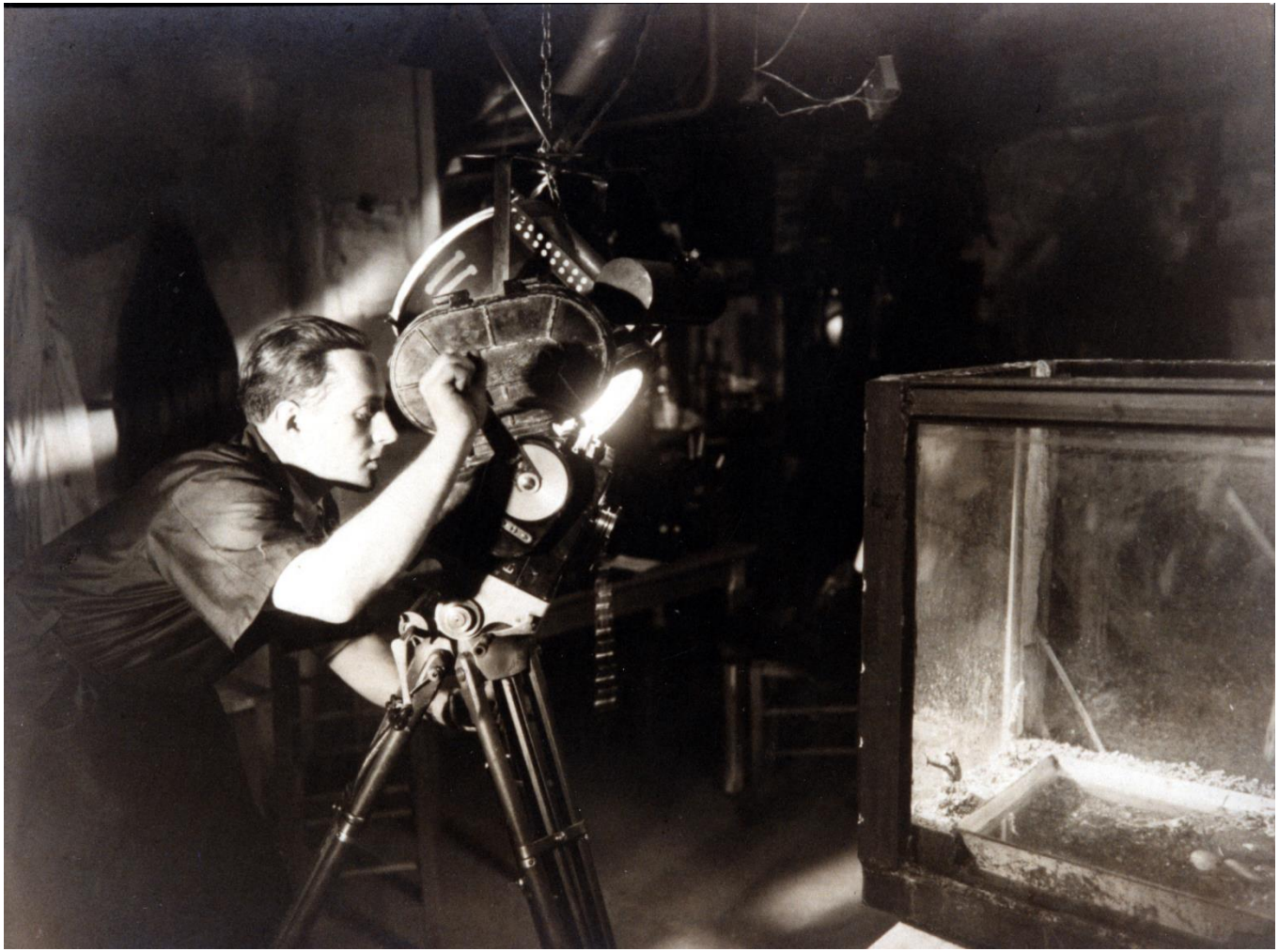

AL
Dr. FLEMING
EN AGRADECIMIENTO
DE LOS TOREROS
14 MAYO 1964

Paul Sandby, *Magic lantern* (1760)



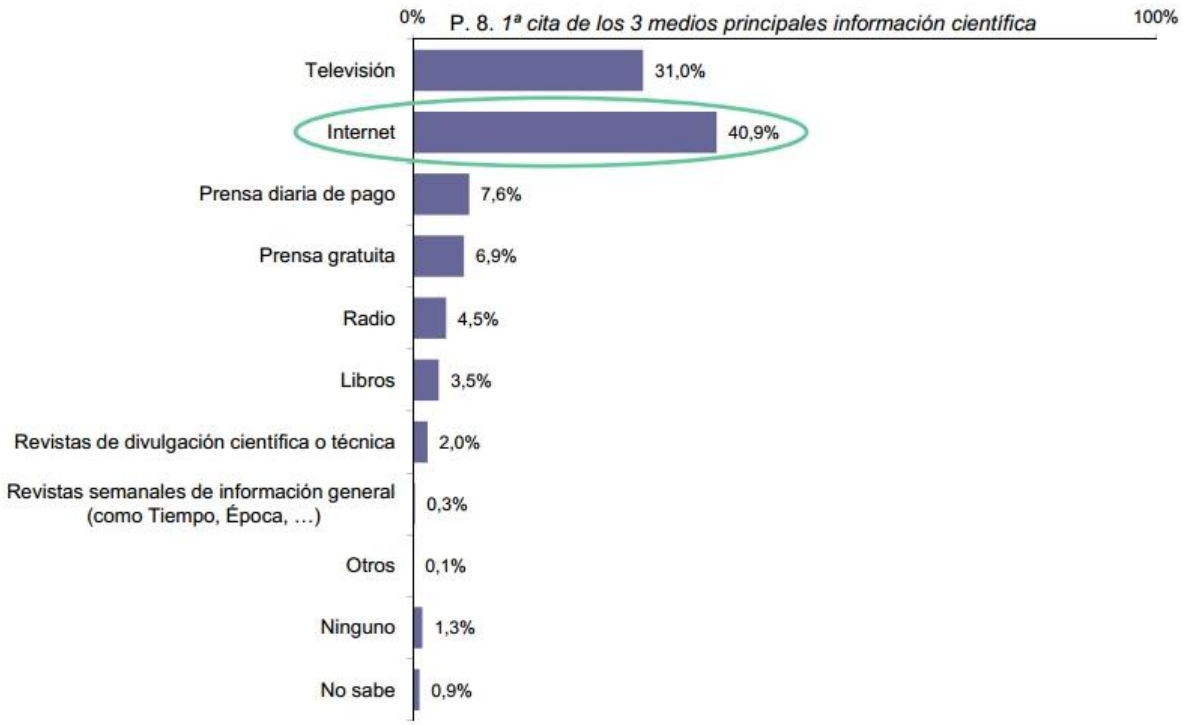
Luis Miravitlles (1930-1995) explaining Einstein's theory of relativity on Spanish television during the 1960s

Félix Rodríguez de la Fuente (1928-1980)



Jean Painlevé (1902-1989) and scientific documentary films

Por primera vez Internet se sitúa, por encima de la TV, como primera fuente de información científica



Source: VI Survey of Social Perception of Science, 2012, FECYT

Aims of popularisation

- ✓ To show the work of The Creator.
- ✓ To show the powers of reason.
- ✓ Political reasons:
  - ✓ Conservatives: natural order = social order.
  - ✓ Reformists: philanthropy and moralisation.
  - ✓ Revolutionaries: social emancipation.
- ✓ To ensure science is present in culture.
- ✓ To decrease the 'fear of science'.
- ✓ To preserve health and fight disease.
- ✓ To show the usefulness of science.
- ✓ To promote technological innovation.

Theme 8. Discipline and Profession

Introduction

This section presents several theoretical points on the concepts of profession, scientific discipline and, in social and health sciences in particular, medical specialities. This will enable us to consider the defining characteristics of these concepts and what society has always expected of the members of these professions. We should also bear in mind that the health-related collegiate professions (medicine, dentistry, nursing, physiotherapy, chiropody, occupational therapy, pharmacy, veterinary science, human nutrition and dietetics) are of huge economic importance (in both material and human resources) because demand for professional services by Spanish families (and those of the developed world as a whole) has been growing since the early twentieth century. In this section we take a brief look at how the production of medicines developed from its beginnings to the contemporary industrialisation in order to illustrate how pharmacy developed as a professional body with a wide range of disciplines. Finally, we include the 2030 Agenda – a future challenge for all sectors of society, especially universities, under the auspices of the United Nations.

Contents

1. Generalities:
    - The concept of profession
    - The concept of discipline
    - The origins of pharmacy
2. The development of pharmacy as a profession and discipline:
    - From guild training to universities
    - Pharmaceutical knowledge
    - Control of the profession
    - Professional societies
    - Codes of ethics
    - The public image of pharmacy
3. Higher education and development cooperation (2030 Agenda)

Objectives

- To learn the specific characteristics of professions and disciplines.
- To study the historical evolution of medicine production up to the introduction of today's industrialisation.
- To identify the characteristics of pharmacy as a profession and discipline.
- To assess the long historical tradition of the apothecary-pharmacy, particularly in Valencia, as an element for properly understanding and evaluating the 'Mediterranean model'.
- Beyond the research work conducted in laboratories, to study and assume the ethical commitments involved in producing and distributing medicines.
- To analyse the basic guidelines of the 2030 Agenda and its repercussions for the future careers of Pharmacy students.

Preliminary activity

Read pages 181-186 of the Handbook for an overview of the creation of the scientific professions and disciplines in general.

Points to consider

- What led to the creation of the professions?
- Why were the disciplines created?
- What traits characterise the professions and disciplines? What does it mean to be a professional?
- What role do the professions play nowadays? What value do they have for their members? And for society?

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8. Discipline and profession

VNIVERSITAT DE VALÈNCIA

Carmel Ferragud, Rafaela Domínguez, Mar Cuenca
History of Science

Documentation and Scientific Methodology
Degree in Pharmacy

1. General concepts:
   - The concept of profession
   - The concept of discipline
2. The origins of pharmacy
3. The development of pharmacy as a profession and discipline:
   - From guild training to universities
   - Pharmaceutical knowledge
   - Control of the profession
   - Professional societies
   - Codes of ethics
   - The public image of pharmacy
4. Higher education and development cooperation (Agenda 2030)

1. General concepts

- The concept of **profession**:
  - The concept of profession is different from that of occupation, whose learning is achieved by practice, i.e. without a pre-established training programme. Examples include: odontologist vs. dentist; physiotherapist vs. masseuse; agronomist vs. farmer.
  - Traditionally, professions are occupations that require a university degree.
  - Medicine and law have been recognised as professions since the Middle Ages because they require a university degree and a regulated training that, through a system of formal evaluation (examinations), lead to a university degree that is recognised by the state.
  - In the employment sphere, professionalisation processes were boosted during the industrial revolution.

Professions require:

- Theoretical knowledge and practical skills that can be applied to solve a wide range of problems.
- A training path that enables acquisition of this knowledge.
- A control system that regulates access to the degree.
- Professional associations responsible for organising and controlling the profession.
- A code of behaviour to ensure professional integrity (an ethical code).
- The provision of a service that is generally considered useful for the common good.

The concept of discipline

- This was originally linked to education: the teacher imparts the doctrine while the disciple is instructed and 'disciplined'.
- The 19th century saw the appearance of the first scientific disciplines in response to:
  - An exponential increase in the volume of knowledge.
  - An increasing difficulty in mastering all the skills.
  - The need to focus on a single field.
  - The teaching model (which was compartmentalised in subjects with a compendium or textbooks).

Disciplines require:

- A body of knowledge (theories, laws, models, paradigms, etc.) and a group of people dedicated to developing that knowledge.
- A literature (journals, books, dictionaries) with a specific language.
- Archetypal images and practices that are more or less coded.
- Acknowledgment of the discipline by society.
- A set of shared values and unsolved issues.
- A genealogy or 'tale of origins' that includes heroic or epic stories about its past.

2. The origins of pharmacy

Symbolic (or sacred) pharmacy

- Animism: medicines are selected according to sacred and symbolic criteria.

- Shamanism: cause of disease and therapeutics; transfer, loss and recovery of the soul; possession and expulsion.

Australian medicine man with a magic healing crystal

- The healer, witch, or shaman communicates with the spiritual world; he knows the plants and their properties and prepares medicines.
- Medications do not heal on their own but are energised by rituals and magic:
  - Expulsive (of evil spirits)
  - Narcotising (access to the spiritual world, diagnosis and prediction of the course of the disease, production of an ecstatic state in the sick, etc.)

Ceremonial mortar produced in andesite stone, Valdivia Culture, Ecuador, *c.* 3800 AC

- Symbolic pharmacy is based on similarities and signs that lead to fictitious properties.

- Mandrake root and ginseng:

  Their human form reinforces the human body (by invigorating and stimulating it)

Root of gingseng
(*Panax ginseng*)

- Many ideas of symbolic pharmacy were perpetuated in the pharmacy of Hippocrates and Galen. The two most famous medicines of Galenism are:
  - **Theriac** (polypharmaceutical). The main ingredient of theriac was snake meat; it was used, for example, as an antidote for snake bites.
  - **Mithridate**. The main Ingredient of mithridate was scorpion meat; it was used as an antidote for scorpion stings.

ELECTUARIA. 103

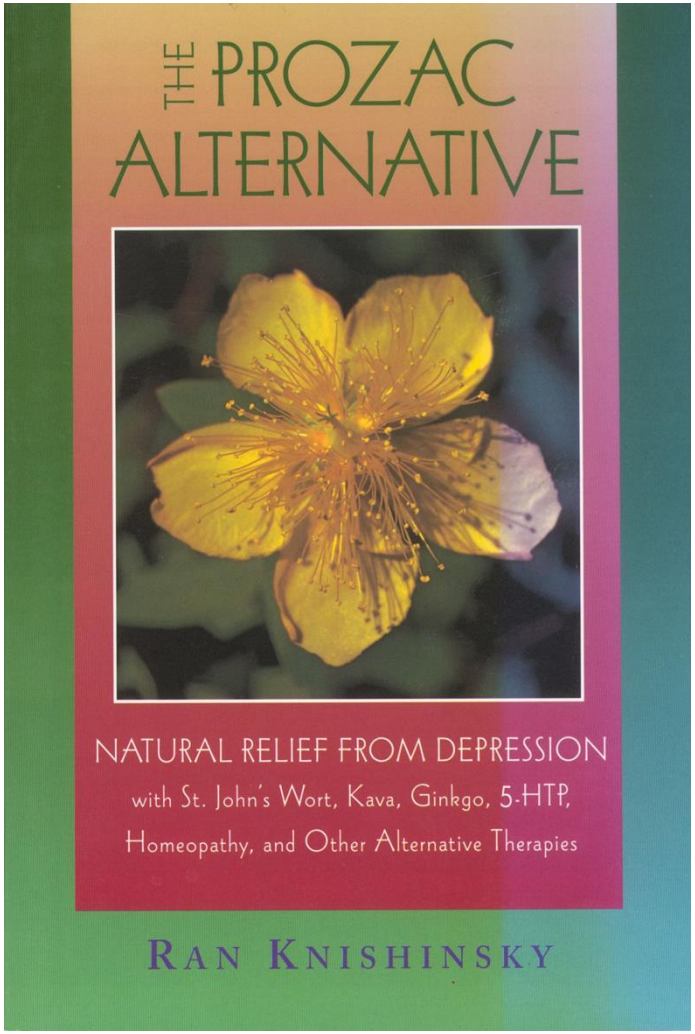
Sem. Napi dulcis,
Cymarum Scordii,
Opobalſami,
Cinnamomi,
Agarici trochiſcati, ana drachmas duodecim.
Myrrhæ,
Coſti odorati, ſeu Zedoariæ,
Croci,
Caſiæ lignæ veræ,
Nardi Indicæ,
Schœnanthi,
Piperis albi,
nigri,
Thuris maſculi,
Dictamni Cretici,
Rhapontici,
Stœchados Arabicæ,
Marrubii,
Sem. Petroſelini Macedonici,
Calaminthes ſiccæ,
Terebinthinæ Cypriæ,
Rad. Pentaphylli,
Zingiberis, ana drachmas ſex.
Cymarum Polii Cretici,
Chamæpityos,
Rad. Nardi Celticæ,
Amomi,
Styracis Calamitæ,
Rad. Mei Athamantici,
Cym. Chamædryos,
Rad. Phu pontici,
Terræ Lemniæ,
Fol. Malabathri,
Chalcitidis uſtæ, vel, ejus loco, Chalcanthi Romani uſti.
Rad. Gentianæ,
Gummi Arabici,
Succi Hypociſtidis,
Carpobalſami, vel Nucis Moſchatæ, vel Cubebarum.
Sem. Aniſi ſiccat.
Cardamomi,
Fœniculi,
Seſeleos,
Acaciæ, vel, ejus loco, Succi inſpiſſati Prunellorum acerborum.
Seminum Thlaſpios,
Summitatum Hyperici,
Sem. Ammeos,
Sagapeni, ana drachm. quatuor.
Caſtorei,
Rad. Ariſtolochiæ longæ.
Bituminis Judaici, vel Succini,
Sem. Dauci Cretici,
Opopanacis,
Centaurii minoris,
Galbani pinguis, ana drachmas duas.
Vini Canarini veteris, q. f. nempe uncias quadraginta, quo diſſolvantur ſimplicia humida & liquabilia.
Mellis optimi deſpumati triplum ad pondus ſpecierum ſiccatarum; Miſce ſecundùm artem.

THERIACA LONDINENSIS.

℞ Cornu Cervini limâ derafi, uncias duas.
Sem. Citri,
Oxalidis,
Pæoniæ,
Ocimi, ana unciam unam.
Scordii,
Corallinæ, ana drachmas ſex.
Rad. Angelicæ,
Tormentillæ,
Pæoniæ,

Fragment from a recipe for the preparation of theriac according to the *Pharmacopoeia Londinensis* (1677)

- Symbolic pharmacy comprises primitive remedies of indigenous communities, sacred and priestly therapies from ancient great cultures such as the Mesopotamian, Egyptian, Iranian and pre-Columbian, and movements developed in technical medicine (e.g. Paracelsus, Mesmerism, etc.).
- It is still present in our societies in alternative medicines and therapies based on energies, emotions, and states of mind.



Early technical pharmacy

- **Mesopotamia:** the tablets of Nippur (the oldest technical text on medicine and pharmacy), the code of Hammurabi (c.1750 BC), and the regulation of medicine.
- **Egypt:** papyri, medicine, mummification. Secular medicine and priestly medicine. Technical pharmacy without sacred components. The Ebers, Smith, and Kahoun Papyri (hieroglyphic writing).
- **Pre-Columbian:** Aztec, Mayan and Inca cultures. Pre-Columbian herbalism is still used (yoloxóchitl infusion for fevers or toloache as an abortive), molle resin (for depression), coca leaves (for pain relief, magic rituals, etc.); balneotherapy.

Excerpt from the Edwin Smith Papyrus (c. 1650 AC)

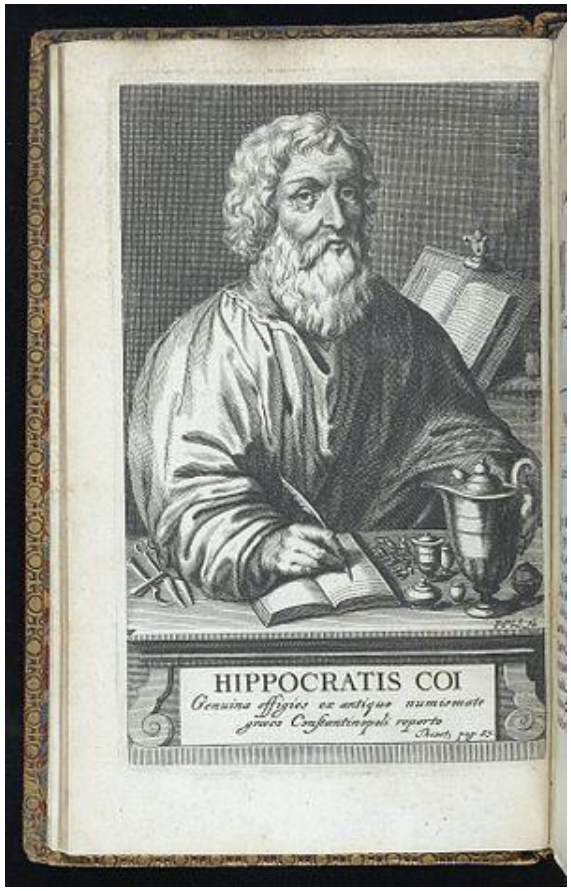
- **China:** Health as harmonic balance. Ying and yang. The five elements. Basic substances. Therapy. Medicines.

- **India:** The pharmacy of harmony. Ayurveda. Elements, flavours, taste, organs, emotions. Medicines.

A Hindu physician converted into an avatar of the god Vishnu

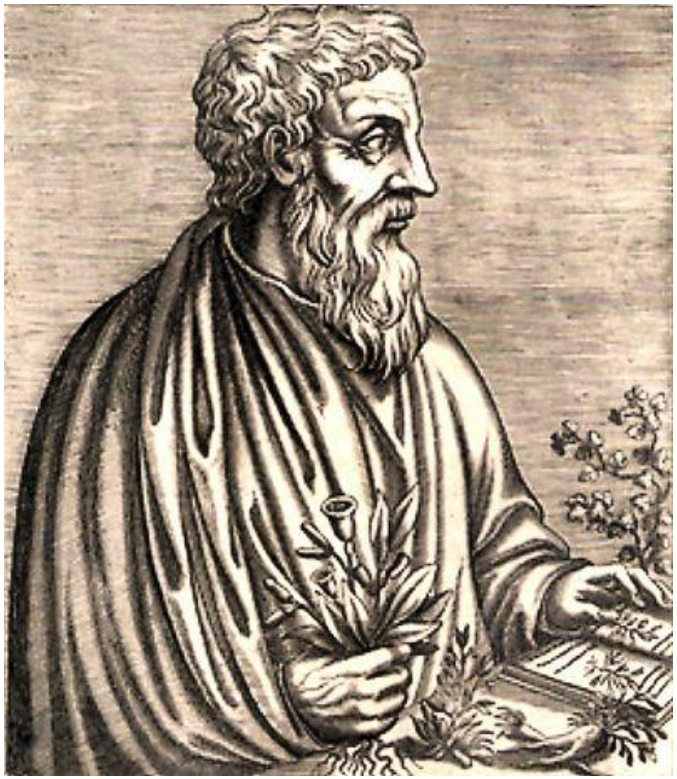
Greco-Roman pharmacy

- **Hippocrates:** Illness is a natural phenomenon. Against the 'sacred disease' (5th century BC).
- The methodical school: clinical observations and theoretical and doctrinal elaboration based on the four constituent elements of matter (air, water, earth and fire) and humoural theory.
- The classification of plants according to their properties.
- Medications act on humours to produce eucrasia (good mix) and physiological isonomy.



Portrait of Hippocrates, *Magni Hippocratis Coi opera omnia,* 1665

- **Dioscorides** was a doctor of Greek origin. Descriptive treaty of 'simples': *De Materia Medica* (600 medicinal plants, 90 minerals and 30 medicines of animal origin).
- Work of reference in the Middle Ages and the Renaissance.

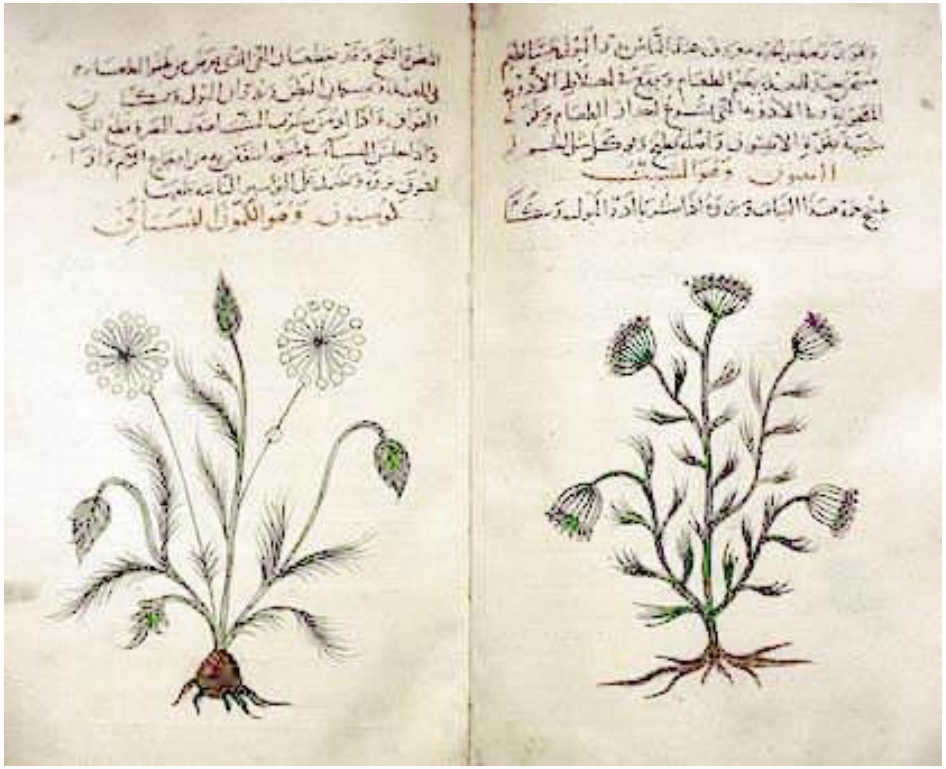


Pedanio Dioscorides (c. 40 – c. 90)

Pharmacy in the Middle Ages

- Byzantium: compilation of Galenism.
- The Arab world: Arabic translations of the *Corpus Hippocraticum*, Galen and Aristotle.
- In the 9th century a hospital was founded in Baghdad: pharmacy
  - Rhazes (865-925), *Liber de medicina ad Almansoren*
  - Avicenna (980-1037), *Canon medicinae*
  - Averroes (1126-1198), *Liber universalis*
- Latin pharmacy: monastic (Salerno, 9th century) and secular (11th century) models.
- 1241: division of medicine and pharmacy (Two Sicilies)
- Medications: poly-drugs (more than 20 different components) with alleged digestive, laxative, diuretic, diaphoretic or analgesic properties. The favourite medication was theriac.

Delivery of medicines (*Tacuinum sanitatis*, siglo XIV)



Arabic book of simple medicines from *De Materia Medica* by Dioscórides. Cumin & Dill. c. 1334

Typical medieval scene: the doctor diagnoses a disease through uroscopy and sends a family member of the patient to the apothecary with the prescription.

Uroscopy and ring of flasks. Ulrich Pinder (doctor of the court of Saxony). *Epiphaniae medicorum*, 1506.

Preparation of theriac in Bolonia. A. Terzi

Theriac, II BC – 1950: *Theriacus*, *Theriaca* ('Counterpoison' in Latin).
Poisonous animal bites.

Made in public.

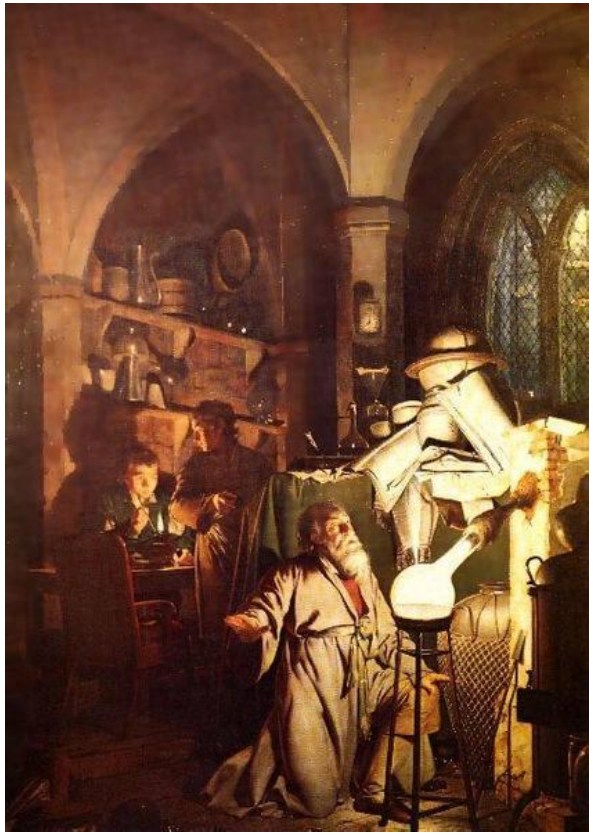
The remedy was practically useless (from the perspective of current medicine) but endowed with a great reputation as a universal panacea.

Nero took it, as probably did Copernicus, Newton, Linnaeus, etc.

It was also prepared by Claude Bernard, the father of modern pharmacology, in the small office where he began his scientific activities.

Pharmaceutical alchemy

- Alchemy is a pharmacy of regeneration and purification. The organism is conceived as a chemical equilibrium (not as a humoural equilibrium). Disease is considered a chemical disharmony.
- The basic principles of alchemy are: humours are replaced by sulphur, mercury and salt (*tria principia* or three principles); symbology
- Pharmacy is related to chemistry: Paracelsus.



Idealised image of an alchemist discovering phosphorus, according to a painting by Joseph Wright of Derby

The ‘discovery’ of America

- The ‘discovery’ of America gave an immense impulse to numerous disciplines, including navigation, cartography, geography, astronomy, natural history, pharmacy, philosophy, and theology.
- *Materia medica* increased exponentially.
- The main objective of the first ‘scientific’ expedition to the American continent (Francisco Hernández, 1574-1577) was to look for medicinal remedies

The Enlightenment

- Chemistry: Lavoisier
- Botany: Linnaeus
- Expeditions to the American continent: Mutis
- Homeopathy: Hahnemann
- Vaccination: Jenner


Organon

der rationellen

Heilkunde

von

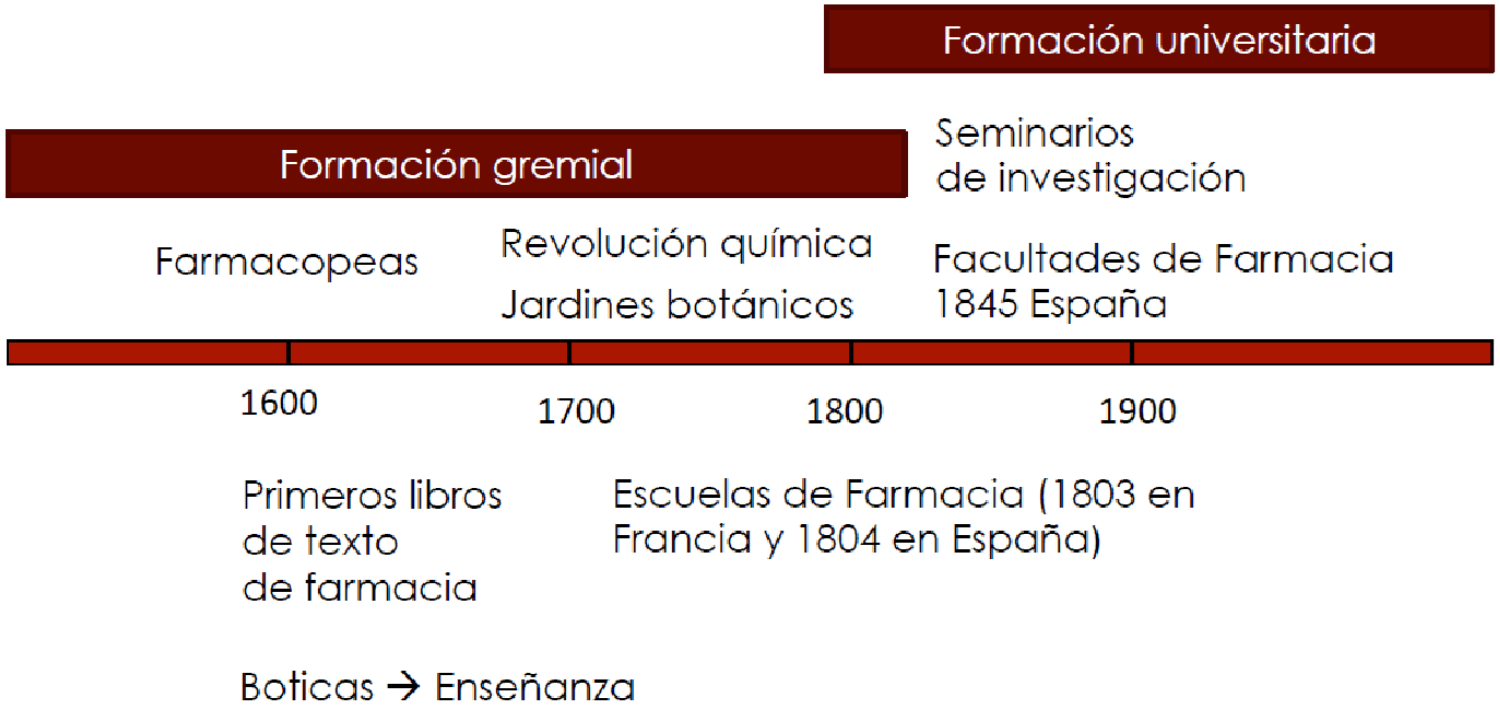
Samuel Hahnemann.

Dresden, 1810.

in der Arnoldischen Buchhandlung.

Treatise on Homeopathy by Samuel Hahnemann. *Organon der…,* 1810

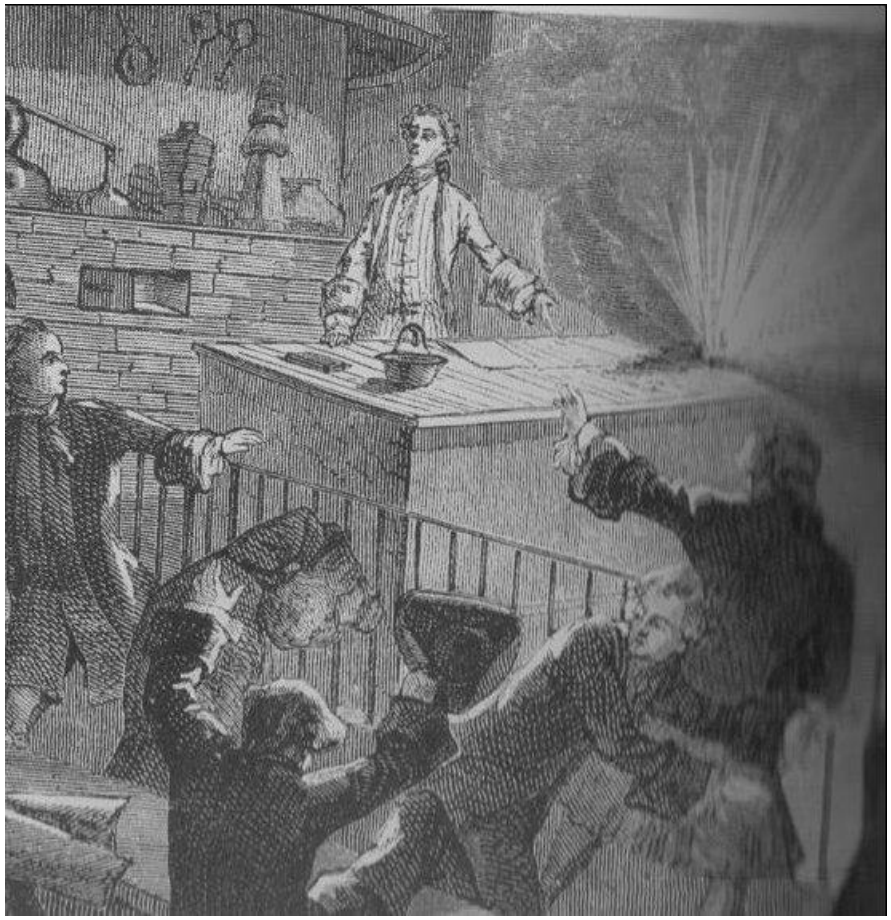
3. The development of pharmacy as a profession and discipline



Annibal Barlet, *Le vray et méthodique cours de la physique resolutive vulgairement dite chymie,* París (1653)

Guild training

- Contract between apprentice and apothecary (master)
- Practical training
- Examination controlled by the guild (initially) and then by the state (*Protomedicato*, governing boards, etc.)
- Training trips



Guillaume F. Rouelle, *Cours de chimie au Jardin du Roi*

- The creation of new training institutions in the 18th century

1. Botanical gardens
2. Chemical courses

University education: the creation of Pharmacy Faculties

- 1803 (France) and 1804 (Spain): initially the institutions were disconnected from universities (Schools).
- Regulated training coexisted with practical formation in guilds.
- Training took roughly 3 years in the Schools (8-year training in the guild could be reduced to 3 years by following School courses).
- Examinations were controlled by the Schools.
- The Pharmacy Schools were integrated into universities in the mid-nineteenth century (Pidal's plan, 1845).

Research seminars

Justus von Liebig's laboratory (1803-1873), Giessen, Germany

Pharmaceutical knowledge

- From the great classical texts to modern treatises on Pharmacy.
- Scientific literature related to Pharmacy.
- Information retrieval systems (databases).

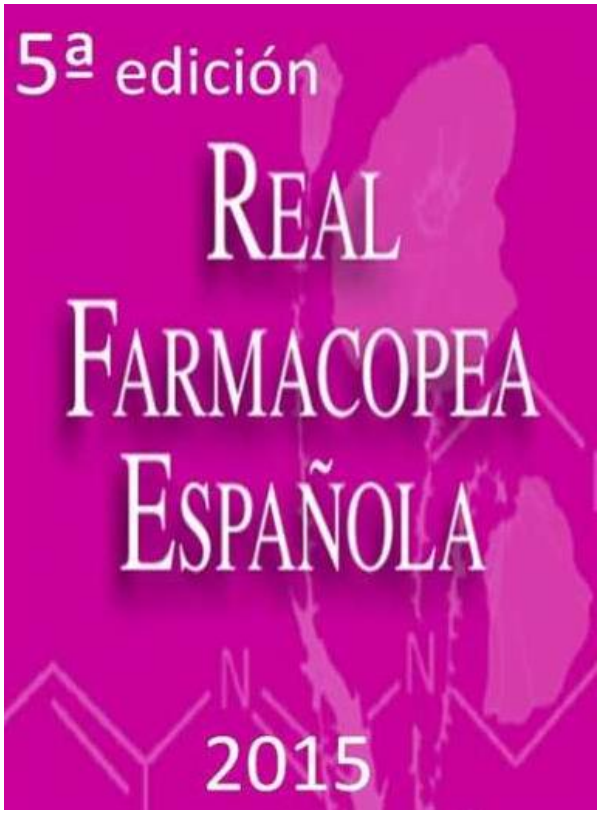
Catalan *Concordia,* edited in Barcelona (1511)

Control of the profession

- Exams and diplomas.
- Limitations on professional practice.
- Management of pharmaceutical pharmacies, hospitals, and laboratories.
- Pharmacopoeias: national codes that regulate pharmaceutical remedies.

The **Royal Spanish Pharmacopoeia** is the legal compendium on the quality of medicines and the reference code for all areas related to the discipline.

According to article 11.3 of Act 29/2006 on guarantees and the rational use of medicines and health products, it is the code that establishes the **quality** required by **active principles and excipients** used in medicinal products for human and veterinary use.



The **fifth edition** of the Royal Spanish Pharmacopoeia was approved by Order SSI/23/**2015**, of January 15 (BOE of January 21, 2015). It is published exclusively in electronic format by the Spanish Agency of Medicaments and Sanitary Products.

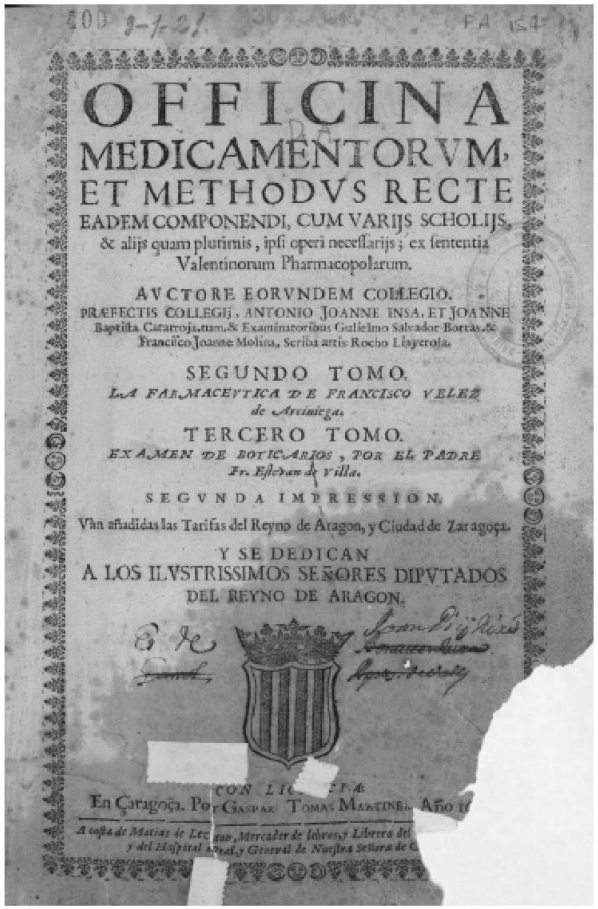
The Royal Spanish Pharmacopoeia (RFE) consists of 3,246 monographs and 332 general methods.

Professional societies

College of Pharmacy of Valencia

- Dona Maria of Castile approved the constitution of the College of Pharmacy of Valencia (Valencia, March 20, 1441).

Archives of the Kingdom of Valencia, Royal Chancellery, 260ss., 83 recto a 86 recto


OFFICINA
MEDICAMENTORVM
ET METHODVS RECTE
EADEM COMPONENDI, CVM VARIJS SCHOLIJS,
& alijs quam plurimis, ipsi operi necessarijs; ex sententia
Valentinorum Pharmacopolarum.
AVCTORE EORVNDEM COLLEGIO.
PRÆFECTIS COLLEGIJ, ANTONIO JOANNE INSA, ET JOANNE
Baptista Catarroja, tum, & Examinatoribus Guilielmo Salvador Borras, &
Francisco Joanne Molina, Scriba artis Rocho Llayerola.
SEGUNDO TOMO.
LA FARMACEVTICA DE FRANCISCO VELEZ
de Arciniega.
TERCERO TOMO.
EXAMEN DE BOTICARIOS, POR EL PADRE
Fr. Esteban de Villa.
SEGVNDA IMPRESSION.
Van añadidas las Tarifas del Reyno de Aragon, y Ciudad de Zaragoça.
Y SE DEDICAN
A LOS ILVSTRISSIMOS SEÑORES DIPVTADOS
DEL REYNO DE ARAGON.
En Çaragoça. Por GASPAR TOMAS MARTINEZ. Año

Officina Medicamentorum (1603)

Professional colleges aim to:

- Order the pharmaceutical profession in any of its modalities within the legal framework for the benefit of society, its members, and the common good.

- Supervise the exercise of the profession, facilitate knowledge and compliance with legal provisions, enforce ethical standards, maintain quality standards, and promote training.

- Defend the interests of the profession.

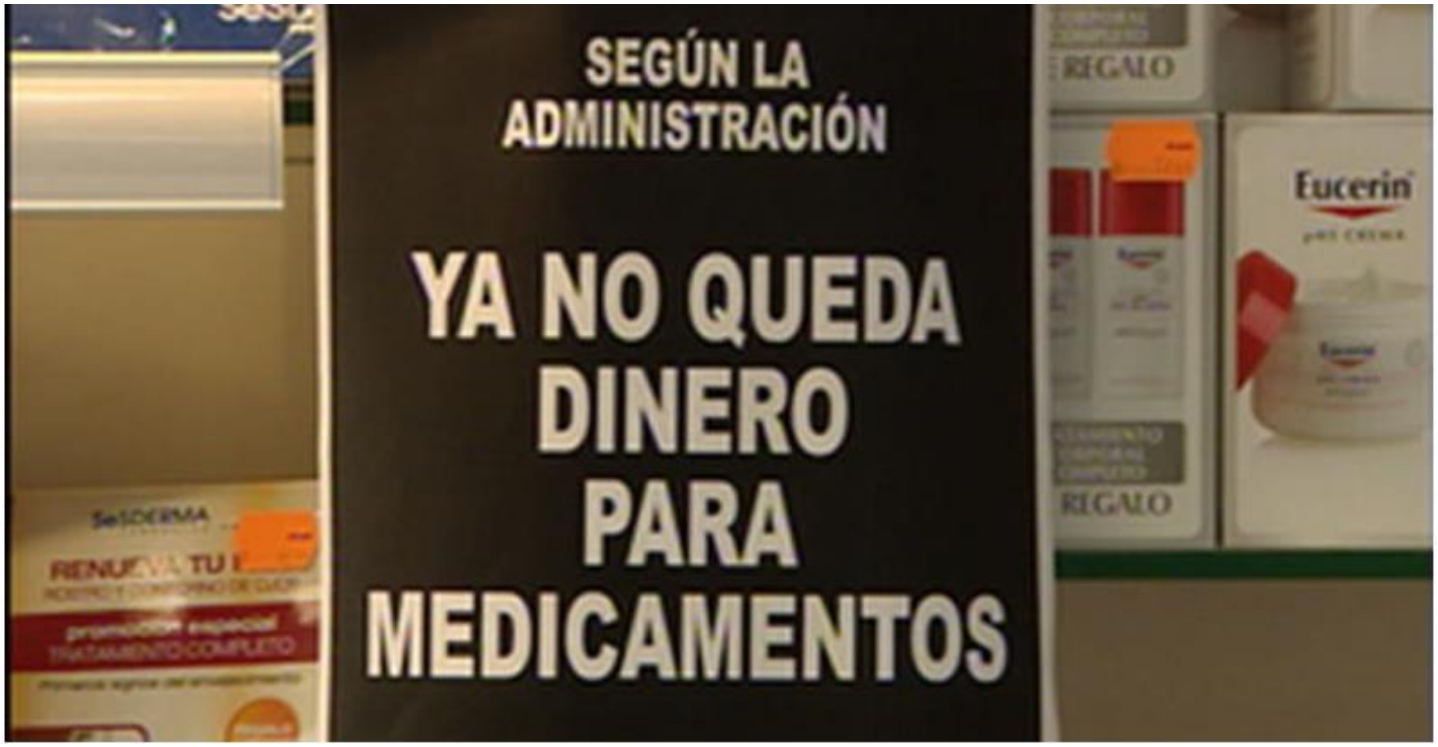
Exercise of the profession

- The production and dispensing of medicines:
  - Retail pharmacies
  - Hospitals
  - Laboratories

Ethical codes

- The Hippocratic oath (c. 500 BC).
- The *Magna Carta* of Pharmacy (Frederick II, 1241).
- The Ethical Code of the American Pharmaceutical Association (1852).
- The Ethical Code of the International Pharmaceutical Federation (1958).
- The Code of Ethics for Pharmacists (Spanish Society of Hospital Pharmacists, 1998).
- Ethical Code and Pharmaceutical Deontology (Spanish General Council of Pharmaceutical Colleges, 2001).

Business or public service?



4. Higher education and development cooperation (Agenda 2030)

- 'Transforming Our World: The 2030 Agenda for Sustainable Development' (August 2, 2015):
  - ✓ Implementing an action plan for people, the planet, and prosperity.
  - ✓ Strengthening universal peace within a broader concept of freedom.
  - ✓ Eradicating poverty, including extreme poverty, is the greatest challenge facing the world and a prerequisite for sustainable development.

Sustainable development

1. End **poverty** in all its forms around the world.

2. End **hunger**, achieve **food security,** improve **nutrition**, and promote sustainable agriculture.

3. Ensure a **healthy life** and promote well-being for all at all ages.

4. Ensure **inclusive, equitable, and quality education** and promote lifelong learning opportunities for all.

5. Achieve **gender** equality and empower all women and girls.

6. Ensure **water** availability and sustainable management and sanitation for all.

7. Ensure access to affordable, secure, sustainable and modern **energy** for all.

8. Promote sustained, inclusive and **sustainable economic growth**, full and productive employment and decent work for all.

9. Build **resilient infrastructures**, promote inclusive and sustainable industrialisation, and foster innovation.

10. Reduce **inequality** within and between countries.

11. Ensure that **cities and human settlements** are inclusive, secure, resilient and sustainable.

12. Ensure **sustainable consumption** and production patterns.

13. Take urgent action to combat **climate change** and its effects.

14. Conserve and sustainably use **oceans, seas and marine** resources for sustainable development.

15. Protect, restore, and promote the sustainable use of terrestrial **ecosystems**, manage forests sustainably, combat desertification, halt and reverse land degradation, and curb the loss of biological diversity.

16. Promote peaceful and inclusive **societies for sustainable development**, facilitate access to justice for all, and create effective, accountable and inclusive institutions at all levels.

17. Strengthen the means of **implementation** and revitalise the Global Partnership for Sustainable Development.

Ángel Gabilondo (Professor of Philosophy, ex-rector of the UAM, and ex-Minister of Education) speaking at the 7th Congress on University and Cooperation (2017)

- Universities must put knowledge at the service of dignity and equality; otherwise, they will merely be schools.
- We must transform the world, not just make palliatives.
- The core of the sense of academic knowledge is to achieve human emancipation.
- Being a college student is the path to becoming an active transformer.
- We must universalise our commitment to other human beings.
- We must promote fraternity rather than paternalism ("I'm going to cooperate").
- Most of the poor are not in the poorest countries ("there are poor people nearby").

Sanitary equipment in Baasneere (Burkina Faso, 11,000 inhabitants in a 10-km radius): Fanta (midwife), Rawa (assistant) and Bryce (Centre Director and nurse). Maternity fund and health centre.

Save the Children

MEDICOS SIN FRONTERAS

Intermón Oxfam

Theme 9. Health sciences and gender

Introduction

In this unit we will show how complex the links between science and gender are in order to reflect on the role of women in science throughout history. To do so we will consider the nature of studies whose aim is to rediscover the practices performed by female scientists and examine the areas of science in which they worked in spite of the legal and invisible barriers they had to overcome. This will enable us to consider the reasons behind the increasing feminisation of healthcare professions in Spain, especially in areas such as nursing, pharmacy and medicine. We will also discuss sex- and gender-related differences, which often appear in the scientific literature, and analyse how the biological, sexual, cultural and social differences between men and women influence their health problems and, therefore, their healthcare needs. Finally, we will discuss the problem of gender violence and examine its consequences on health.

Contents

Objectives

- To learn how complex the links between science and gender have been throughout history.
- To understand the mechanisms used to exclude women from science.
- To discuss the historical evolution of women's roles in scientific institutions.
- To analyse the growing feminisation of the healthcare professions.
- To assess how biological, sexual, cultural and social differences influence health problems and healthcare needs in men and women.
- To assess the magnitude of the problem of gender violence and its impact on health.

Preliminary activity

Read the article by Enrique Gracia and Juan Merlo entitled *"Intimate partner violence against women and the Nordic paradox". Social Science & Medicine*, 157, 27-30 (2016).
You can find this article at the following link:

http://authors.elsevier.com/a/1SqOi_6KUSg0Uy

See also:
https://www.uv.es/uvweb/universidad/es/listado-noticias/describen-paradoja-nordica-mayor-igualdad-genero-mas-altos-indices-violencia-pareja-europeos-1285846070123/Noticia.html?id=1285966463901

Points to consider

- What is the 'Nordic paradox'?
- What strategies are believed to respond more effectively to this social and public health problem?
- What problems for health and healthcare needs do you think could be caused by inequality between men and women?

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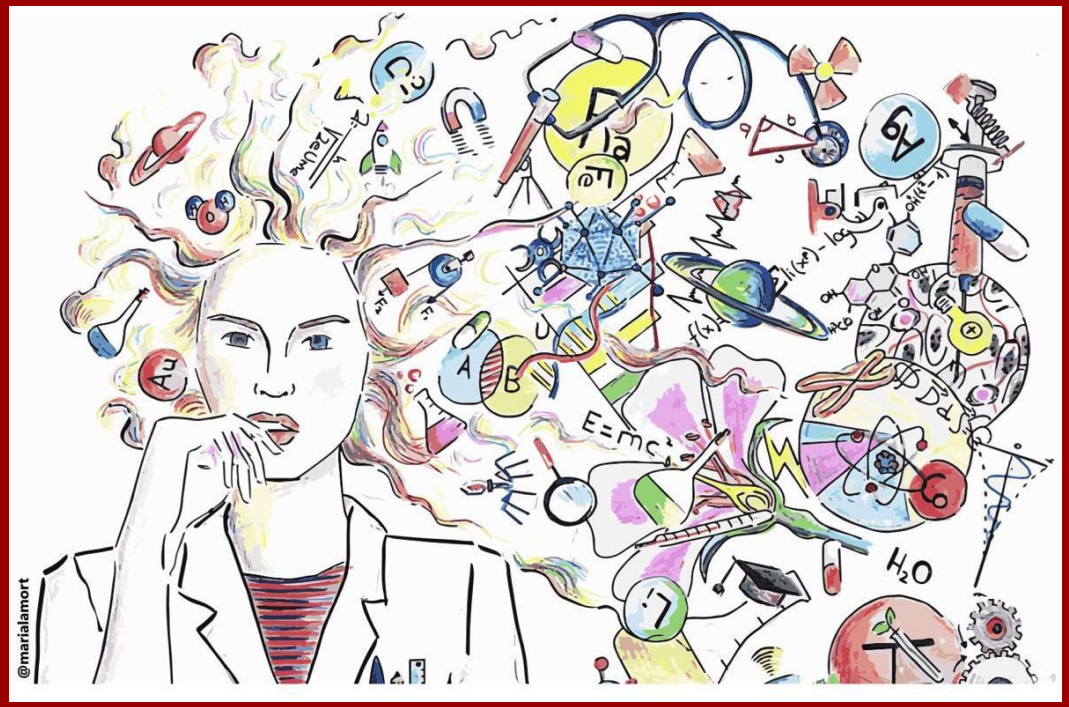
The WomanStats Project: http://www.womanstats.org/about.html

OMS, Violencia contra la mujer. https://www.who.int/topics/gender_based_violence/es/



Theme 9. Health sciences and gender

VNIVERSITAT DE VALÈNCIA

Carmel Ferragud, Rafaela Domínguez, Mar Cuenca **Documentation and Scientific Methodology**
History of Science
Degree in Pharmacy

1. Introduction
2. Is science masculine?
    2.1. Women in scientific institutions
    2.2. The feminisation of healthcare professions
3. Clinical manifestations of gender differences
    3.1. The concepts of sex and gender
    3.2. Differences in health according to sex
    3.3. Differences in health according to gender
4. Gender violence
5. Conclusions

1. Introduction

- Feminist criticism of science reveals the mechanisms for excluding women from science:

- Women's movements in the late 19th century.
- The incorporation of women into universities.
- The impact of the world wars.
- The emergence of a new image of science in the 1960s.
- The birth of modern feminism in the 1970s.

2. Is science masculine?

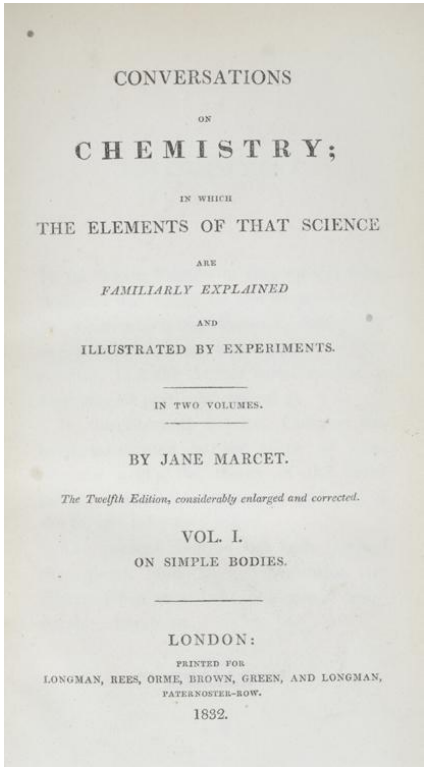
- In recent years, studies of the history of science that have analysed the role of women in science highlight the following problems:

- Invisibility
- Impediments
- Naturalisation

a) Invisibility

- Personalities, spaces and practices associated with women in the history of science and in manuals.
- The recovery of female personalities, practices of science teaching and education.
- The role of salons in the 18th and 19th centuries.

Jane Marcet (1769-1858)



CONVERSATIONS

ON

CHEMISTRY;

IN WHICH

THE ELEMENTS OF THAT SCIENCE

ARE

FAMILIARLY EXPLAINED

AND

ILLUSTRATED BY EXPERIMENTS.

IN TWO VOLUMES.

BY JANE MARCET.

The Twelfth Edition, considerably enlarged and corrected.

VOL. I.

ON SIMPLE BODIES.

LONDON:

PRINTED FOR

LONGMAN, REES, ORME, BROWN, GREEN, AND LONGMAN,

PATERNOSTER-ROW.

1832.

b) Impediments

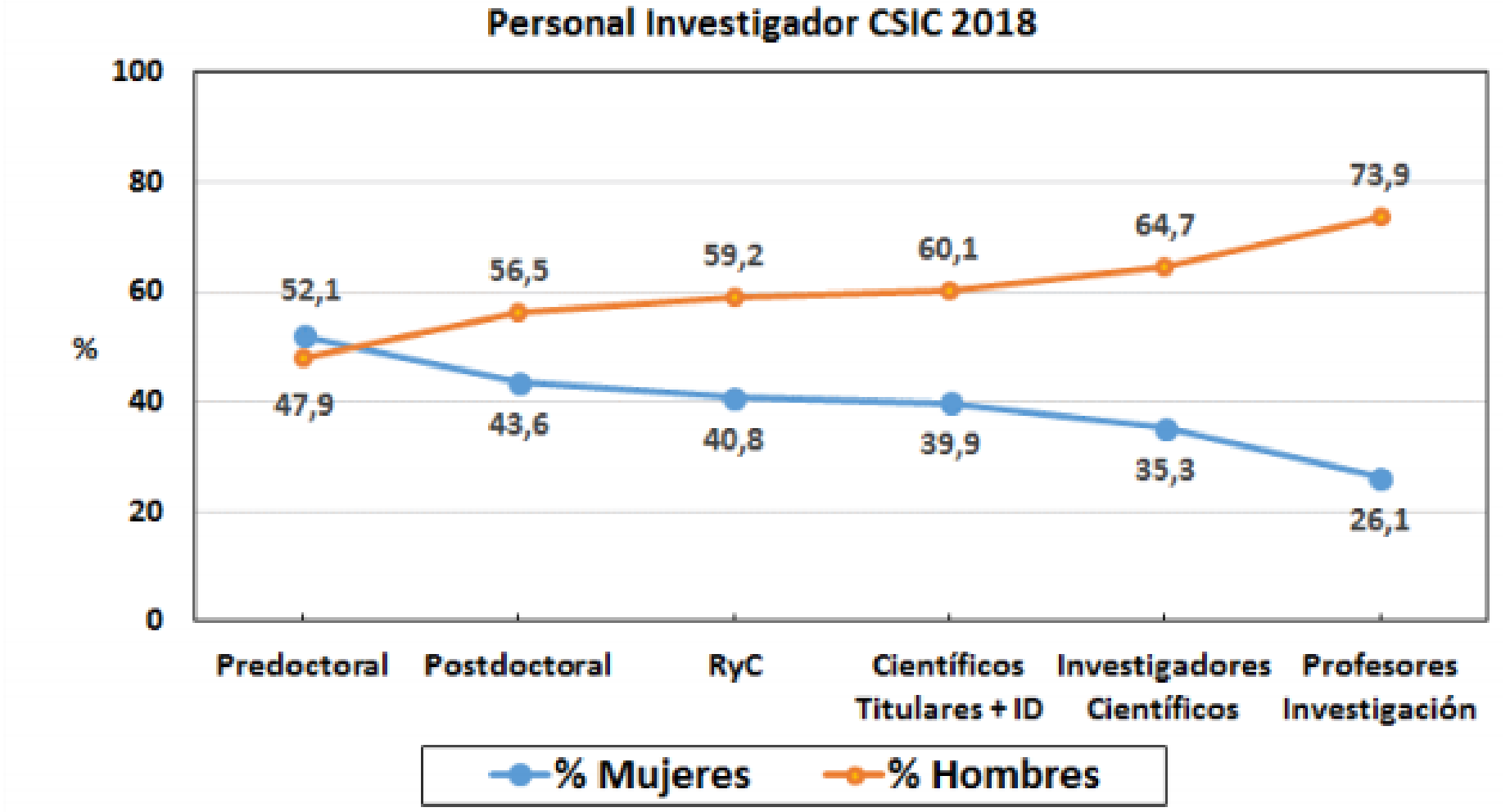
- Legal barriers and invisible barriers.

- Some higher education institutions and some scientific societies refused to admit women:

- Until 1910 it was very difficult for women to gain admission to higher education in Spain.

''Matilda effect" (M. Rossiter): negative or biased evaluation of women's contributions compared to men's.

'Glass ceilings'.



CMYC CSIC 2019

c) Naturalisation

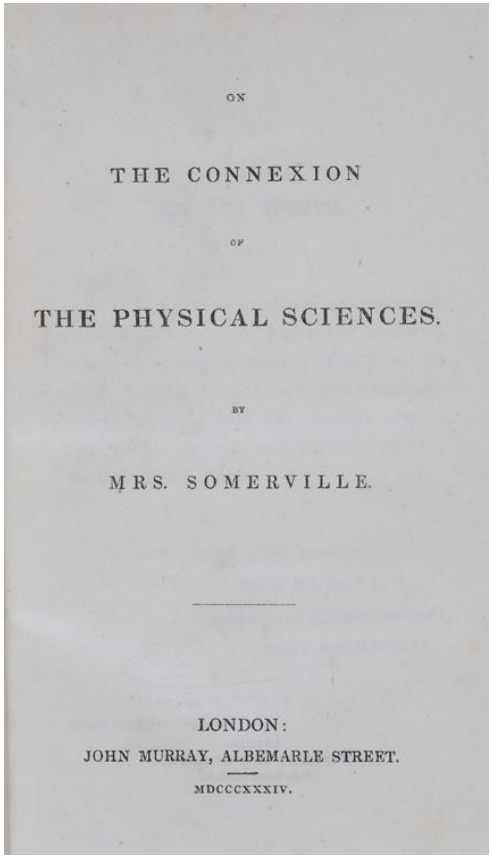
Attempts were made to naturalise certain barriers through scientific or medical discourse.

Example: Mary Somerville (1780-1872) and the description by William Whewell (1794-1866).

- Such claims served to limit women's activities in science.
- In the 19th century women became authors of works popularising science and gave public courses on physics and chemistry.

- "Notwithstanding all the dreams of theorists, **there is a sex in minds**. One of the characteristics of the female intellect is a clearness of perception, as far as it goes: with them, action is the result of feeling; thought of seeing; their practical emotions do not wait for instruction from speculation; their reasoning is undisturbed by the prospect of its practical consequences"

Mary Somerville (1780-1872)



ON

THE CONNEXION

OF

THE PHYSICAL SCIENCES.

BY

MRS. SOMERVILLE.

LONDON:
JOHN MURRAY, ALBEMARLE STREET.
MDCCCXXXIV.

William Whewell (1794-1866)

2.1. Women in scientific institutions

- **Classical Greece**:

  - In general, women were excluded from public life but had access to places of knowledge; women in disguise attended Plato's Academy; women enjoyed active participation among the Pythagoreans.

- **Middle Ages**:

- From the 6th to the 12th centuries, the Church monopolised education in Western Europe. The medieval monastery was the centre of scholarly knowledge.
- Access to knowledge was more limited but there were female monasteries (women without family obligations devoted themselves to study).
- From the 12th century onwards, medieval universities appeared: there were fewer educational opportunities for women but there were also exceptions, such as Italy (13th century).

- **The Renaissance and the Scientific Revolution**

- The universities were revitalised but there were no great changes (women were excluded).

Bassi (a doctor at the University of Bologna in 1733, a professor of physics, and a member of the Academy of Sciences in Bologna).

- In scientific academies (17th century), women were prevented from being members of societies and entering meeting halls.

Ex: Margaret Cavendish: philosophical treatises that discussed fundamental ideas of her era.

- Matrimony as a route for women to practise science: *Creative couples in Science*.

Ex: women did not become members of the most important Academies until the 20th century. However, they were regularly admitted to certain Italian institutions (e.g. Bologna, Padua, Rome).

- **The Enlightenment**

- New spaces: the salons of Paris competed with the academies for the attention of scholars.

- Intellectual institutions were directed by women.

- Women of notable social standing dominated meetings in private residences.

Bestuzhev courses for women (St Petersburg). Late 19th century.

Foster Laboratory, Residence for young ladies (Madrid). First third of the 20th century.

2.2. The feminisation of the healthcare professions

- In Spain, feminisation has been increasing in nursing, pharmacy and medicine in the last two decades.
- Medicine, dentistry and veterinary sciences have traditionally been occupied by men.
- Women occupied the healthcare professions with lower rates of technification and in undergraduate studies (3 years).
- Nowadays, women opt for preventive care, while men opt for more invasive procedures such as surgery.
- Reasons:
    - Gradual growth in the 'salaried employee rate'.
    - Dedication to the public sector.
    - More flexible and less risky working environments.
    - Fewer differences in salaries than in any other sector.
- Women have been prominent in healthcare throughout history in both informal environments (the domestic sphere) and formal environments the (public sphere).

3. Clinical manifestations of gender differences

3.1. The concepts of sex and gender

- Although the concepts of 'sex' and 'gender' are different, they are frequently swapped around in the scientific literature.

- **Gender** is a cultural concept that incorporates the social factors associated with:

- Family roles.

- Job expectations.

- The type of occupation.

- The social culture.

- Sex is a biological concept that includes the physical and physiological differences between men and women and determines their reproductive function.
- Biological sex: differences in the effects of treatments, results of diagnostic tests and the presentation of clinical signs and symptoms. There is a problem of clinical trials being done only with men and the results being also applied to women.
- Reproductive sex: women's specific needs.
- The biological, sexual, cultural and social differences between men and women play a part in what their health problems are and, therefore, in what their healthcare needs are.

3.2. Differences in health according to sex

Differences exist in the prevalence of illnesses according to sex (according to basic physiopathological differences and epidemiological studies):

- Some illnesses are more prevalent in one sex.
- Some illnesses have different ages of onset, symptomatology, response to treatment and prognosis in one sex than in the other.
- Some illnesses are unique to one sex (associated with reproduction).

- These differences influence the:
  - Healthcare process (diagnostic: unequal access, delays and waiting time for appropriate healthcare).
  - Therapeutic effort (types of therapeutic strategies, consumption and cost per sex, over-prescription of therapies).

Examples:

- Women have greater longevity.
- Women have greater morbidity and mortality in relation to reproduction.
- HIV/AIDS: women are at a greater risk of contagion.
- Ischemic cardiomyopathy is presented later in women, who suffer from different symptoms.
- With regard to respiratory illnesses, in women the manifestations are more serious, the symptomatic expression is greater, and the impact on quality of life is stronger.
- Strokes are the top cause of death in women in Spain. Fewer diagnostic tests and fewer treatments are available for women than for men.

3.3. Differences in health according to gender:

- There is greater **morbidity** in women due to:

✓ Poverty (70%).
✓ Family responsibilities.
✓ Gender violence.
✓ Sexual mutilation.
✓ Lack of attention in pregnancy and childbirth.

- **Gender biases in diagnoses and treatments**

Women receive:

✓ Fewer diagnostic explorations.
✓ More prescriptions of medicines, especially analgesics and psychotropic drugs.
✓ More explanation of their symptoms as psychosomatic manifestations.
✓ Fewer hospital admissions, e.g. acute myocardial infarction.

4. Gender violence

- Every person has the right to a life without violence and therefore not to be assaulted (physically, psychologically, sexually or verbally) by their sexual partner or anybody else.

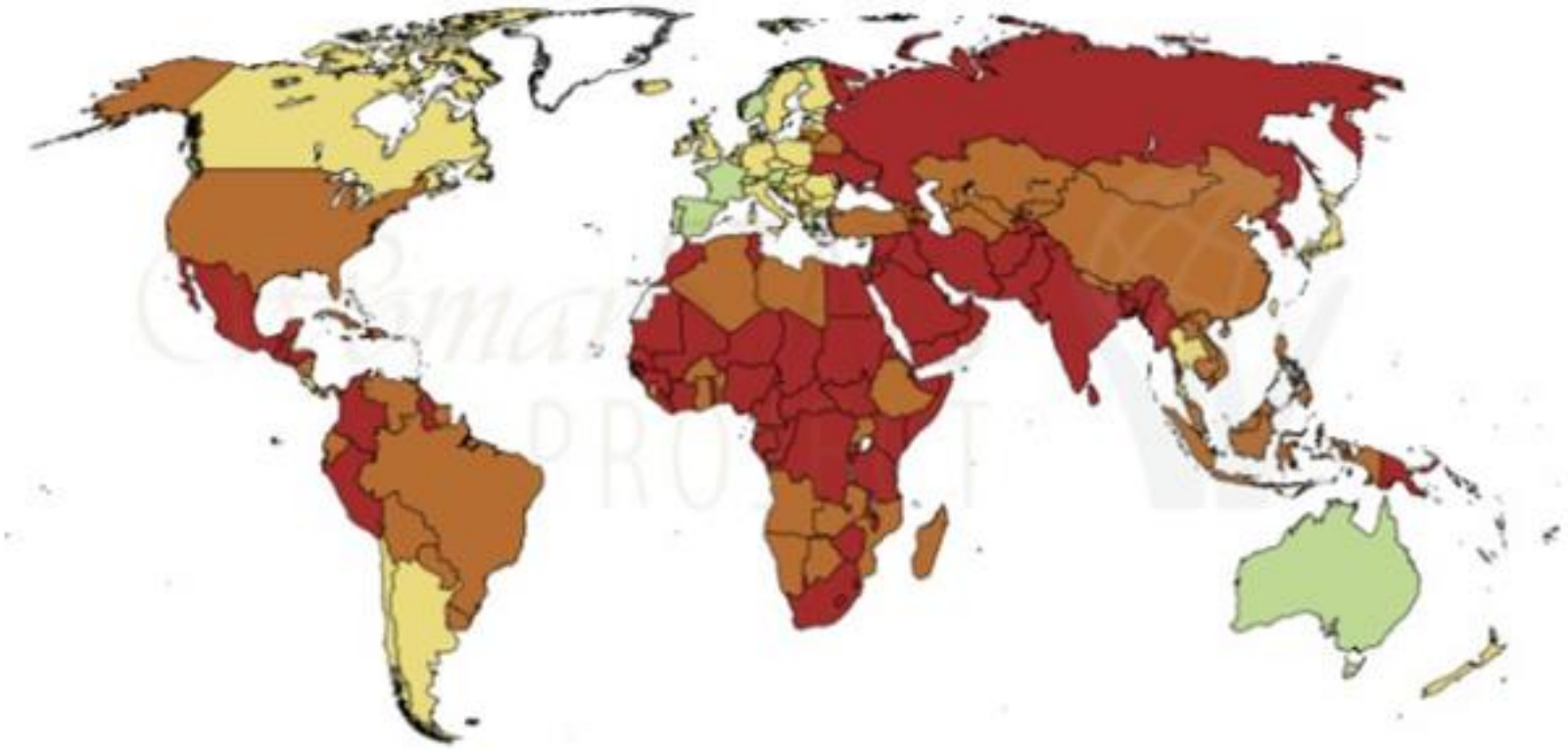
- Gender violence is an obstacle to health and to women exercising their sexual and reproductive rights: rape, harassment, abuse of minors, domestic violence, etc.

Size of the problem in Europe

- One of every three European women between the ages of 18 and 74 has suffered physical or sexual violence since the age of 15 (62 million women).
- 22% of women who have been in a relationship with a man have suffered physical or sexual violence by him.
- 5% of European women over 15 have been raped (9 million women).
- 43% of European women have suffered some form of psychological violence by their current male partner or a previous one.
- 38% of the total number of female homicides in the world are due to conjugal violence.

Physical Security of Women

Scaled 2019



WOMAN STATS PROJECT

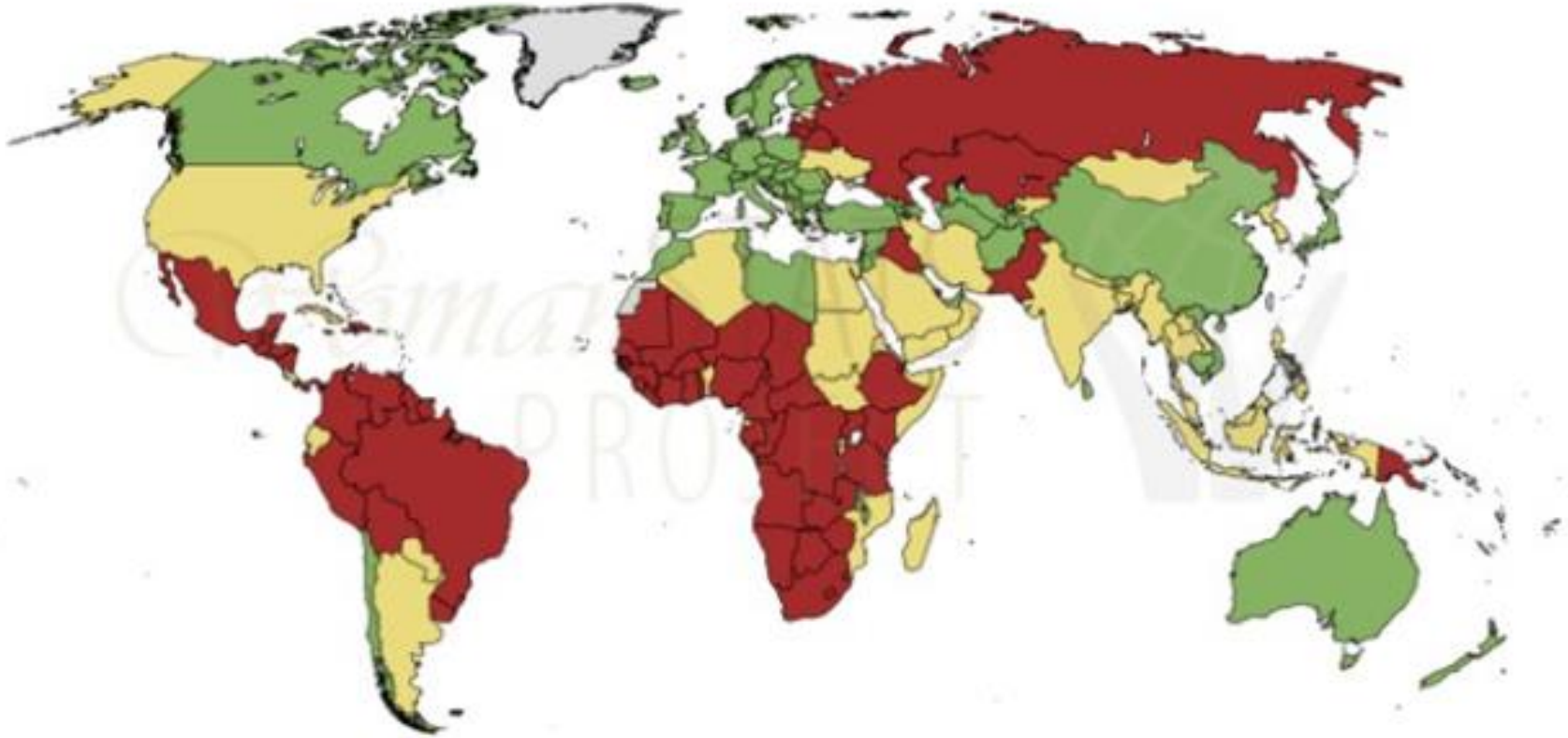
MULTIVAR-SCALE-1
Data The WomanStats Project
http://womanstats.org

- Women are physically secure
- Women have fairly high levels of physical security
- Women have moderate levels of physical security
- Women have low levels of physical security
- Women lack physical security
- No Data

VisualLightBox.com

Rate of Murder of Women, All Ages

Scaled 2019



WOMAN STATS PROJECT

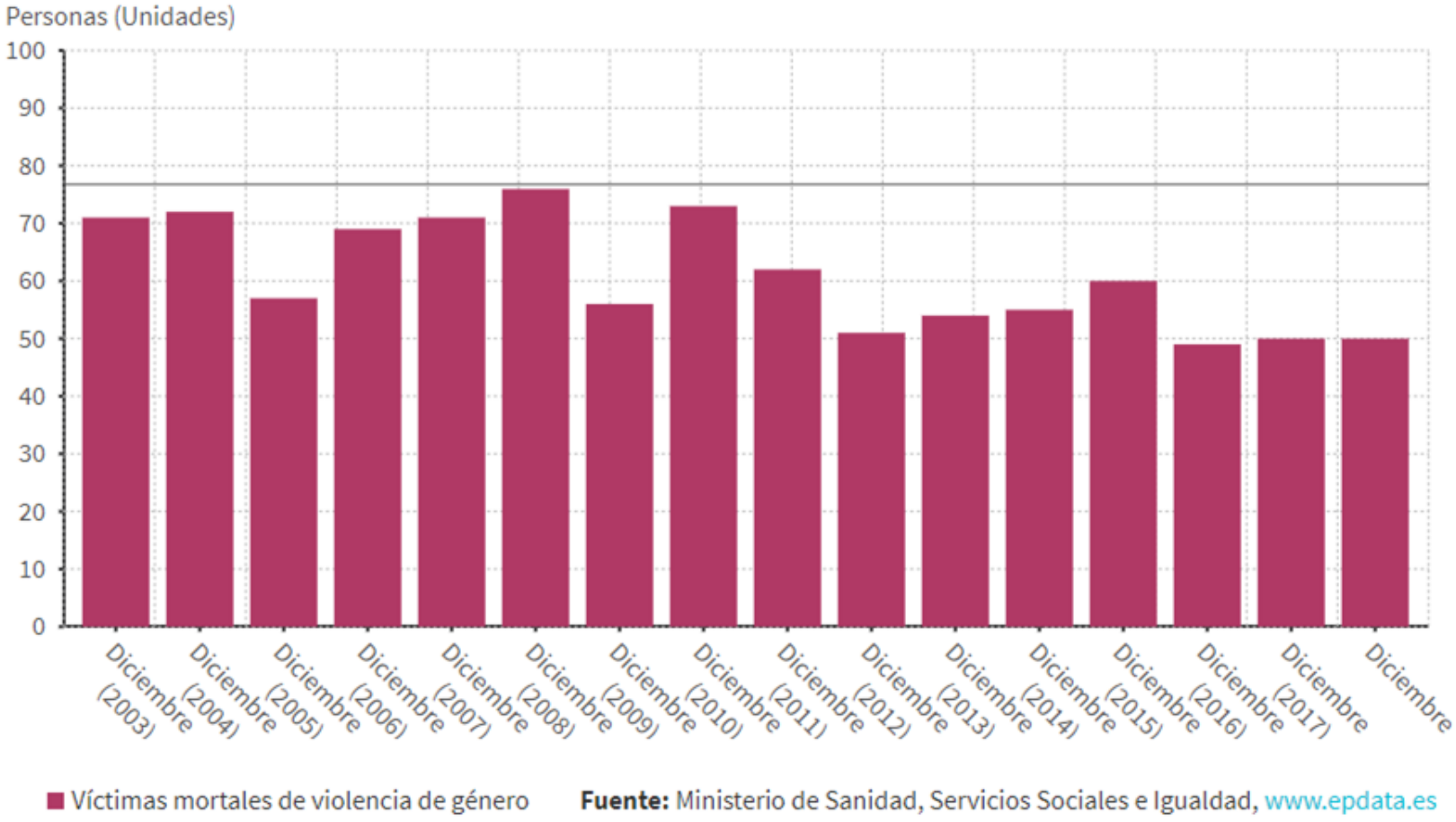
MURDER-SCALE-4

Data The WomanStats Project

http://womanstats.org

- Frequency low- 0 to 1.29 total female murder rate (ages 15 to 44) per 100,000 total female population
- Frequency medium- 1.30 to 2.99 total female murder rate (ages 15 to 44) per 100,000 total female population
- Frequency high- 3.00 and above total female murder rate (ages 15 to 44) per 100,000 total female population
- No Data

Víctimas mortales por violencia de género, año a año



Fuente: Ministerio de Sanidad, Servicios Sociales e Igualdad, www.epdata.es

Health consequences of gender violence:

- Suicides, homicides.
- Physical problems: unwanted pregnancies, injuries, disabilities, STDs.
- Psychological problems: depression, anxiety, sexual dysfunctions, obsessive/compulsive disorders.

La violencia contra la mujer **repercute gravemente en su salud.**

Muerte

Lesiones físicas

Embarazos no deseados, abortos inducidos

Infecciones de transmisión sexual, incluida la infección por VIH

Depresión, trastorno de estrés postraumático

Uso nocivo de tabaco, drogas y alcohol

£ € $ ¥ ﷼ ₱ ৳ ₳

Impacto económico

El costo económico de la violencia de pareja y sexual para los países es muy elevado. Ello incluye la provisión de **servicios de salud, sociales y jurídicos, así como los ingresos perdidos.**

5. Conclusions

- Women's access to science has been determined by legal and invisible barriers.
- The healthcare professions have experienced increasing levels of feminisation in recent decades.
- The biological, sexual, cultural and social differences between men and women play a part in their health problems and, therefore, in their healthcare needs.
- Gender violence is an obstacle to health and prevents women from exercising their sexual and reproductive rights.

Theme 10. The Conscience of Science: Bioethics

Introduction

The rapid development of the natural sciences and technology has hugely improved people's conditions and quality of life despite the enormous differences depending on where they live. However, all things connected with science and technology affect both society and the environment and entail a series of ethical aspects. The consequences of technologies can be devastating and often generate fear, distrust and uncertainty about the future of humanity. Society expresses its concern over these issues, especially with regard to the legal loopholes that usually exist. Sometimes these biotechnological risks are discussed and controlled but often they are not sufficiently considered. Citizens see their rights and aspirations for well-being jeopardised. The new problems generated by science have demanded reflection. Bioethics as a discipline must be understood in this context. In this topic we explore the context that led to its birth and development and the various theoretical approaches that have been adopted.

Contents

Introduction: from the 'natural order' to the 'order of freedom'
1. The birth and development of bioethics
2. Theoretical approaches:
    a. Professional ethics
    b. Utilitarianism
    c. Principlism
    d. Virtue ethics
    e. Feminist ethics
    f. Casuistry and deliberation
    g. Healing ethics
3. Example: human embryos and genetic manipulation

Objectives

- To study the origins and process that formed bioethics as a discipline.
- To examine the theories developed in relation to decision-making in bioethics.
- To analyse a case study as a model for identifying the difficulties of applying bioethics to specific cases.
- To form a critical opinion in relation to biomedicine and what impact does it have in the body.

Preliminary activity

Read the text entitled *El manejo del dolor* on page 273 of the Handbook.

El manejo del dolor

El respeto a la persona incorpora dos convicciones éticas: que toda persona debe ser tratada como ente autónomo y que las personas con autonomía disminuida tienen derecho a ser protegidas. En el caso que nos ocupa, respetar la autonomía del paciente supone, por una parte, hacer partícipe al paciente de su tratamiento, creer en el dolor que manifiesta, informarle de las alternativas disponibles para tratar su dolor y diseñar con él el plan analgésico. Informar adecuadamente y respetar las preferencias del paciente ayuda a disminuir la ansiedad que produce el dolor y va a favorecer su pronta recuperación. Por otra parte, sabemos que el dolor destruye a la persona y merma considerablemente su autonomía, haciéndola más dependiente, con lo que el inadecuado tratamiento del dolor contribuye a perpetuar esa merma de la autonomía. El principio de *beneficencia* nos exige ante todo buscar el bien para el paciente. Permitir que un paciente sufra dolor, sin poner los medios necesarios para evitarlo, vulnera abiertamente el principio de beneficencia. Pero, además, y dado que el dolor en sí produce su propia morbilidad, el tratamiento adecuado del dolor mejora el pronóstico del paciente y facilita su recuperación.

El principio de *no maleficencia*, asociado tradicionalmente al *primum non nocere*, nos exige evitar cualquier daño gratuito que pudiera infligirse al paciente y minimizar los riesgos de una intervención. Hay situaciones en las que no es posible evitar un trauma al paciente, dado su carácter cruento, como es el caso de intervenciones quirúrgicas, pruebas diagnósticas invasivas, etc. En estos casos, el no poner todos los medios necesarios para evitar o aminorar en lo posible el dolor producido por el trauma de la intervención es actuar produciendo dolor y por tanto sufrimiento, y esto es hacer un daño que se puede evitar. La ignorancia nunca puede ser una excusa o defensa. La falta de una adecuada formación acorde con el trabajo que se realiza y el estado de los conocimientos en cada momento conduce directamente hacia una mala praxis.

Tanto los médicos como los otros profesionales que trabajan en el cuidado de los pacientes tienen la responsabilidad de estar cualificados adecuadamente y de estar al día en el conocimiento de los medicamentos y otras técnicas que beneficien a los pacientes. En el caso de que esto no fuera posible, tenemos la responsabilidad y el deber ético de consultar a aquellos profesionales que están formados para manejar adecuadamente el dolor. Defender la ignorancia viola los objetivos de la medicina y el deber básico que el médico tiene con sus pacientes.

La no utilización de los recursos disponibles para aliviar el dolor debe considerarse como un acto de negligencia profesional, ya que está produciendo un daño no justificado a la persona que lo sufre. Antes, incluso, de cualquier análisis ético, procede comprobar la corrección técnica de la intervención.

Por otra parte, el principio de no maleficencia obliga a sopesar el beneficio-riesgo de cada intervención analgésica, y a conocer los efectos secundarios de los fármacos y las técnicas analgésicas; nos obliga a elegir los que presentan un mejor perfil terapéutico y de seguridad, teniendo en cuenta la situación clínica y las características del paciente. Los profesionales sanitarios, como agentes morales, tenemos la responsabilidad ética de tratar a nuestros pacientes de forma que maximicemos los beneficios y minimicemos el daño.

El principio de *justicia* reclama la igualdad en el trato médico de los distintos pacientes, y este se vulnera cuando a unos se les trata adecuadamente el dolor y a otros no, en función de los profesionales o las instituciones en los que son atendidos. La justicia dictamina qué situaciones médicas similares deben tratarse de forma similar. Todos los pacientes tienen derecho a que se les valore y trate el dolor adecuadamente. La ignorancia o la desigual distribución de recursos sanitarios no es una excusa o defensa en una sociedad que garantiza la universalidad y la equidad en el acceso a la atención sanitaria.

Desde el punto de vista de la disponibilidad y distribución de recursos, aunque existen técnicas cuyo coste es elevado, el tratamiento analgésico en general es de los más

asequibles, ya que dispone de una variada oferta de fármacos de gran potencia y reducido coste.

Soler Company E. El derecho a no sentir dolor. Aspectos éticos en el tratamiento del dolor. *Mètode*, 71 (otoño, 2011) [http://metode.cat/es/Revistas/Monografics/La-cara-del-dolor/El-dret-a-no-sentir-dolor].

Points to consider

- How could the issue of euthanasia be approached based on the principles (beneficence, autonomy, non-maleficence, justice) used to handle pain in the text you have just read?

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Theme 10. The conscience of science: Bioethics

Carmel Ferragud, Rafaela Domínguez, Mar Cuenca
History of Science

Documentation and Scientific Methodology
Degree in Pharmacy

VNIVERSITAT DE VALÈNCIA

Introduction: from the 'natural order' to the 'order of freedom'

1. The birth and development of bioethics

2. Theoretical approaches:

a. Professional ethics
b. Utilitarianism
c. Principlism
d. Virtue ethics
e. Feminist ethics
f. Casuistry and deliberation
g. Healing ethics

3. Example: human embryos and genetic manipulation

Introduction: from the 'natural order' to the 'order of freedom'

- The ideal of autonomy and human rights.
- The Protestant reformation and modern philosophy.
- From hierarchical order to the democratic ideal.
- Modern political revolutions.
- The individual as an autonomous moral agent.
- (Moral) pluralism as a right.
- In the field of medicine: the emergence of bioethics (20C).

1. The birth and development of bioethics

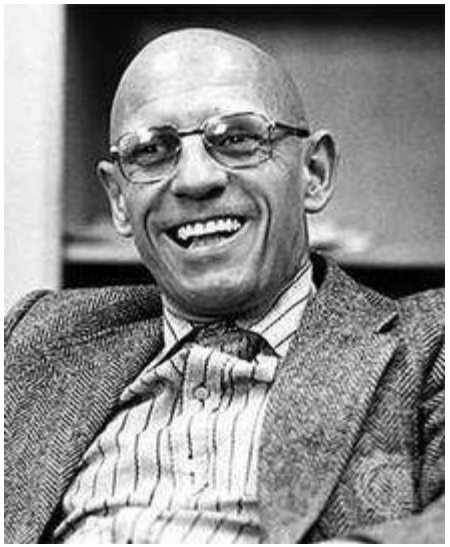
- Founders:
- Van Rensselaer Potter (University of Wisconsin) 1970: maintaining the planet's ecological balance.
- André Hellegers (University of Georgetown): future implications of progress in life sciences (malleable man).
- Biomedical ethics and ethics in life sciences.

Van Rensselaer Potter (1911-2001)

André Hellegers (1926-1979)

- Publicly exposing the abuse of medicine on bodies.
- Questioning the hegemony of the Catholic Church.
- The struggle for empowerment: women, sexuality, the mentally ill.
- Patients' rights.
- The crisis of medical humanism (appeal to universal moral principles, in which the doctor is not an expert *per se*).

- The panorama is confusing: the conventional certainties about human life and the biological frontiers have been broken, as has moral authority.
- Science, technology and the health industry need regulating: vulnerability.
- Global problems exist, such as organ trafficking, health tourism, bioterrorism, etc.
- The main problems are solved with interdisciplinarity.



Michel Foucault (1926-1984)

- Pragmatism and decision-making in relation to important problems: the end of life, genetics, global health, cloning and stem cells, public health, disability.

- Technology as applied to the body:

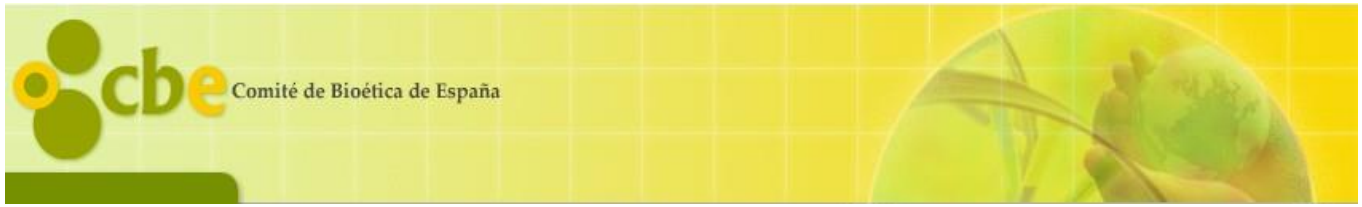
  - The body as a primary space inscribed by power (Foucault).

  - Post-humanism: biology is not an end; we can go beyond it.

Neil Harbisson is the first human officially considered a cyborg.

- Need for global bioethics (Potter, 1988).
- WHO and UNESCO (International Bioethics Committee – Universal Declaration on Bioethics).
- Necessary dialogue, without dismissive insults: respect, tolerance, civility and a rapprochement between the secular and the religious.

The Spanish Bioethics Committee was created by Law 14/2007, of 3rd July, of Biomedical Research (BOE, 4 July) as a "collegiate, independent and consultative body that will carry out its functions, completely transparently, on matters related to the ethical and social implications of Biomedicine and Life Sciences". The Committee was established on 22 October 2008 and reports to the Ministry of Health, Social Services and Equality.



2. Theoretical approaches

- Bioethics is not limited to using theoretical ethics to solve a problem; there are no formulas.
- Consensus in the results but not in the reasons.
- Moral relativism and the need for universal moral laws.

a. Professional ethics

- Strict moral rules that are abstract and difficult to apply (Catholic Church opposition to abortion and euthanasia).
- Kant and moral autonomy.
- Are human beings special in creation?
- God as the source of morality and the sacredness of life.

Immanuel Kant (1724-1804)

b. Utilitarianism

- Actions are good if they offer the maximum usefulness.
- Replacing the religious view.
- The importance of sentient animals.
- Maximizing the patient's wellbeing.

C. Principlism

- The most widespread option in biomedicine (created by Beauchamp and Childress, 1978, based on the Belmont Report).
- **Beneficence**: seeking the greater good, without paternalism (informed consent).
- **Non-maleficence**
- **Autonomy** or respect for people.
- **Justice**: equal treatment for all.

d. Virtue ethics

- Means acting in accordance with a chosen virtue.
- Good deeds and good reasons must go hand in hand with virtue.

e. Feminist ethics

- Means considering equality between men and women.
- Is interested in abortion, reproductive medicine, exploitation and abuse, contraception, HIV-Aids, resources, etc.

d. Casuistry and deliberation

- Case-based method, guided by paradigms (solid philosophical principles).
- Rules are not universal but advisable in each case.
- Inductive reasoning.

e. Healing ethics

- Priority given to healing people.
- Not only healing but also caring and alleviating suffering.
- Compassion, affection and a commitment to the patient.

3. Example: human embryos and genetic manipulation

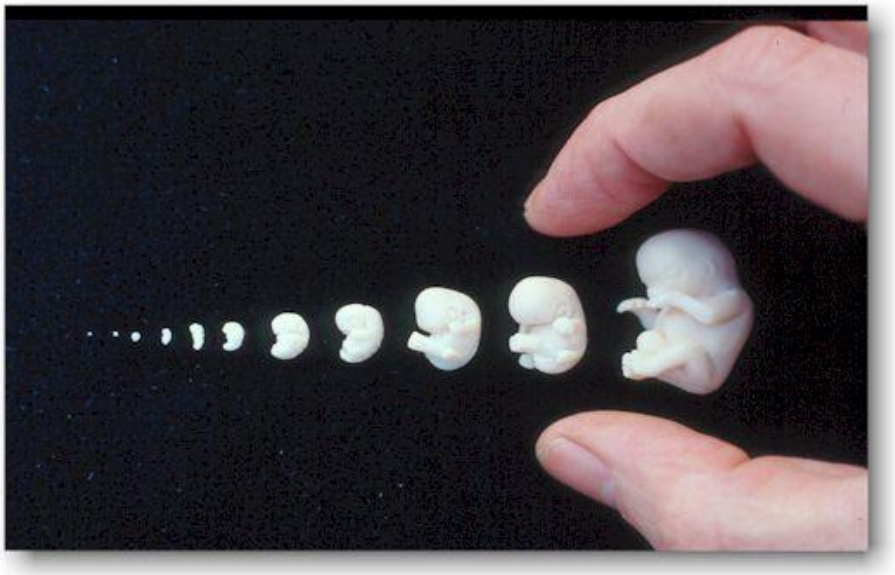
"No biological discovery has perhaps generated more attention and controversy than the isolation of embryonic germ cells."

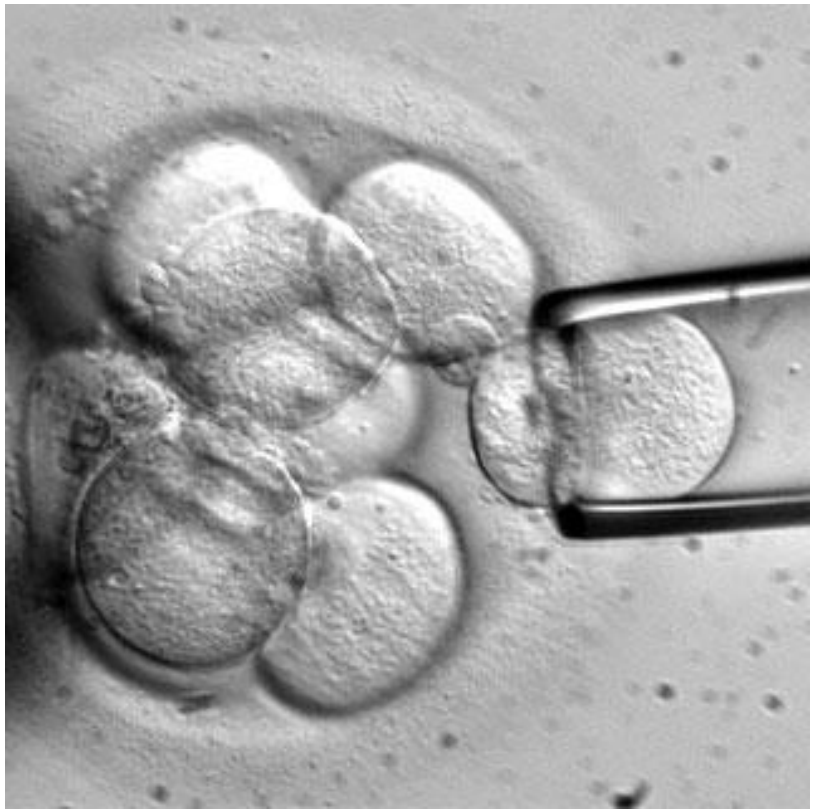
The importance of experimenting with embryos lies in finding an answer and solution to aspects of inheritance, cell biology, autoimmune diseases, developmental disorders, cancer, etc.

These issues and techniques operate at the limits of what is ethical.

Is there any alternative to experimentation/ clinical trials with humans in relation to research in new drugs or genetic diseases?

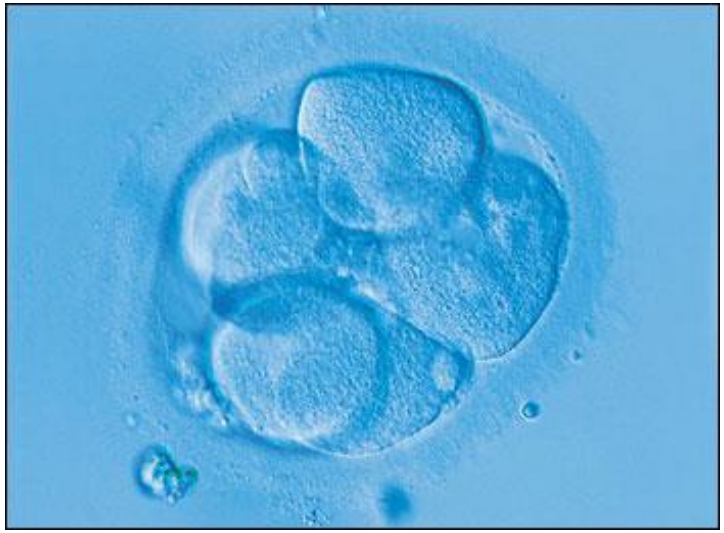
Experimentation with embryos and stem cells

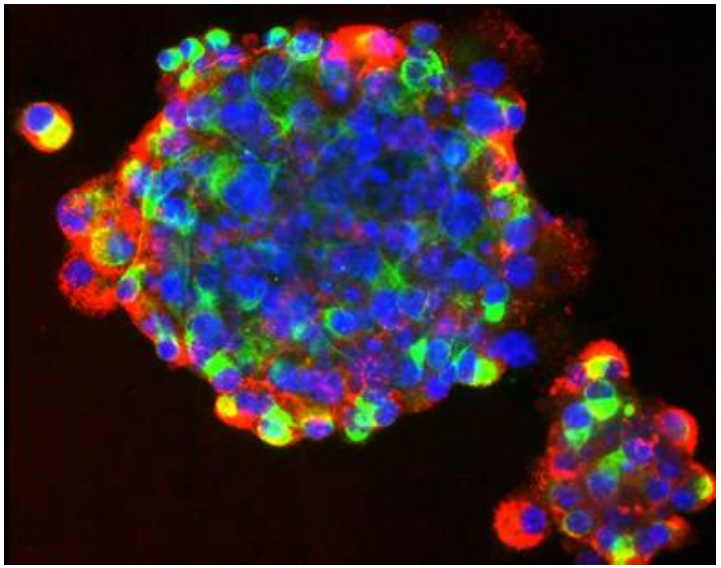




Embryonic or adult stem cells

- **Embryonic:** pluripotent, capable of indefinite reproduction.
- **Adult:** multipotent, from an already formed individual.



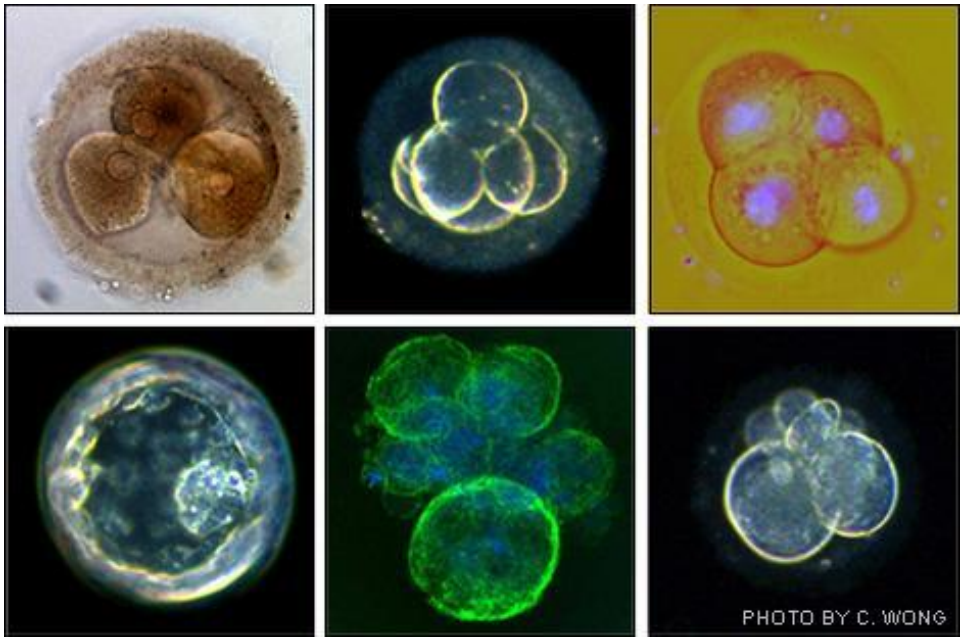


The manipulation of embryos

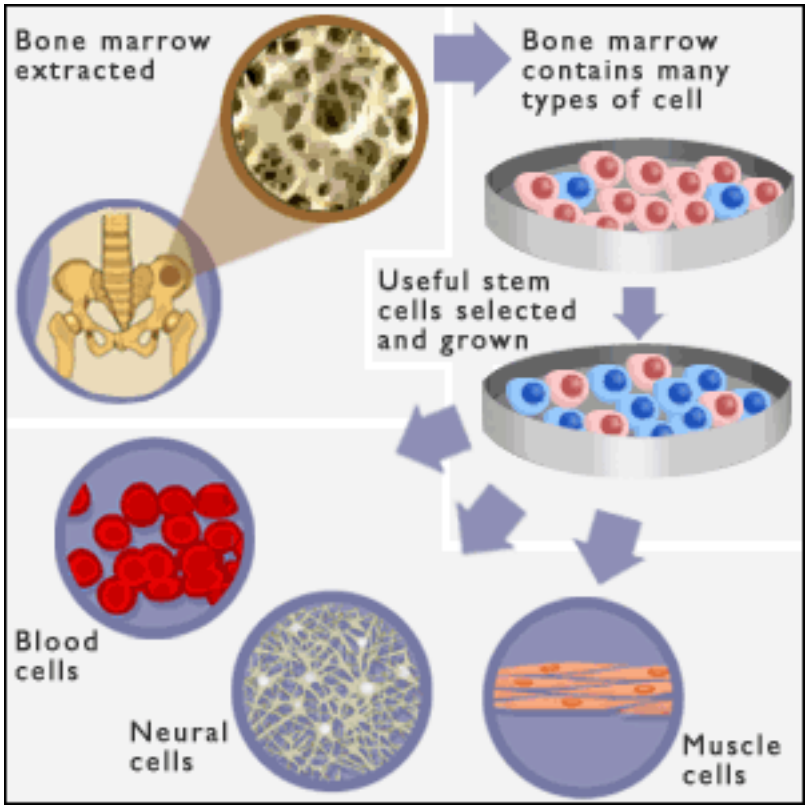
Selection and elimination

Donation for research

Conservation at low temperatures



Use of adult stem cells



Leukaemia

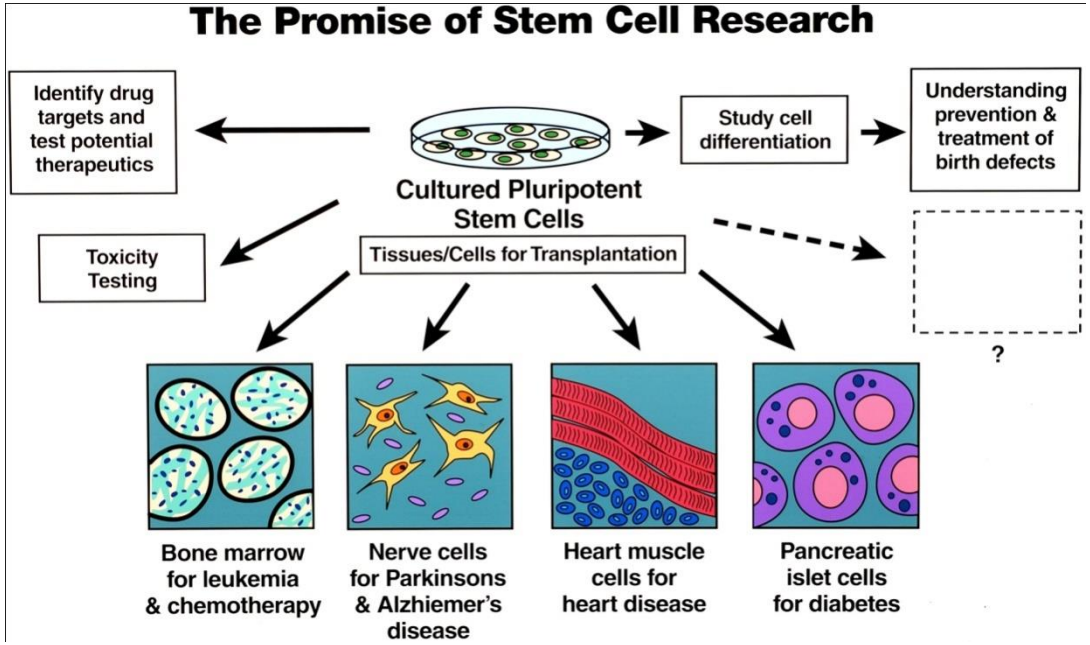
Tissue regeneration: heart, brain, blood vessels, etc.

Cancer

Bone marrow

NO CONTROVERSY

Use of embryonic cells



Cloning
Transplantation
Genetic diseases

CONTROVERSY

Theme 11. A Necessary Evil: Animal Experimentation

Introduction

Animals have been used since Antiquity as 'tools' from which to obtain information about bodies and how they work. Over history these uses have increased and diversified, enabling analogies to be generated that help us to explain human physiology and anatomy, conduct research into poisons, and study processes such as the chemistry of gases, etc. While sensitivity to pain and suffering has been evident since the earliest times, it was not until the late 19th and early 20th centuries that our view of animals based on philosophical and ethical considerations forced us to reflect on basic parameters that guide animal use in scientific investigation with clear references and legislative frameworks for governing such interventions. We should also bear in mind that using animals for research purposes is currently unavoidable if we wish to continue pushing forward the boundaries of knowledge – especially in biomedicine and medicine production.

Contents

1. The history of animal experimentation
    - Antiquity
    - The Middle Ages and the Renaissance
    - The scientific revolution
    - Experimental physiology in the 19th century
2. Laboratory animals
    - Definition
    - Types
3. Significance and uses
    - Experimental models
    - Uses
4. Ethical and legal aspects
    - Movements opposed to animal experimentation
    - Limiting pain and the number of animals killed
    - The legislation and ethics of animal experimentation

Objectives

- To understand animal experimentation as a feature of science from the beginning.
- To define what a laboratory animal is, learn which animals are most often used, and study how these have changed over time.
- To understand the importance of laboratory animals for science, especially in biomedical research.
- To understand the challenges involved in applying, in humans, the information obtained from animals via experimental models.
- To understand and reflect upon the ethical and legal aspects of animal experimentation.
- To analyse statistical data by working together in a group and present opinions in a reasoned manner in public.

- To analyse the use of laboratory animals as one of many scientific controversies and debates in the public sphere.
- To study legislation and the regulation of trials currently in force in Europe and Spain.
- To assess the evaluation stage of clinical trials as a guarantee of patients' rights and good practices in matters of healthcare.
- To examine the development of clinical trials in different parts of the world and analyse current trends.
- To study cases where clinical trial protocols were not considered when research was conducted on humans (this objective is linked to seminar 4).
- To work as a group to solve a problem arising in class.

Preliminary activity
Observe the images below and reflect upon them.

EXPERIMENTACIÓN CON ANIMALES ›

Los laboratorios que experimentan con animales comienzan a abrir sus puertas

Dos años después de la firma de un acuerdo de transparencia, el 20% de las instituciones reconoce que ni siquiera ha ofrecido la posibilidad de visitar sus animalarios

MANUEL ANSEDE
11 SEP 2018 - 16:57 CEST

MALTRATO ANIMAL ›

Monos obligados a girar, gatos con 13 extracciones al día

Destapado en Alemania un gran caso de maltrato animal en el laboratorio LPT, que realiza pruebas para la industria química y farmacéutica

Points to consider

- What do the above images suggest to you? Do you feel the same way about each image?
- What is your view of this issue? Are these experiments necessary? Should they be prevented?
- What steps should be taken to avoid abuses?

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11. A necessary evil: animal experimentation

VNIVERSITAT DE VALÈNCIA

Carmel Ferragud, Rafaela Domínguez, Mar Cuenca
History of Science

Documentation and Scientific Methodology
Degree in Pharmacy

1. The history of animal experimentation
2. Laboratory animals
3. Significance and uses
4. Ethical and legal aspects

1. History of animal experimentation

- Precedents in classical antiquity:
  - There was a predominance of observation in the *Corpus Hippocraticum* and Aristotle.
  - The School of Alexandria (Herophilus and Erasistratus) justified and practised vivisection.
  - Mithridates VI (132-63 BC) conducted animal tests to observe the toxic action of poisons and their antidotes.
  - Galen (130-210 AD) and the dissection of animals: techniques improved and dissections increased in diverse species (descriptions of nerves and interpretations of organ functions).

Renaissance and scientific revolution

- Dissection of living animals in anatomical theatres.
  - Blood and lymphatic circulation.
- 'Infusion surgery' (c.1665).
  - Between animals (dogs, sheep).
  - Between animals and humans.
- Experiments on the role of air in respiration.
  - Correspondence between respiration and combustion.
  - The 'air pump'.
- Mechanistic conception of animate beings.
  - *Traité de l'homme,* Descartes.
  - The soul of animals (brutes).
  - The inability of animals to suffer pain.

- Richard Lower (1631-1691): First dog-dog and dog/sheep-human blood transfusions.
- Intravenous administration of drugs (bevelled pen and bladder).

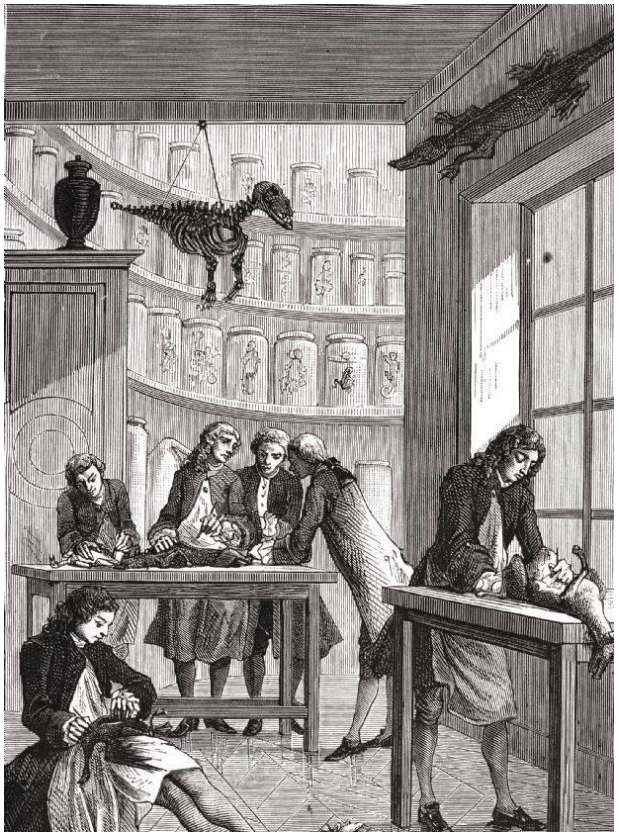
Enlightenment

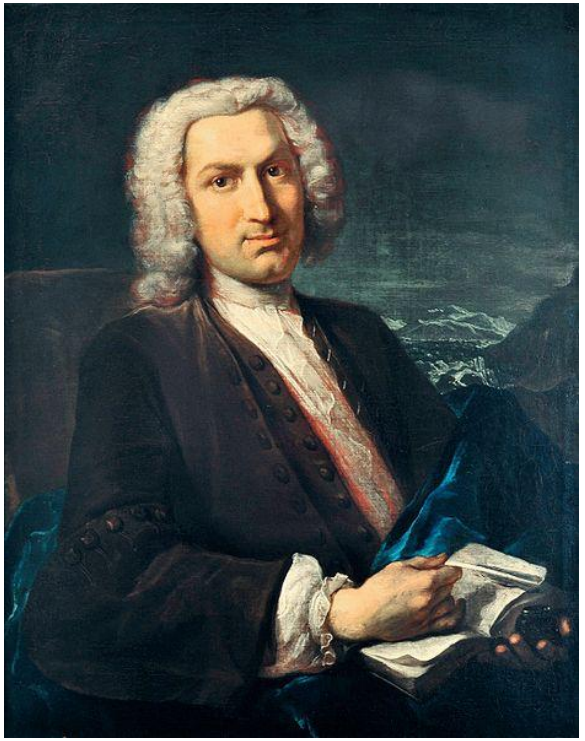
- The number of experiments increased: 'experimental results are of greater certainty than the dark and contradictory statements of classical authorities' (Johan Jakob Harder (1656-1711)).

- Experiments with electricity: Alessandro Volta and Luigi Galvani.

- Experiments on respiration: Antoine Lavoisier (1743-1794).

- Experiments on the action of drugs and poisons.





- Henri Duhamel Dumenceau (1700-1782): utility justifies sacrifice.
- Albrecht von Haller (1708-1777) raised doubts about the morality of experimenting with animals.

Experimental physiology (19th century)

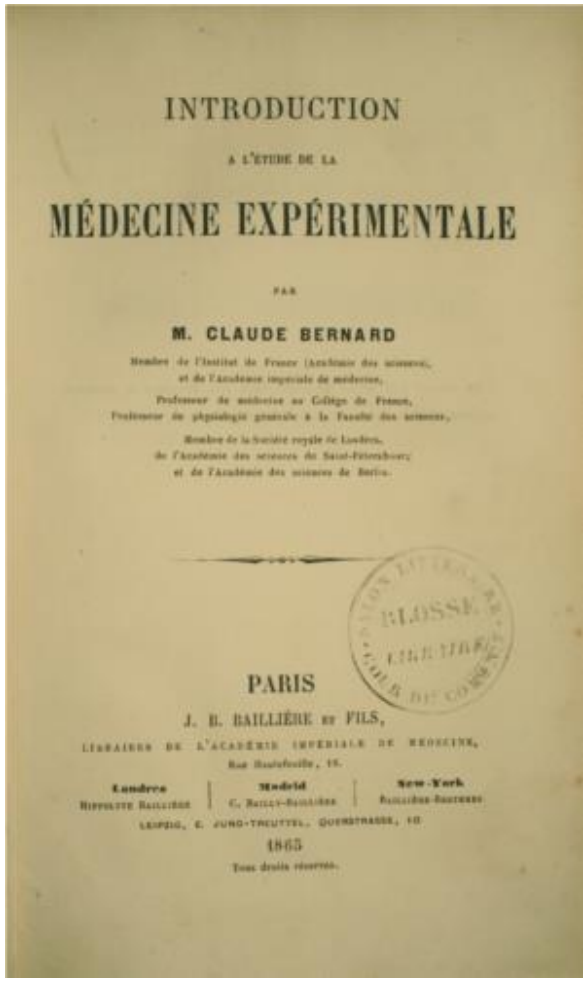
- François Magendie (1783-1885): "the functions of the organs can only be studied with experiments" (experimental physiology and pharmacology).
- Doubts about the possibility of transferring results to humans.
- Controversies over his public experiments with animals.

Introduction à l'étude de la médecine experimentale (1865)

- Was the most important work of Claude Bernard (1813-1878), a disciple of François Magendie and a professor of the *Collège de France*.

- Consecrated laboratory and animal experimentation as the fundamental method of physiology and medicine.

- The 1867 separation between Claude Bernard and his wife, Françoise Martin, founder of the *Société Protectrice des Animaux,* was significant.


INTRODUCTION

A L'ÉTUDE DE LA

MÉDECINE EXPÉRIMENTALE

PAR

M. CLAUDE BERNARD

PARIS

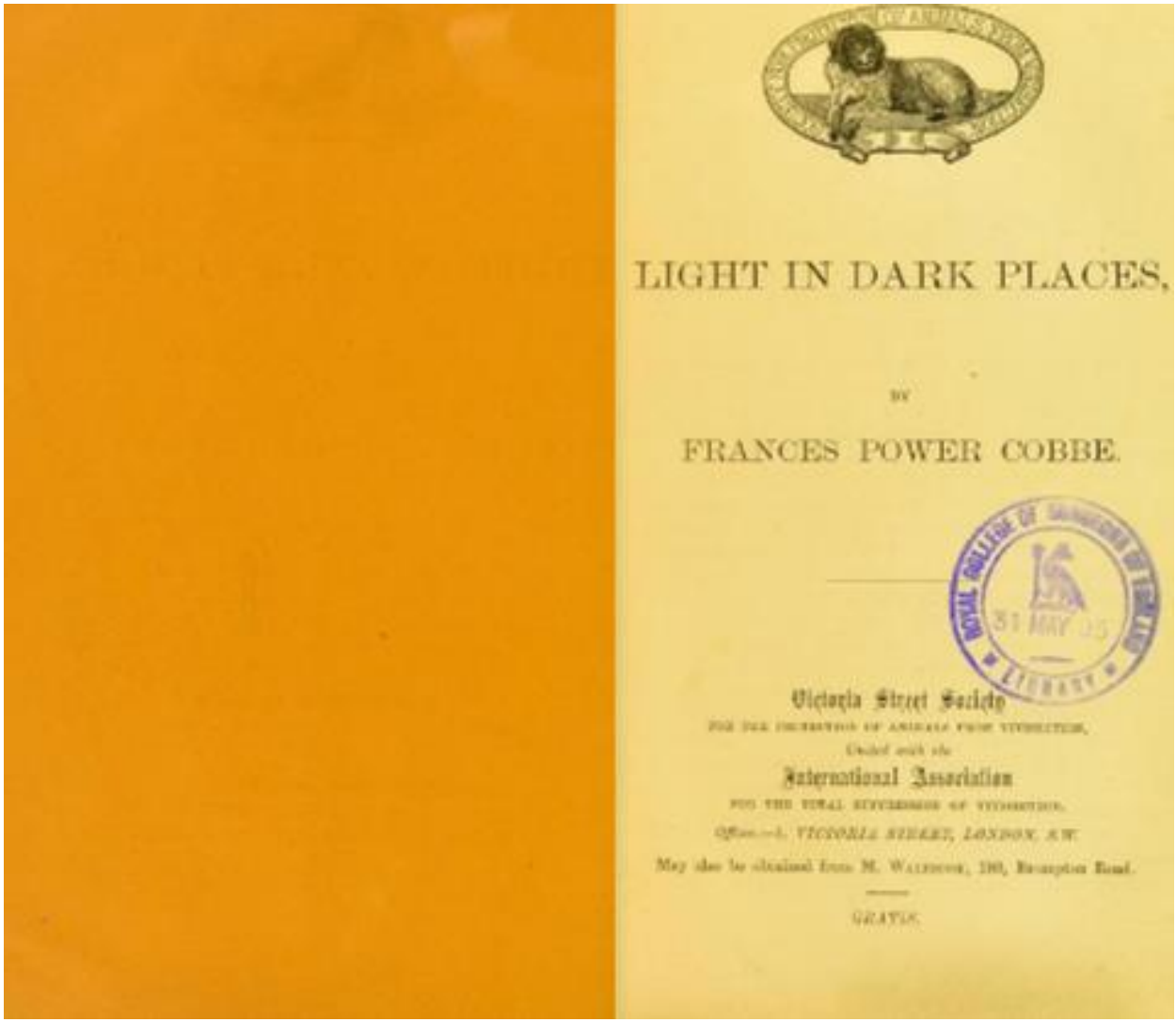
J. B. BAILLIÈRE ET FILS,

1865

Léon Lhermitte, *Claude Bernard* (1889)

- In the second half of the 19th century, the experimental method was consolidated in physiology, pharmacology, microbiology, clinical medicine, surgery, toxicology, food production, and cosmetics, etc.
- At the same time, vivisection and cruelty to animals became matters of public debate:
  - The start of the protectionist movement (protective societies) and the emergence of the first societies against vivisection (1875).
  - First protectionist legislation: *Cruelty to Animals Act* (UK, 1876).
- In the first half of the 20th century, the use of animals in laboratories increased substantially.
- Conditions improved (anaesthesia) and techniques were refined.
- New regulations have recently led to a relative decrease in AE.

https://archive.org/details/b22396421/page/16



LIGHT IN DARK PLACES.

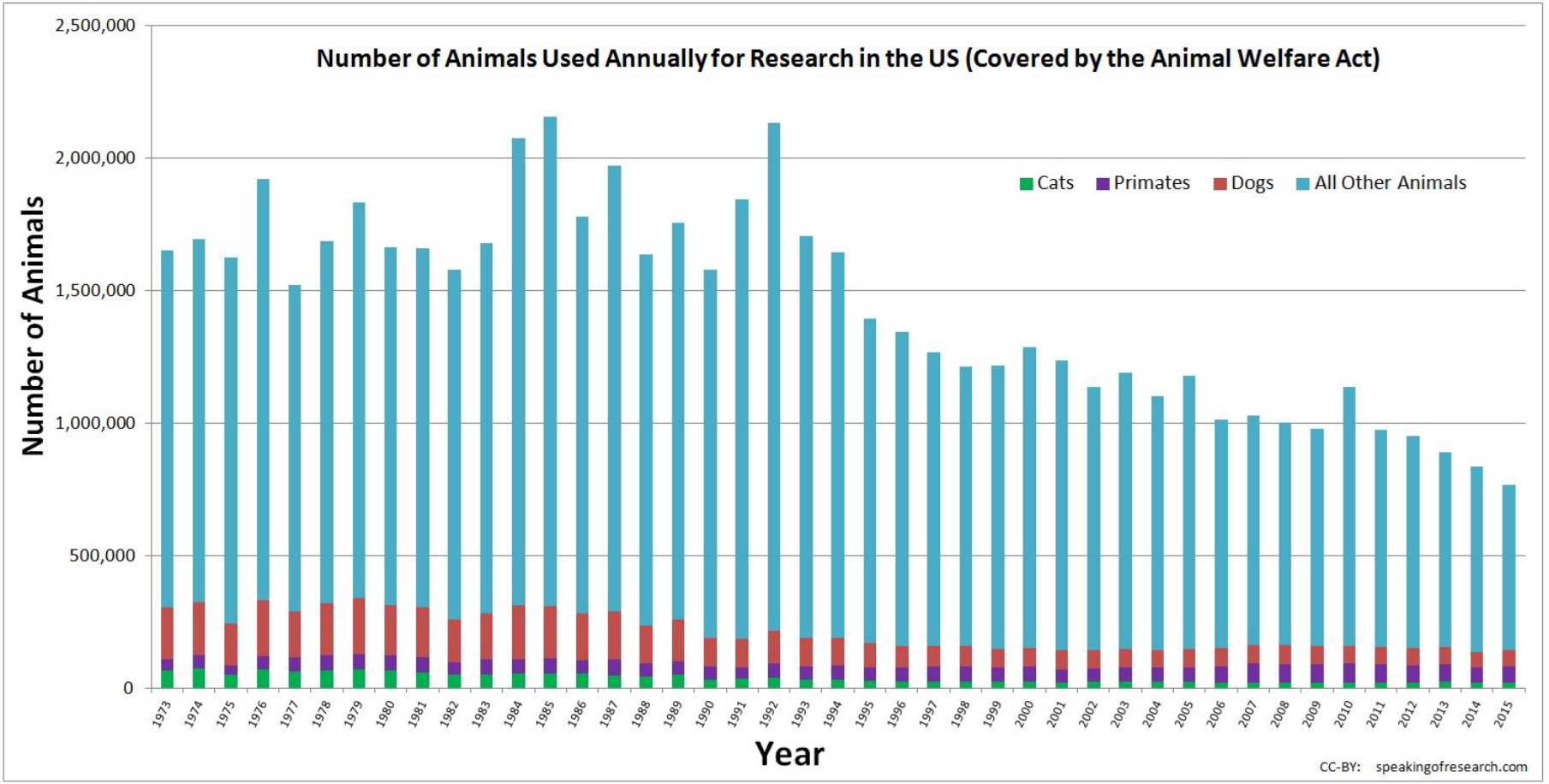
BY

FRANCES POWER COBBE.

Victoria Street Society

International Association

- **Polio**. It is estimated that in the first four decades of the 20th century over one million primates were killed in experiments to obtain the vaccine.
- The United States had to maintain commercial relations with several countries to buy animals (at exorbitant prices).


Number of Animals Used Annually for Research in the US (Covered by the Animal Welfare Act)
Number of Animals
2,500,000
2,000,000
1,500,000
1,000,000
500,000
0
Cats
Primates
Dogs
All Other Animals
1973 1974 1975 1976 1977 1978 1979 1980 1981 1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015
Year
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2. Laboratory animals

- Biomedicine, veterinary science, agriculture, etc.
- The concept of biological reagent: depending on the object of study, animals can provide a reliable and reproducible answer. Monitoring purity: somatic, genetic, and sanitary homogeneity.
- Biologically standardised and genetically uniform through collective selection according to certain criteria.
- Centres dedicated to obtaining animals: companies, technical services, etc.

- Rodents: the development of laboratory rats (albino rats). These animals have been bred since the last third of the 19th century.
- Guinea pigs and rabbits; pigs and monkeys (retreat).
- Progressive incorporation of other animals: invertebrates, coelenterates, worms, crustaceans, insects, fish, amphibians, reptiles, and birds.
- There are several thousands of typical laboratory animals.

Drosophila melanogaster

- In the second half of the 20th century, drosophilae were used to investigate diverse issues such as mutations produced by radiation, embryonic development of the nervous system and biological rhythms.

- In the early 21st century, research with this fly also includes study of neurodegenerative diseases such as Huntington's disease and Alzheimer's.

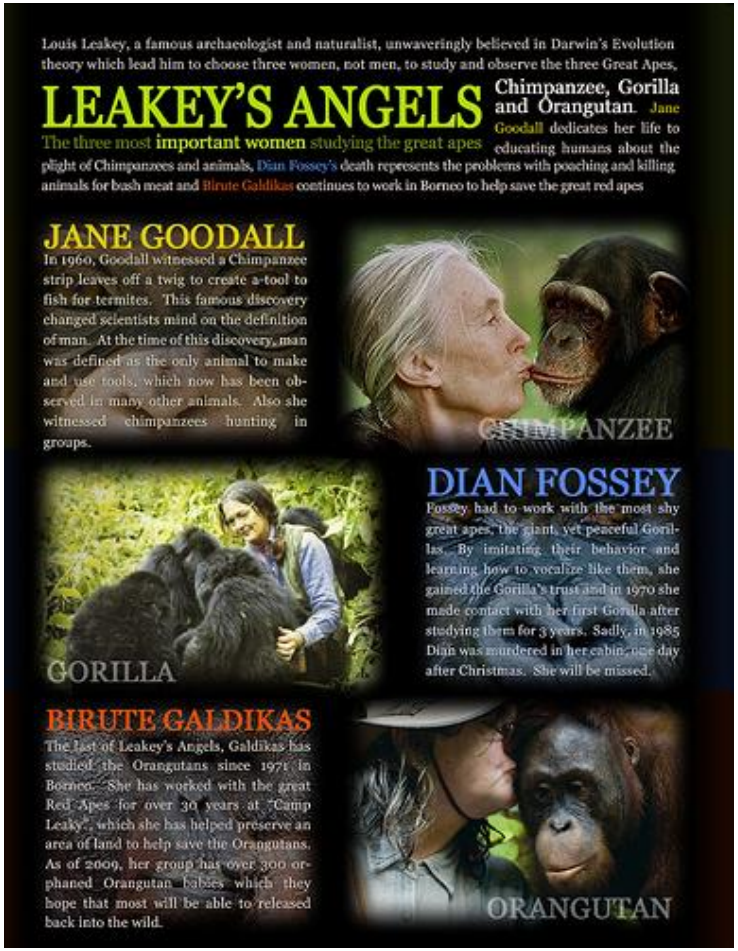
3. Significance and uses

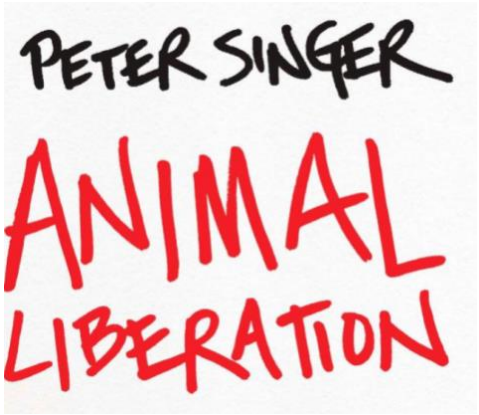
- Definition: utilitarian (to discover/clarify phenomena).
- Based on:
  a) Transferring the results of experiments from one species to another.
  b) Infinite experimental animal models of metabolic and physiological systems, pathological processes, etc. that can be applied to humans (and other animals).
  c) The lack of a perfect animal experimentation model applicable to humans.

- Pathology: study of diseases (AIDS, cancer, infectious diseases, cardiovascular diseases, etc.).
- Clinical diagnosis: non-invasive techniques (ecography, PET, CT).
- Pharmacology: mechanism of action of drugs, toxicology, etc.
- Surgery: open-heart surgery, transplants, pacemaker implants, etc.
- Physiology: nervous, cardiovascular, locomotor systems, etc.
- Agro-food: transgenic plants.
- Environment: pollutants.
- Genomic research: physical and genetic mapping, identifying disease-causing genes.

4. Ethical and legal aspects

- Progress in ethology: pain, stress, depression, anxiety, fear, etc.
- Reconsideration of the problem: the potential of animals to experience suffering is greater than once thought.





- **Animal suffering:** opposition to discrimination (speciecists = racists) of a living being according to the species to which it belongs. Equal consideration should be given to all beings capable of suffering. To give less importance to living beings because they have wings or fur is like discriminating against a person because of the colour of their skin.

- **Vegetarianism** does not condemn the use of animals for human use provided the methods used to kill them do not cause suffering. However, to avoid controversy, the most practical solution is to adopt a vegetarian diet.
- **Vivisection** is condemned but some experiments with animals may be acceptable if the benefits (improved medical treatment, etc.) outweigh the damage caused. There are many difficulties, however, in defining benefits.

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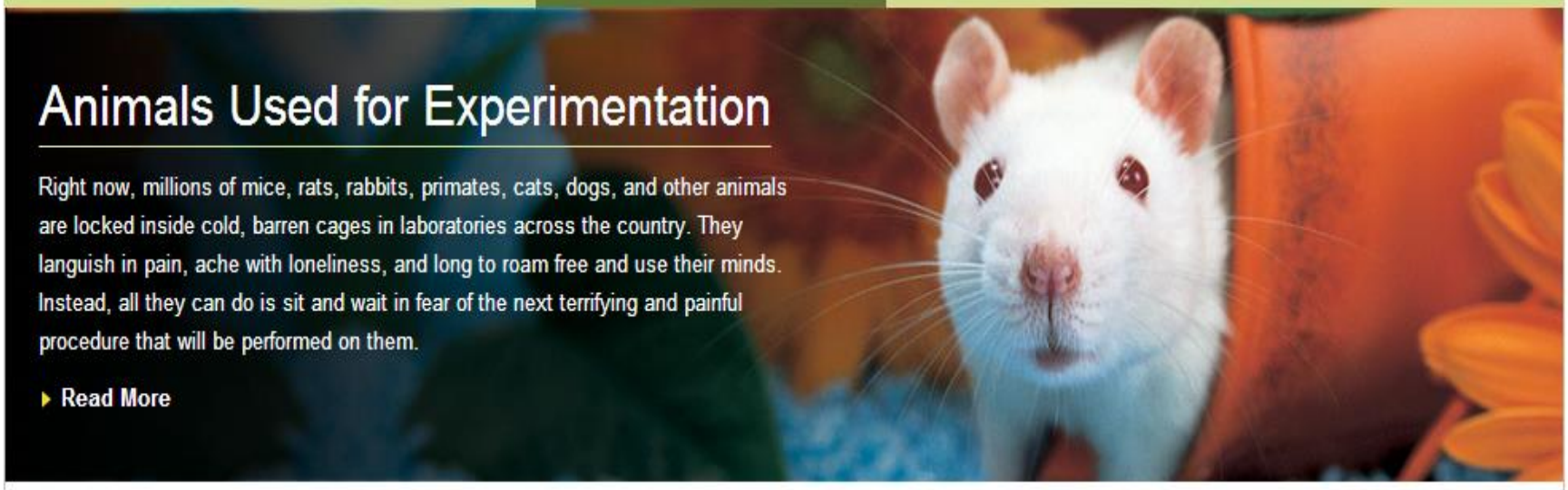

Animals Used for Experimentation

Right now, millions of mice, rats, rabbits, primates, cats, dogs, and other animals are locked inside cold, barren cages in laboratories across the country. They languish in pain, ache with loneliness, and long to roam free and use their minds. Instead, all they can do is sit and wait in fear of the next terrifying and painful procedure that will be performed on them.

▸ **Read More**

POPULAR RESOURCES

- Most current regulations are inspired by the three Rs: reduce, refine and replace (William Russell & Lex Burch, *The Principles of Humane Experimental Technique*, 1959).

- Directive 2010/63 of the European Union:
  - Minimise the number of animals used.
  - Improve and refine breeding, housing and care, and eliminate or minimise the pain, suffering and distress of laboratory animals.
  - As far as possible, apply procedures that do not involve the use of living animals.

DIRECTIVAS

DIRECTIVA 2010/63/UE DEL PARLAMENTO EUROPEO Y DEL CONSEJO

de 22 de septiembre de 2010

relativa a la protección de los animales utilizados para fines científicos

(Texto pertinente a efectos del EEE)

BOLETÍN OFICIAL DEL ESTADO

Núm. 34 Viernes 8 de febrero de 2013 Sec. I. Pág. 11370

I. DISPOSICIONES GENERALES

MINISTERIO DE LA PRESIDENCIA

1337 *Real Decreto 53/2013, de 1 de febrero, por el que se establecen las normas básicas aplicables para la protección de los animales utilizados en experimentación y otros fines científicos, incluyendo la docencia.*

"The most important issues in debate about animal experimentation are the assessment of the **scientific value** of an experiment, of the **knowledge or benefit to be gained**, and of the **suffering** (if any) involved, and the question of **how to balance** these. It is ultimately a **moral** problem, and a question of responsibility borne both by the **scientist and by the rest of society** in the characteristically human task of removing ignorance and minimising suffering".

William Paton
Vivisection, morals, medicine: commentary from a vivisecting professor of pharmacology
Journal of Medical Ethics 1983; 9: 102–4.

Theme 12. Testing therapies: clinical trials

Introduction

A clinical trial may be defined as the method used to test the effectiveness and safety of therapeutic procedures against any type of illness or health problem (both human and animal). Basically, these procedures are drugs (though they may also be surgical procedures, devices, preventive methods or healthcare strategies) that are compared with others already available on the market or with placebos. In medicines the aim is mainly to determine their effects (including adverse reactions), which may be pharmacological, pharmacokinetic (processes of absorption, distribution, metabolism and excretion of the medicine) or pharmacodynamic (the noticeable and/or measurable effects produced by a drug in the organisms of humans or animals, and the duration and time course of those effects). The huge development of the pharmaceutical industry has been closely linked to the boom in clinical trials. The ten most important drug companies currently claim to invest 40% of their R+D outlay in clinical trials. These data show the huge importance of this instrument of research in health care. The heavy demands placed on the commercialisation of a drug by control agencies and the already consolidated history of assessment of these therapies have also significantly influenced their development. In fact, the number of clinical trials has doubled in the last ten years. However, there is much controversy over several aspects associated with clinical trials, including whether they are needed, the non-publication of adverse results, whether bringing out new medicines and their patents is justified if they produce no substantial improvement on existing medicines, relocation to developing countries, etc. All in all, this field requires a thorough reflection.

Contents

1. Introduction
2. Methodology
3. Sample size
4. Randomisation
5. Masking
6. Types of clinical trials
7. Phases and evaluation
8. Ethical problems
9. Current legislation

Objectives

- To explain which elements are methodologically necessary when setting up a clinical trial.
- To analyse the various types of clinical trial.
- To critically assess the importance of trials in the production of medicines, particularly through the ethical challenges they present.
- To distinguish between clinical trials and other ways to obtain clinical information.
- To know the role played by the Spanish Agency of Medicines and Medical Devices in drugs management.

- To examine the legislation and regulation of trials currently in force in Europe and Spain.
- To assess the evaluation stage of clinical trials as a guarantee of patients' rights and good practices in healthcare matters.
- To see how clinical trials are evolving around the world and observe current trends.
- To study cases where clinical trial protocols have not been observed when research has been conducted in humans (this objective is linked up with seminar 4).
- To work as a group to solve a problem raised in class.

Preliminary activity

A continuación tienes los elementos que configuran los tres ensayos clínicos (pruebas en humanos) del siguiente medicamento.

Fase I

Título. Farmacocinética y farmacodinamia de dosis crecientes de propionato de fluticasona, usando diferentes fuerzas de propelente hidrofluoroalcanos (HFA) y la comparación con el producto comercializado con el propulsor de clorofluorocarbonos (CFC).

Justificación. El propionato de fluticasona (FP) es un glucocorticoide utilizado para tratar el asma, y los inhaladores de dosis medida presurizados (IDM) se utilizan en el tratamiento de la enfermedad respiratoria. Los clorofluorocarbonos (CFC) se utilizan ampliamente como propelentes de aerosoles medicinales en los IDM pero la amenaza medioambiental que suponen para la atmósfera resultan bien conocidos. Los propelentes alternativos deben introducir de forma eficiente y segura el medicamento a los pulmones. Los hidrofluoroalcanos, compuestos no clorurados (HFA), concretamente el GR106642X (HFA-134a) utilizado en este estudio, se aclara principalmente por la exhalación (en promedio, <10% permanece después de 5 minutos de una inhalación), y es un compuesto

esencialmente no tóxico. La relación entre la exposición sistémica y el aumento de las dosis administradas por diferentes fuerzas y el efecto de propelente fueron examinados en este estudio.

Población de estudio - Tamaño de la muestra. 24 adultos voluntarios sanos, con edades comprendidas entre 18 y 50 años. Las mujeres elegidas debían asegurarse de no estar embarazadas o estar usando anticonceptivos. Todos debían ser no fumadores y abstenerse de cafeína. También fueron excluidos individuos con historia de infecciones respiratorias y alergias a fluticasona o lactosa.

Periodo de duración. 8 de enero de 2001 a 13 de febrero de 2001

Tratamiento. Cada uno de los sujetos fueron aleatorizados y recibieron cada uno de los siguientes tratamientos con una simple dosis, separada por un periodo de 5 a 7 días de lavado entre las secuencias del tratamiento:

- 352mcg (8 x 44mcg) FP a través de un inhalador HFA
- 880mcg (8 x 110mcg) FP a través de un inhalador HFA
- 1760mcg (8 x 220mcg) FP a través de un inhalador HFA
- 1760mcg (8 x 220mcg) FP a través de un inhalador de CFC
- HFA-que contiene un inhalador placebo (PBO)

Cada periodo de estudio duró aproximadamente 36 horas.

Diseño del estudio: sobre abierto con nombres de los participantes, aleatorizado, estudio híbrido (5 alternativas; ver tratamiento)

Centros: Un solo centro en Reino Unido

Los resultados del estudio se publicaron en: Bioavailability of orally administered micronised fluticasone propionate. Falcoz, C., Oliver, R., McDowall, J. E., Ventresca, P., Bye, A., and Daley-Yates, P. T. Clin Pharmacokinet 2000; 39 Suppl 1(9-15)

Fase II

Título: Un estudio doble ciego, aleatorizado, controlado con placebo, de tres vías de cruce en pacientes asmáticos leves para evaluar el efecto de la condición de fumar en la atenuación de los corticosteroides inhalados de la respuesta asmática inducida por alérgenos.

Periodo de estudio: 20 de julio de 2011 a 12 de diciembre de 2012

Diseño del estudio: aleatorizado, doble ciego, con grupo controlado con placebo, de tres alternativas y dos centros de estudio. El estudio consistía en escanear tres periodos de tratamiento (cada periodo consistía en 7 días, con un periodo de lavado entre cada tratamiento), seguido por un periodo individual de seguimiento.

Centros: una sede en el Reino Unido y una sede en Bélgica

Justificación objetivos. Investigar el efecto de la condición de fumar en la atenuación de la respuesta asmática inducida por alérgenos, a través de dos dosis de corticosteroides inhalados en comparación con el placebo.

Número de pacientes. 38

Resultado. Se observó una supresión de la respuesta asmática tardía inducida por alérgenos tanto en fumadores y no fumadores asmáticos tratados con 100 mcg y 500mcg BID de propionato de fluticasona no fumadores. Los sujetos asmáticos que recibieron placebo y que fumaban cigarrillos demostraron una respuesta asmática general atenuada tardía tras la exposición al alérgeno en comparación con los sujetos que tomaron placebo y que no eran fumadores.

Tratamiento. Cada sujeto recibirá el siguiente tratamiento (uno por periodo de tratamiento):

100 mcg propionato de fluticasona BID durante 6 días consecutivos, con una simple dosis el día 7

500 mcg propionato de fluticasona BID durante 6 días consecutivos, con una simple dosis el día 7

Placebo BID durante 6 días consecutivos, con una simple dosis el día 7

Fase III

Título. Un estudio aleatorizado, doble ciego, de grupos paralelos, controlado con placebo, de 12 semanas de prueba de inhalación de propionato de fluticasona 88mcg BID, BID 220mcg, y el BID 440mcg versus placebo, con Propulsor GR106642X, en adolescentes y adultos sujetos asmáticos tratados con corticoides inhalados.

Periodo de estudio. 26 de octubre de 2000 a 31 de julio de 2001

Justificación. El propionato de fluticasona (FP) / GR106642X ha sido desarrollado como un producto de reemplazo del aerosol de inhalación de FP que se formula con el propelente de clorofluorcarbono (CFC) 11/12. Este aerosol de propionato de fluticasona de inhalación ha estado en desarrollo clínico para el tratamiento de mantenimiento del asma en los adolescentes y adultos.

Diseño del estudio. Aleatorizado, doble ciego, diseño paralelo, controlado con placebo y doce semanas de estudio.

Número de pacientes. 414.

Centros. Un total de 123 centros (79 activos) de los EEUU.

Resultados. El primer objetivo de este estudio era asegurar la eficacia y seguridad de FP 88mcg, 220mcg, y 440mcg BID frente al placebo BID en aerosol GR100642X HFA

cuando se administraba vía inhalador (MDI) durante 12 semanas a adolescentes y adultos con asma que previamente habían sido tratados con corticosteroides inhalados (ICS).

Tratamiento:

FP 44mcg/actuation (ex-actuator) en hidrofluoroalcano (HFA) aerosol vía inhalación, 2 inhalaciones al día [BID]);

FP 110mcg/actuation (ex-actuator) en HFA aerosol vía inhalación, 2 inhalations BID;

FP 220mcg/actuation (ex-actuator) en HFA aerosol vía inhalación, 2 inhalations BID;

Placebo in HFA aerosol, 2 inhalaciones BID.

Resultado. El propionato de fluticasona con HFA 134-a mejora significativamente el control del asma mediante corticosteroides inhalados en enfermos asmáticos.

Points to consider

- Analyse the differences between these three clinical trials.

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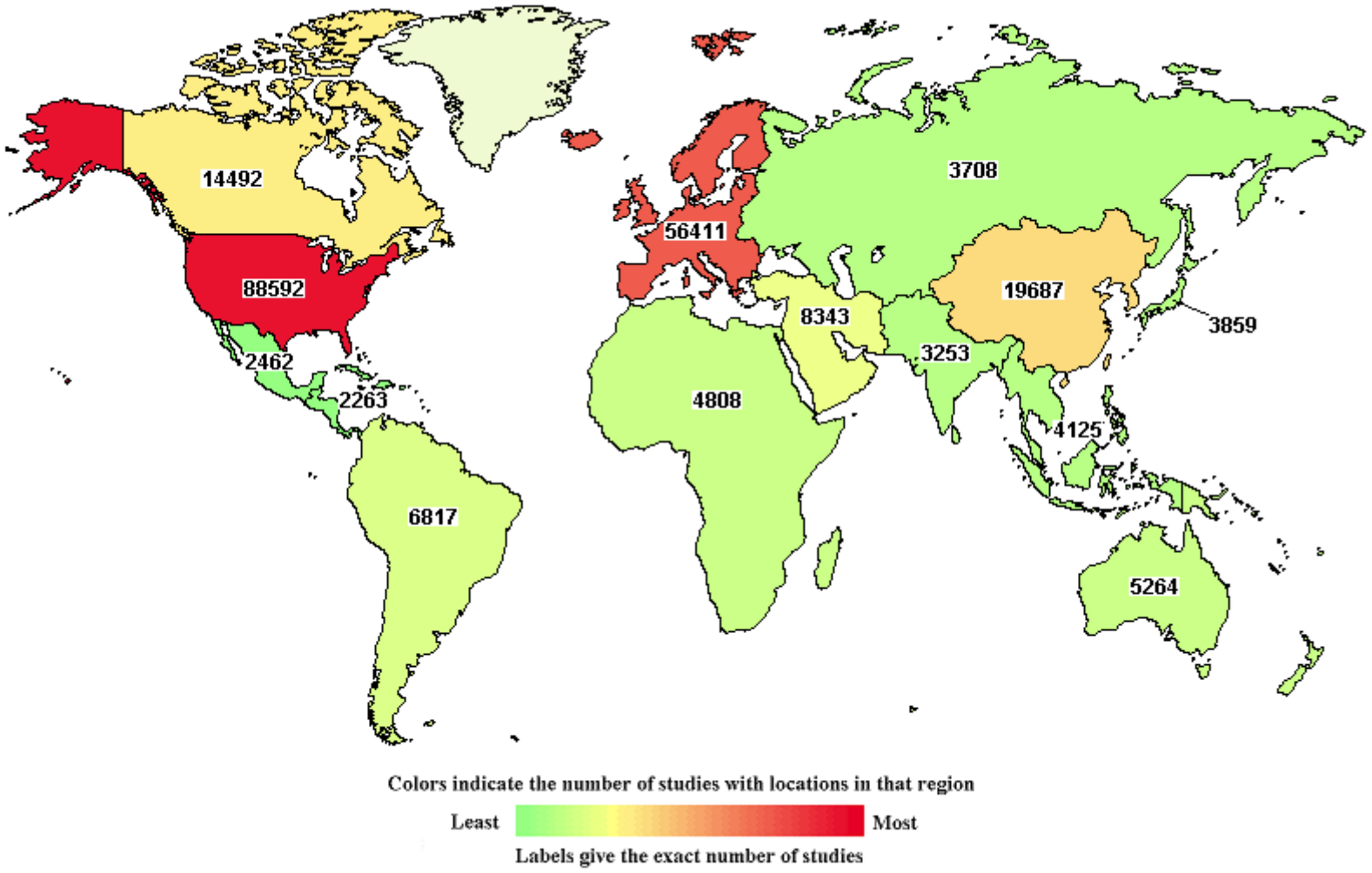
12. Testing therapies in humans: clinical Trials

Carmel Ferragud, Rafaela Domínguez, Mar Cuenca
History of Science

Documentation and Scientific Methodology
Degree in Pharmacy

1. Introduction
2. Methodology
   - Sample size
   - Randomisation
   - Masking
3. Types of clinical trials
4. Phases and evaluation
5. Ethical problems
6. Current legislation



2015: 220,000 clinical trials

- Factors:
- State power.
- Expert knowledge in the bureaucratic system.
- Marketing strategies: purity of method or its principle.

1. Introduction

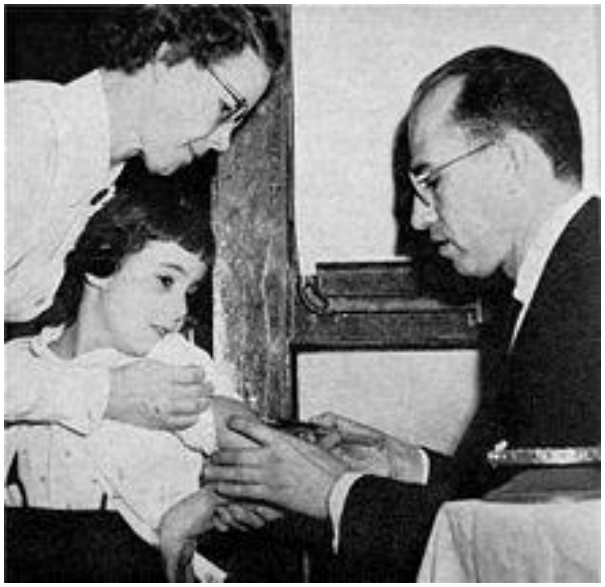
- 1860-1870: Studies on placebos.
- 1920s: Statistics, randomisation.
- 1940s-1950s: Multiple centres.
- 1950-60: Ethical aspects, consent.
- 1964: Helsinki Declaration.
- 1990: International Conference on Harmonisation (ICH) - 2000 CTD.

Legacy: between therapeutical proof and medical truth

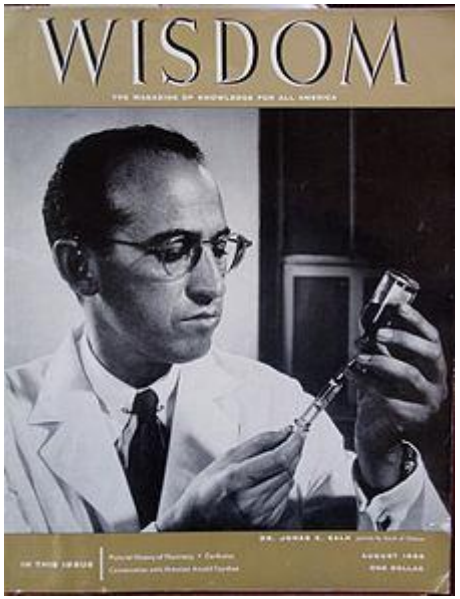
Studies involving drugs have been performed for centuries. They are not a novelty of industry and the laboratories.
A common problem is the tension between therapeutic experiment and clinical experience (generalisation, bioequivalence, biosimilarity, chemical composition, etc.).

Examples:
- Montpellier University (14th Century): search for knowledge about the medicines used in Galenism.
- Assays to find antidotes to poisons (16th century). Can the antidotes be applied to everybody?
- Thermal water properties (18th century) and chemistry. Concentration?
- Claude Bernard, animal vivisection and the difficulties involved in standardising the human body in experiments.

Dr. Jonas Salk [...], along with his wife and children, allowed themselves to be used as 'human guinea pigs'. In November 1953, at a conference in New York's Waldorf-Astoria Hotel, Salk said, "I will be personally responsible for the vaccine". He announced that his wife and three sons had been among the first volunteers to be inoculated with his vaccine.



The field trial to test the vaccine developed by Salk and his research team was, according to O'Neill, "the most elaborate program of its kind in history, involving **20,000 physicians** and public health officers, 64,000 school personnel, **and 220,000 volunteers**". Over **1,800,000** school children participated in the trial.



Definitions

- **General definition:** A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

1. Interventions include but are not restricted to drugs,
2. cells and other biological products
3. surgical procedures
4. radiological procedures, devices
5. behavioral treatments
6. process-of-care changes
7. preventive care

(WHO)

- **Clinical trial of drugs:** a systematic study of pharmaceutical products on human subjects in order to determine or verify the clinical, pharmacological and adverse effects with the objective of determining their safety and efficacy.

Cohort studies

- These are **observational studies** that compare the frequency of a disease (or specific outcome) between two populations, one of which is exposed to a particular exposure or risk factor to which the other is not.
- They can be used, for example, to study cardiovascular risk factors in smokers and non-smokers.

BRITISH MEDICAL JOURNAL

LONDON SATURDAY SEPTEMBER 30 1950

SMOKING AND CARCINOMA OF THE LUNG

PRELIMINARY REPORT

BY

RICHARD DOLL, M.D., M.R.C.P.

Member of the Statistical Research Unit of the Medical Research Council

AND

A. BRADFORD HILL, Ph.D., D.Sc.

Professor of Medical Statistics, London School of Hygiene and Tropical Medicine; Honorary Director of the Statistical Research Unit of the Medical Research Council

In England and Wales the phenomenal increase in the number of deaths attributed to cancer of the lung provides one of the most striking changes in the pattern of mortality recorded by the Registrar-General. For example, in the quarter of a century between 1922 and 1947 the annual number of deaths recorded increased from 612 to 9,287, or roughly fifteenfold. This remarkable increase is, of course, out of all proportion to the increase of population—both in total and, particularly, in its older age groups. Stocks (1947), using standardized death rates to allow for these population changes, shows the following trend: rate per 100,000 in 1901–20, males 1.1, females 0.7; rate per 100,000 in 1936–9, males 10.6, females 2.5. The rise seems to have been particularly rapid since the end of the first world war; between 1921–30 and 1940–4 the death rate of men at ages 45 and over increased sixfold and of women of the same ages approximately threefold. This increase is still continuing. It has occurred, too, in Switzerland, Denmark, the U.S.A., Canada, and Australia, and has been reported from Turkey and Japan.

Many writers have studied these changes, considering whether they denote a real increase in the incidence of the disease or are due merely to improved standards of diagnosis. Some believe that the latter factor can be regarded as wholly, or at least mainly, responsible—for example, Willis (1948), Clemmesen and Busk (1947), and Steiner (1944). On the other hand, Kennaway and Kennaway (1947) and Stocks (1947) have given good reasons for believing that the rise is at least partly real. The latter, for instance, has pointed out that "the increase of certified respiratory cancer mortality during the past 20 years has been as rapid in country districts as in the cities with the best diagnostic facilities, a fact which does not support the view that such increase merely reflects improved diagnosis of cases previously certified as bronchitis or other respiratory affections." He also draws attention to differences in mortality between some of the large cities of England and Wales, differences which it is difficult to explain in terms of diagnostic standards.

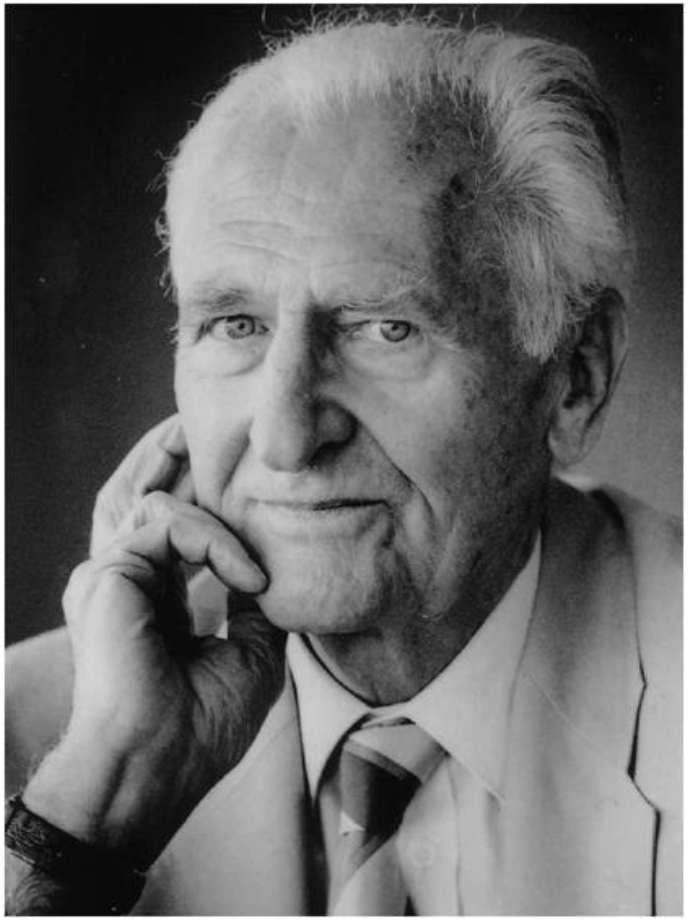
The large and continued increase in the recorded deaths even within the last five years, both in the national figures and in those from teaching hospitals, also makes it hard to believe that improved diagnosis is entirely responsible. In short, there is sufficient reason to reject that factor as the whole explanation, although no one would deny that it may well have been contributory. As a corollary, it is right and proper to seek for other causes.

Possible Causes of the Increase

Two main causes have from time to time been put forward: (1) a general atmospheric pollution from the exhaust fumes of cars, from the surface dust of tarred roads, and from gas-works, industrial plants, and coal fires; and (2) the smoking of tobacco. Some characteristics of the former have certainly become more prevalent in the last 50 years, and there is also no doubt that the smoking of cigarettes has greatly increased. Such associated changes in time can, however, be no more than suggestive, and until recently there has been singularly little more direct evidence. That evidence, based upon clinical experience and records, relates mainly to the use of tobacco. For instance, in Germany, Müller (1939) found that only 3 out of 86 male patients with cancer of the lung were non-smokers, while 56 were heavy smokers, and, in contrast, among 86 "healthy men of the same age groups" there were 14 non-smokers and only 31 heavy smokers. Similarly, in America, Schrek and his co-workers (1950) reported that 14.6% of 82 male patients with cancer of the lung were non-smokers, against 23.9% of 522 male patients admitted with cancer of sites other than the upper respiratory and digestive tracts. In this country, Thelwall Jones (1949—personal communication) found 8 non-smokers in 82 patients with proved carcinoma of the lung, compared with 11 in a corresponding group of patients with diseases other than cancer; this difference is slight, but it is more striking that there were 28 heavy smokers in the cancer group, against 14 in the comparative group.

Clearly none of these small-scale inquiries can be accepted as conclusive, but they all point in the same direction. Their evidence has now been borne out by the results of a large-scale inquiry undertaken in the U.S.A. by Wynder and Graham (1950).

Wynder and Graham found that of 605 men with epidermoid, undifferentiated, or histologically unclassified types of bronchial carcinoma only 1.3% were "non-smokers"—that is, had averaged less than one cigarette a day for the last 20 years—whereas 51.2% of them had smoked more than 20 cigarettes a day over the same



Richard Doll (1912-2005)

2. Methodology

- Objective: to detect *real* differences between compared drug/therapeutic strategies and eliminate non-real differences (e.g. random, non-homogeneous groups, subjectivity, etc.).
- To do this, the following must be controlled:
    1. Sample size.
    2. Sample selection: randomisation.
    3. Masking.

Sample size

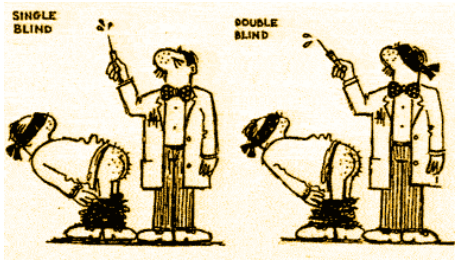
- Variables involved: hypotheses (quantitative – weight, blood pressure, etc.; or qualitative – deaths, dropouts, etc.).
- Size of the effect: clinically relevant (+ small = + sample).
- Variability of the main variable: greater variability, larger sample; relevant, assessable, unbiased, cheap, sensitive.
- Possible errors:
  - Alpha: probability of a false positive (new drug better, but not true).
  - Beta: probability of a false negative (we cannot demonstrate that the new drug is better than the placebo, but it is better).

Sample selection

- All patients should be equally likely to belong to one or the other group. Better: random numbers. Blind.
- Three types:
  - Simple.
  - By blocks (each half receives treatment).
  - Stratified (by categories, gradients): to ensure equal distribution of factors that may influence results. Example: separate smokers and non-smokers and randomise within each group.

Masking

- Means concealing the treatment to avoid influencing its evaluation.
- Placebo effect: the word **placebo** (Latin) means 'to please'. It is an inert product, with no known therapeutic effects, that the patient is offered in clinical trials in order to compare it with another therapeutically active product. The placebo effect is an improvement, apparent or otherwise, in a patient's symptoms when a substance is taken without effects directly related to the treatment of the disease causing the symptoms.
- Types of masking: **open** (unmasked), **single blind** (patient), **double blind** (patient + researcher), **triple blind** (patient + researcher + analyst), or **blind for third parties** (the patient and researcher know but a third analyst does not).



3. Types

- Classification according to:
  1. The design.
  2. The phase of the study.
  3. The objective.

According to design

1. **Not controlled:** no comparison or historical comparison. Risk of bias. Possible cases: low incidence and predictable disease (historical controls), severe illness without effective treatment (not ethical to use a placebo), etc. Cheaper.

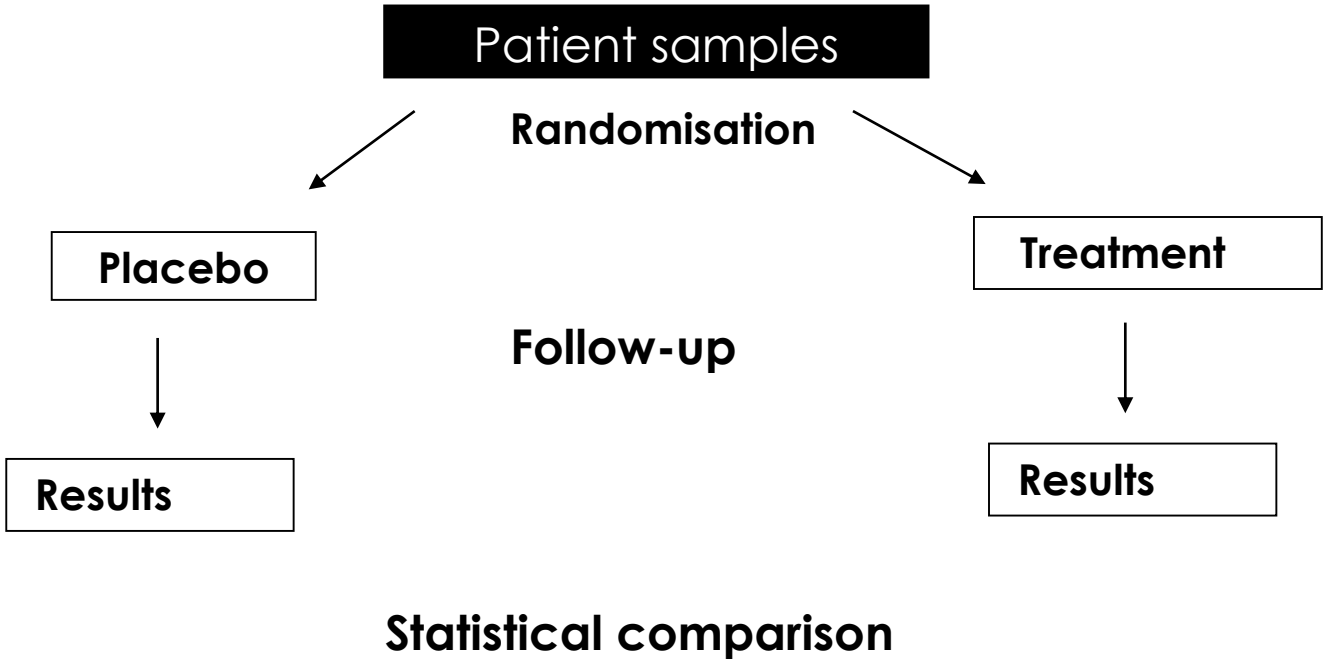
2. **Controlled:** comparison between groups

    a) Parallel design.

    b) Crossed design.

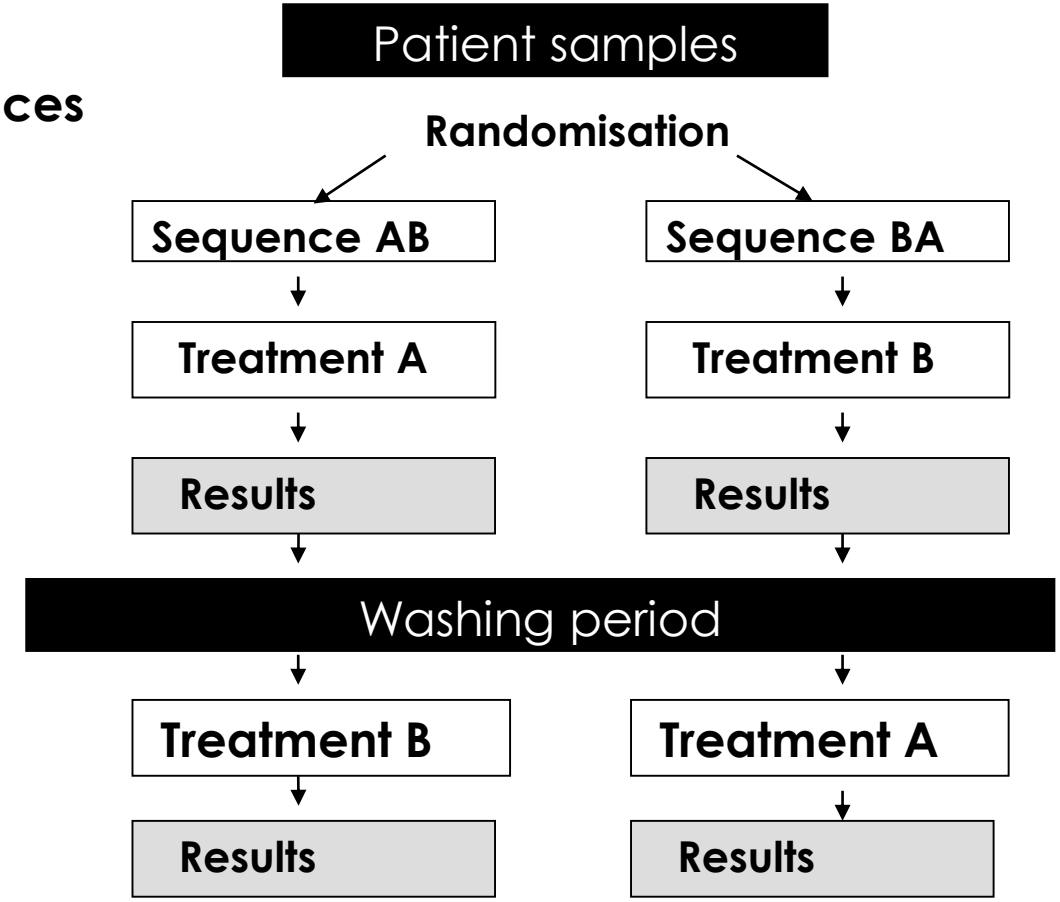
    c) Factorial design.

Parallel design



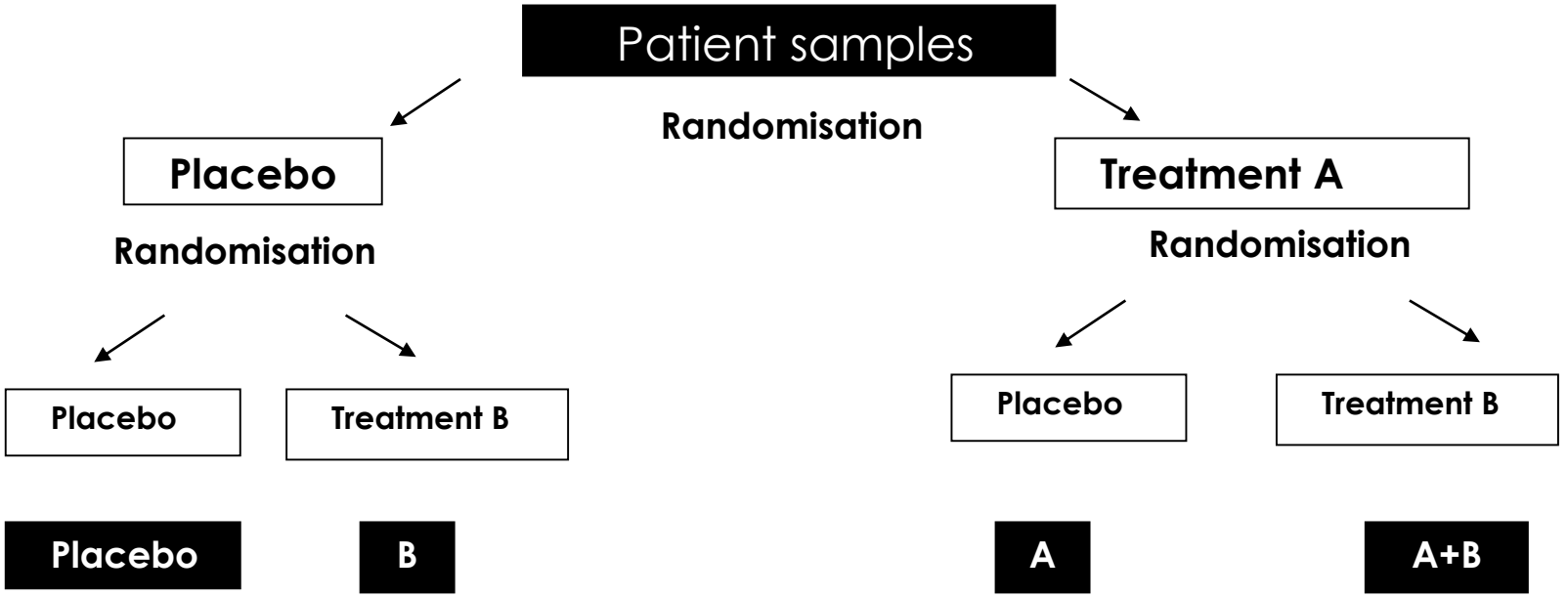
Crossed design

Two sequences



Chronic diseases

Factorial design



Factorial design: Patients are randomised twice: first on treatment A or placebo and second on treatment B or placebo, so that ultimately there are four treatment groups: placebo, only A, only B, and both treatments (A and B).

Both treatments

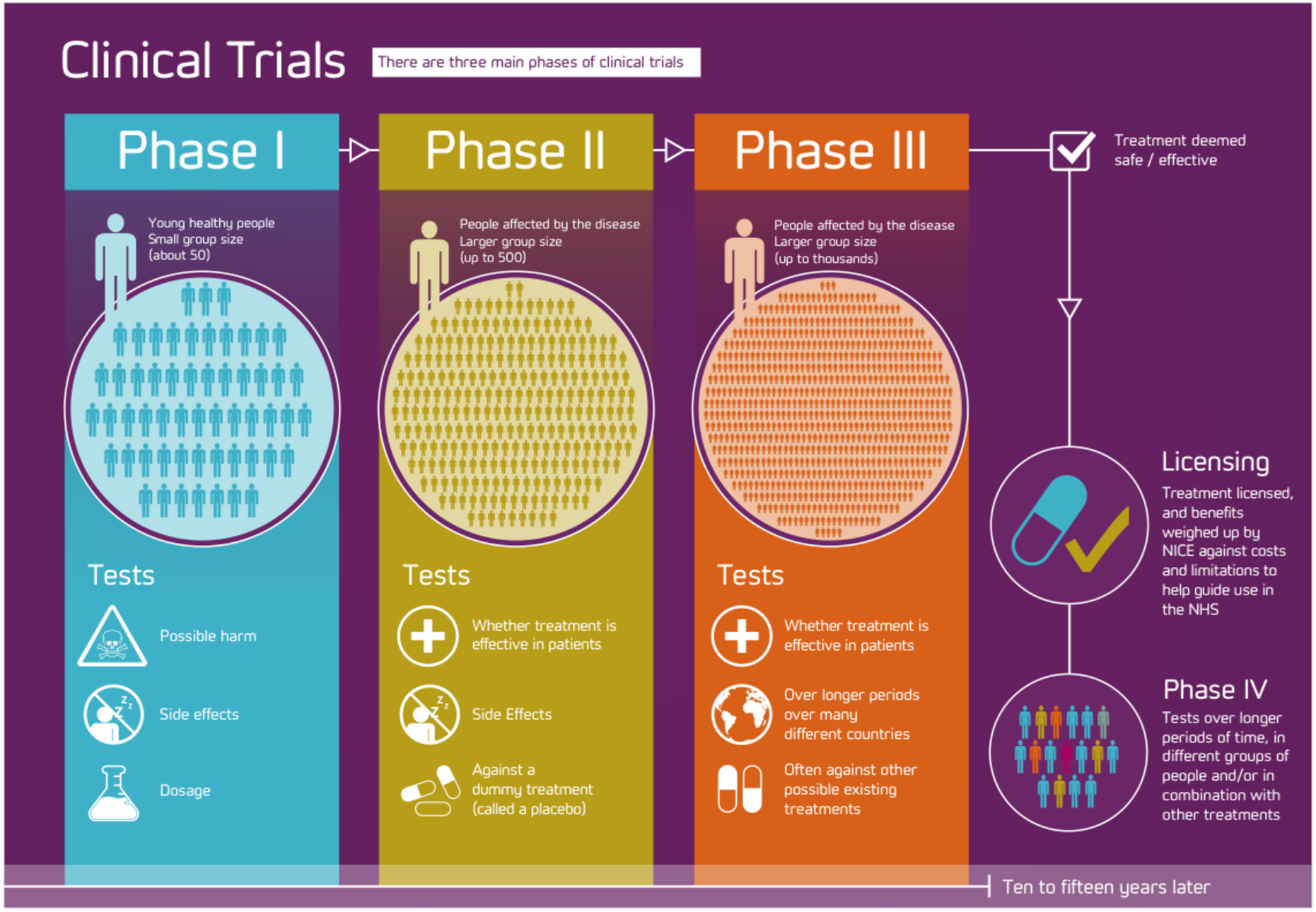
According to study phase

a) **Phase I:** first studies with humans. Objective: safety and tolerability. Very low doses that are increased. Healthy volunteers (informed consent). Small samples (<100).

b) **Phase II:** first studies on efficacy, dose, and form of treatment, mechanism of action, pharmacokinetics and risk in patients. Samples of 100 to 400 highly homogeneous subjects.

c) **Phase III:** to investigate the active principle for the specific disease. Highly rigorous. Large samples (1,000-3,000). Broad spectrum. Two phase-III trials are usually needed.

d) **Phase IV:** After commercialisation. Objective: new indications, new ways of administration, effectiveness, efficiency, pharmacovigilance, comparison with other drugs. Large number of patients (> 5000).


Clinical Trials
There are three main phases of clinical trials
Phase I
Young healthy people
Small group size
(about 50)
Tests
Possible harm
Side effects
Dosage
Phase II
People affected by the disease
Larger group size
(up to 500)
Tests
Whether treatment is effective in patients
Side Effects
Against a dummy treatment (called a placebo)
Phase III
People affected by the disease
Larger group size
(up to thousands)
Tests
Whether treatment is effective in patients
Over longer periods over many different countries
Often against other possible existing treatments
Treatment deemed safe / effective
Licensing
Treatment licensed, and benefits weighed up by NICE against costs and limitations to help guide use in the NHS
Phase IV
Tests over longer periods of time, in different groups of people and/or in combination with other treatments
Ten to fifteen years later

According to the objective

	Explanatory studies	Pragmatic studies
Aim of the study	Knowledge of a treatment	Decide on clinical use
Phase of clinical development	Phase I, II, and early III	Phase: late III and IV
Inclusion criteria	Restrictive	Less restrictive
Type of patients	Homogeneus sample	Heterogeneus sample
Sample size	Small	Large
Randomisation	Conditions differ from clinical practice	Conditions are similar to those in clinical practice
Objectives	Pharmacokinetics, pharmacodynamics, dose-response, efficacy	Effectivity, tolerability, safety, efficiency
Main variable	Biological relevance	Clinical relevance
Statistical analysis	Protocol	Treatment intention

4. Phases and evaluation

1. Approach
2. Selection of parameters
3. Selection of control (placebo)
4. Type of design
5. Eligible population
6. Sample size
7. Random assignation
8. Evaluation of response
9. Statistical analysis
10. Assessment of the clinical impact of results

- **METHODOLOGICAL EVALUATION:** Justification, definition of objectives, design, selection criteria, definition of experimental treatment, randomisation, measurement of results, main evaluation variable, evaluation criteria, statistical design, data collection and recording method, good clinical practices, informed consent, researcher and facility adequacy, justified conclusions, etc.

- **ETHICAL EVALUATION:** Principle of **non-maleficence** (safety clauses, justification of placebo, periods of treatment, research team skills, etc.), principle of **justice** (fair sample selection, safety and risks, social and economic repercussions), and principle of **autonomy** (informed consent).

Limitations of clinical trials

	Clinical trials	Clinical practice
Number of patients	Small	Large
Duration	Short	Long
Type of patients	Adults	Adults, children, elderly, pregnant
Indications	Restricted	Less restricted
Associated pathologies	No	Yes
Interactions	Limited	Broad
Dose	Standardised	Variable
Therapeutic compliance	Controlled	Non-controlled

5. Ethical problems

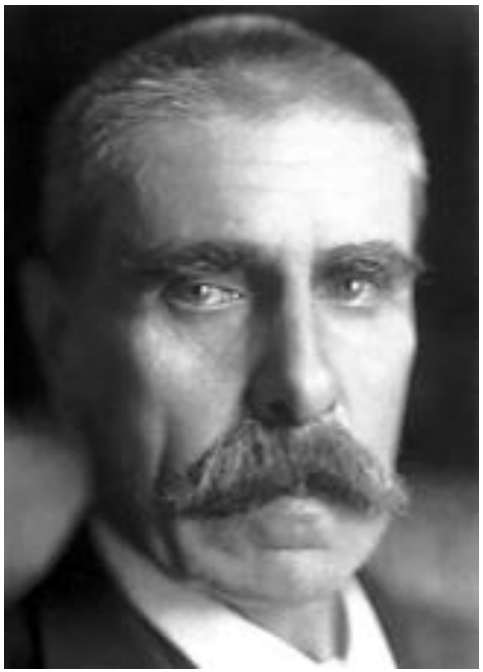
- 18th-19th century: experimental research: vaccines, microbes, blood analysis, fluids, etc.
  1796 Edward Jenner.
  1884 Jaume Ferran.

- 20th century: experiments with prisoners, children and psychiatric patients.

- At the Nuremberg Trials in 1946 and 1947, some 20 doctors were judged for crimes in human experimentation and eugenics; seven of them were sentenced to death.

- Herta Oberheuser (1911-1978).

Jaume FERRAN I CLUA (1851-1929)



Julius WAGNER-JAUREGG (1857-1940)

Pyrotherapy: malaria inoculation for the treatment of syphilis.

Nobel Prize, 1927.

Antonio EGAS MONIZ (1874-1955)

"Prefrontal leucotomy is a simple operation, always safe, which may prove to be an effective surgical treatment in certain cases of mental disorder".

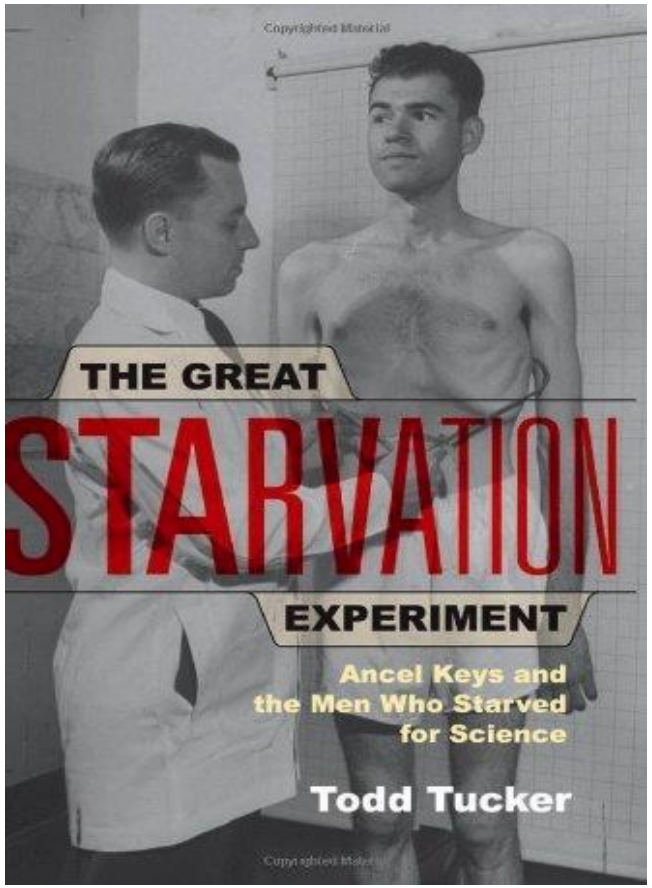
Nobel prize, 1949.

Nuremberg code (1947)

- The atrocities committed during the Second World War led to one of the first codes of conduct on clinical trials. It stipulated, for example, that:
  - Participants should give their voluntary consent.
  - The trial should not have alternatives for avoidance.
  - The procedure should avoid unnecessary suffering.
  - The degree of patient risk should be consistent with the humanitarian relevance of the study.
  - Patients can interrupt their participation at any time with no other reason than a wish to do so.
  - The study must be performed by skilled personnel.

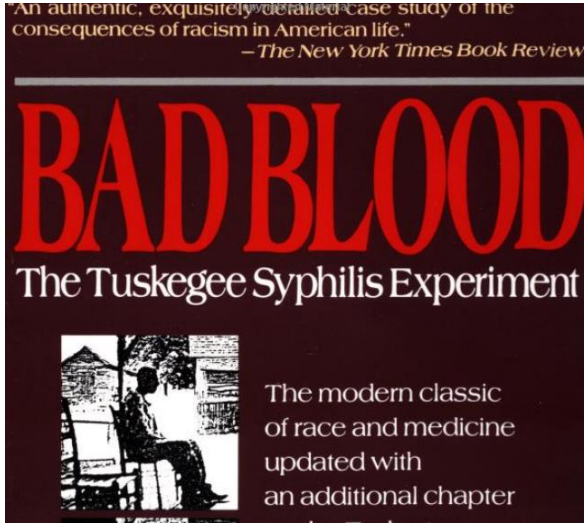
Year	Document	Authority
1947	Nuremberg Code	
1948	Universal Declaration of Human Rights	United Nations General Assembly
1964	Declaration of Helsinki (1)	World Medical Association [15]
1966	International Covenant on Civil and Political Rights	United Nations General Assembly
1975	Declaration of Helsinki (2) – Tokyo	World Medical Association
1983	Declaration of Helsinki (3) – Venice	World Medical Association
1989	Declaration of Helsinki (4) - Hong Kong	World Medical Association
1991	International Guidelines for Ethical Review of Epidemiological Studies	CIOMS / WHO
1993	International Ethical Guidelines for Biomedical Research Involving Human Subjects	CIOMS / WHO
1995	Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products	WHO
1996	Declaration of Helsinki (5) - South Africa	World Medical Association
1996	International Conference on Harmonisation (ICH) Guidance on Good Clinical Practice	CPMP/ICH

Minnesota Starvation Experiment



- This clinical study was conducted at Minnesota University between November 19th, 1944, and December 20th, 1945.
- The aim was to determine the physiological and psychological effects of severe and prolonged dietary restriction and the effectiveness of dietary rehabilitation.
- The effects of starvation based on laboratory simulation were published in a treatise.
- The results were used to guide and assist famine victims in Europe and Asia at the end of WWII.

The Tuskegee Syphilis Study

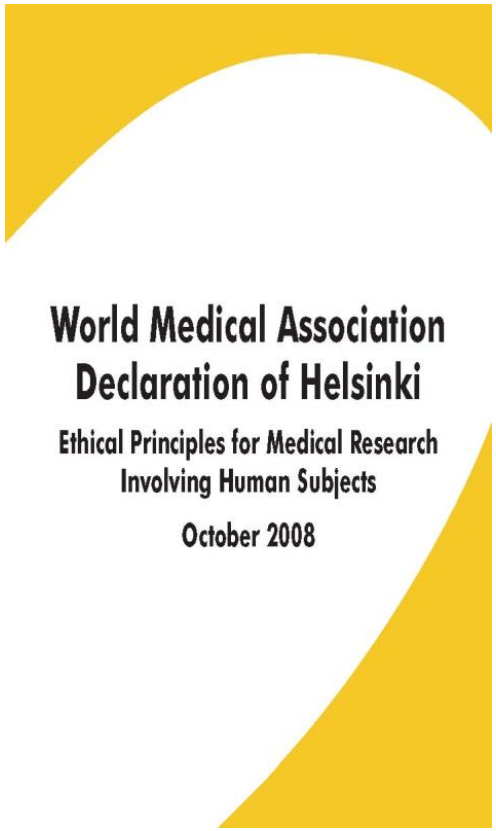


For 40 years (between 1932 and 1972), 399 African-American males, deceived by officials of the United States Public Health Service, were denied treatment for syphilis. As part of a study conducted in Macon County, Alabama, poor sharecroppers were told they were being treated for 'bad blood'. In fact, the physicians in charge of the study ensured that the men went untreated. In the 25 years since its details were first revealed, the Tuskegee Syphilis study has become a powerful symbol of racism in medicine, ethical misconduct in human research, and government abuse of the vulnerable.

Revision of the Nuremberg Code:

The Helsinki Declaration(1964)

The Declaration has been revised several times. It is still in force.



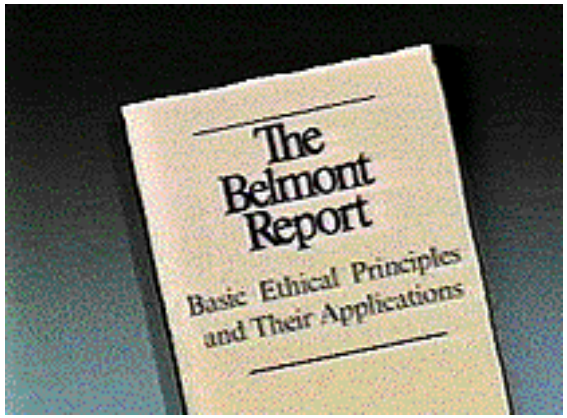
Belmont Report(1978)

Ethical Principles and Guidelines for the Protection of Human Subjects of Research – National Commission for the Protection of Human Services of Biomedical and Behavioral Research.

1. **Respect** autonomy and consent.
2. **Beneficence:** well-being.
3. **Justice:** cost-benefit.

"DO NOT HARM, AND MAXIMIZE POSSIBLE BENEFITS AND MINIMIZE POSSIBLE HARMS."

https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html



6. Current legislation

- On13th January, 2016, Royal Decree 1090/2015 of December 4th entered into force in Spain. This Decree regulates clinical trials with drugs, ethical committees on research with drugs (CEIm), and the Spanish Registry of Clinical Trials.
- Regulation (EU) 536/2014 of the European Parliament and the Council of Europe was implemented on 16th April 2014.
- Clinical trials with medicinal products are subject to prior authorisation by the AEMPS following scientific and ethical evaluation of the requested documents.

1. Clinical trials should be performed under conditions of **respect for the fundamental rights of the person**, the ethical postulates that affect biomedical research, the Declaration of Helsinki, and any other relevant international instruments signed by Spain.

2. No clinical trial may be initiated until **sufficient scientific, pharmacological and toxicological data** on animals are available to ensure that the risks involved with participating people are admissible.

3. To **avoid obsolete or repetitive research**, clinical trials may only be initiated to demonstrate the efficacy and safety of the proposed therapeutic modifications.

4. The subject of the trial shall give their written **consent** freely, after being **informed** of the nature, importance, implications, and risks of the clinical trial. The subject participating in a clinical trial, or their representative, may at any time revoke their consent without providing any cause.

5. In the case of persons who cannot freely issue their consent, such consent must be granted by their **legal representative** after previous instruction of the scope and risks of the trial.

6. No clinical trial may be conducted without a favourable prior report from an **Ethical Committee for Clinical Research**, which will be independent of the promoters, researchers and health authorities.

NORMATIVA LEGAL REFERENTE A ÉTICA Y DERECHOS DEL PACIENTE

- **Ética**
  - Declaración de Helsinki. Disponible en: http://www.wma.net/es/30publications/10policies/b3/17c_es. (Acceso 29 de septiembre de 2010)
- **Derechos del paciente**
  - Ley 41/2002 (Autonomía del Paciente). Disponible en: http://www.boe.es/diario_boe/txt.php?id=BOE-A-2002-22188 (Acceso 29 de septiembre de 2010)
  - Ley Orgánica 15/1999 de Protección de Datos. Disponible en: http://www.boe.es/boe/dias/1999/12/14/pdfs/A43088-43099 (Acceso 29 de septiembre de 2010)
  - Real Decreto 1720/2007 (Desarrollo de la LOPD). Disponible en: www.boe.es/aboe/consultas/bases_datos/texto_boe.php. Referencia: BOE-A-2008-979 (Acceso 29 de septiembre de 2010)

AEMPS (the Spanish Agency of Medicines and Medical Devices) is the independent body responsible for guaranteeing – from the perspective of public service – the quality, safety, efficacy, and correct information of medical products and medical devices (from their research to their use) with the aim of protecting and promoting human health, animal health, and the environment. Its activities include:

- Evaluating and authorising medical products for human and veterinary use.
- Continuously monitoring the safety of medical products once they are marketed, and ensuring their quality control.
- Authorising and inspecting pharmaceutical laboratories.
- Monitoring the supply of medicines.
- **Authorising clinical trials.**
- Combatting illegal and falsified medicines and health products.
- Certifying, controlling, and monitoring medical devices.
- Monitoring the safety of cosmetics and personal care products.
- Providing information on all matters related to these aspects for the general public and health professionals.
- Preparing the necessary regulations.

Offshoring clinical trials

- Clinical trials are increasingly taking place in developing countries.
- The advantages for multi-national companies are speed, easy recruitment, low drop-out, lower cost, favourable sanitary conditions, more permissive legislation, and less training of local committees.

The constant gardener (2005)

- The advantages for countries are the opportunity to obtain sanitary equipment, train professionals, and dispense treatment.
- **The risk of ethical transgression is higher** under these conditions.

Specific ethical problems

- **Informed consent**

  Informed consent may be diluted (due to difficulties in language and understanding, less individualism, less respect for autonomy, and greater economic and social coercion).

- **Standard of care** or usual local treatment

  What treatment will be followed by the control group?

- **Local relevance** of the research

  Research should respond to the health needs and priorities of the country's population (many trials investigate the problems of developed countries alone).

- **The future availability** of treatments

  Any intervention or product developed in a community should be available for the benefit of that community.

- **Respect for culture** and traditions

Specific ethical requirements

- The protocol for each trial should be ethically and scientifically evaluated by the sponsoring country first.
- Ethical standards should not be less strict.
- The host country's authorities and committees should ensure that the research responds to that country's needs and priorities and meets ethical standards.

Theme 13. Science, Medicine and Technology

Introduction

There can surely have been no greater change in medicine over the last hundred years than the technology that has been applied to it. At the end of the 19th century doctors had little more than stethoscopes and ophthalmoscopes to help them make their diagnoses. Today, however, a veritable arsenal of sophisticated and expensive instruments and devices has gradually been introduced that has transformed clinical practice. This equipment has required ever more space, hospital buildings have had to be adapted to accommodate it, and specialised technicians have been needed to handle and operate it. The importance of this technology is based on a cultural and organisational change, with hospital work being reorganised and professionals' interest in this technology being increasingly identified. However, to understand how we have arrived at this situation, we need to understand the transformation that has taken place in medicine over the last two centuries.

First we discuss the profound changes and critical thinking that took place in the late 18th century and analyse the development of clinical medicine based on the systematic study of always visible and sensorially perceptible signs, symptoms and causes of illnesses. For centuries the most common occurrence was consultation at the home of the doctor or patient. The new scenario for these practices and the teaching of medicine, however, was the hospital.

We then continue by analysing how laboratory medicine evolved in the 19th century and how the development of microscopy and chemistry led to a transformation in medical, surgical and pharmaceutical therapeutics as a new way of thinking about illness.

Illness had traditionally been understood as a multidimensional concept. First, there were primary somatic causes, such as a weak constitution, bad air and miasmas. Then there were moral and religious primary personal causes such as vices and intemperance. Even witchcraft and possession by the devil were believed to be possible causes of illness. Only the medical materialism of the 19th century changed this situation. Moreover, this new knowledge also led to different ways of characterising illness.

Contents

1. Anatomo-clinical medicine
2. Laboratory medicine
3. Physiopathology
4. Medical microbiology
5. Physics and medicine
6. The technification of medicine

Objectives

- To analyse how the current model prevalent in biomedical practice has been shaped.

- To learn the concepts of anatomo-pathology and physiopathology as conductors for present-day medical practice.

- To discuss medical microbiology and examine how the first medicines were developed in relation to microbial diseases.

- To understand the role instruments have played in clinical practice.

- To understand how certain diagnostic instruments (X-rays, ultrasound scans, MRI, CT scans, etc.) were introduced and how they have contributed to medicine.

- To critically assess the negative consequences of the technification of medicine and the excessive medicalisation of society.

Preliminary activity

Read section 3 of this topic (no. 14) in the Handbook (pp. 203-206).

Points to consider

- What role do technologies play in medicine today? How do you assess their (positive and negative) effects based on your experience and on what the text says?

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13. Science, Medicine and Technology

VNIVERSITAT DE VALÈNCIA

Carmel Ferragud, Rafaela Domínguez, Mar Cuenca
History of Science

Documentation and Scientific Methodology
Degree in Pharmacy

1. Anatomo-clinical medicine
2. Laboratory medicine
   - Physiopathology / pathophysiology
   - Medical microbiology
3. Physics and medicine
4. The technification of medicine

1. Anatomo-clinical medicine

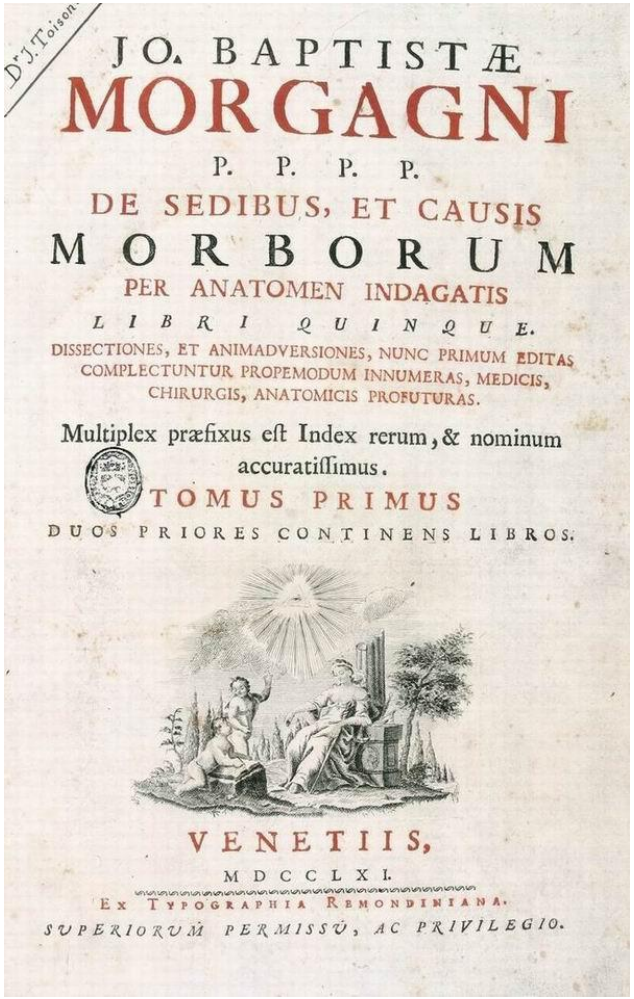
- The concept of morbid species (Sydenham, 1676).
- Speculative and empirical localisationism.
- Stages in the interpretation of the anatomic lesion (AL).
  1. AL as an autopsy finding.
  2. AL as a key to diagnosis.
  3. AL as the foundation of clinical practice and pathology.

Thomas Sydenham (1624-1689)

"Determiné de abrir algunos cuerpos de los que morían de dicha enfermedad pestilencial y en ellos hacer anatomía, para ver y conocer el humor malo y predominante, su origen y asiento y a qué parte se inclinaba, y la causa de los grandes y fuertes accidentes que consigo traía, no obstante que era enfermedad contagiosa y de gran peligro"

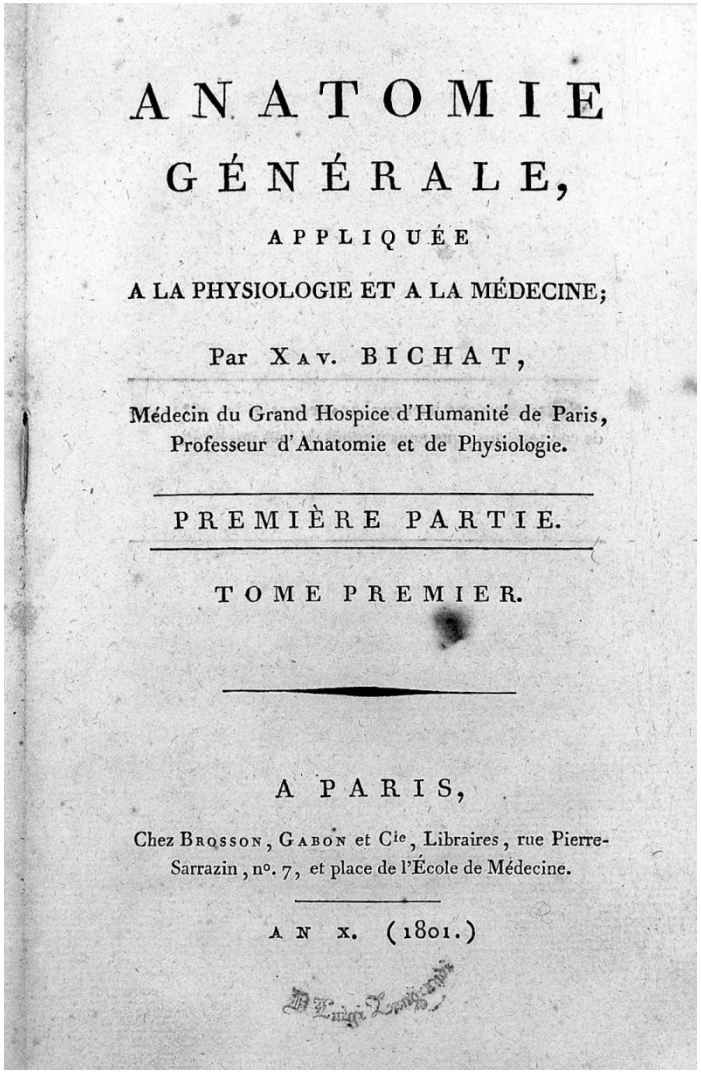
Tomás Porcell, *Información y curación de la peste de Zaragoza* (1556)

- From the end of the 17th century, diagnosis covered two objectives:
  - Determine the morbid species.
  - Establish the AL causing the illness.
- Consequences:
  - Autopsy as evidence of good diagnosis in clinical practice.
  - A new intention in relation to autopsies and a new attitude to AL.
- AL as the key to diagnosis.



Giovanni Battista Morgagni
(1682-1771)

"Medicine has been rejected for a long time from the realm of the exact sciences; it will have the right to approach them, at least with respect to the diagnosis of disease, when strict observation has been joined by the examination of alterations present in organs […]. What is indeed clinical observation if the seat of evil is ignored?"



ANATOMIE
GÉNÉRALE,
APPLIQUÉE
A LA PHYSIOLOGIE ET A LA MÉDECINE;

Par Xav. BICHAT,

Médecin du Grand Hospice d'Humanité de Paris,
Professeur d'Anatomie et de Physiologie.

PREMIÈRE PARTIE.

TOME PREMIER.

A PARIS,

Chez Brosson, Gabon et Cie, Libraires, rue Pierre-Sarrazin, no. 7, et place de l'École de Médecine.

AN X. (1801.)

- Systematic relationship between clinical observation of patients and anatomic lesions found at autopsy.
- Project to obtain an in vivo diagnosis of the lesion:
  - Percussion (Auenbrugger, Corvisart).
  - Immediate (Bayle) and using auscultation (Laennec).

Théobald Chartran (1891), *Laënnec*

- Development of a semiology based on AL.
- The 'monarchy of the physical sign' (Laín).

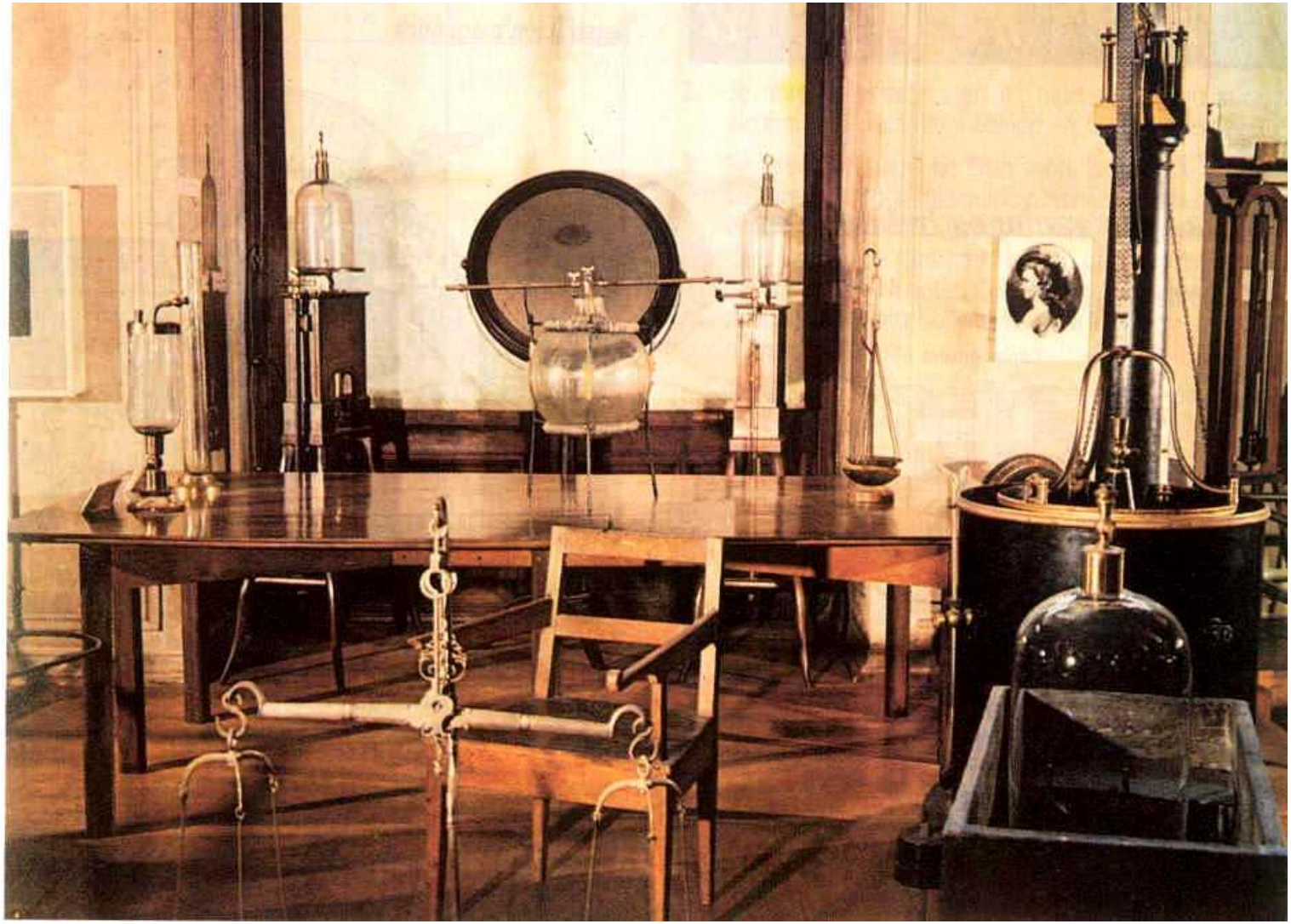
JEAN LOUIS ALIBERT "Cancer Anthracine". Lámina de *Nosologie naturelle, ou les maladies du corps humain distribuées par familles*, Paris, Caille et Ravier, 1817.

- The anatomo-clinical mentality: the central and basic reality of the disease consists of the AL that determines it.
- Scientific knowledge of AL is the best approach for turning medical knowledge into a true science.
- The symptomatic picture has two key points:
    - The ‘functional deficit’ derived from the AL.
    - The ‘reaction’ of the organism to the AL.

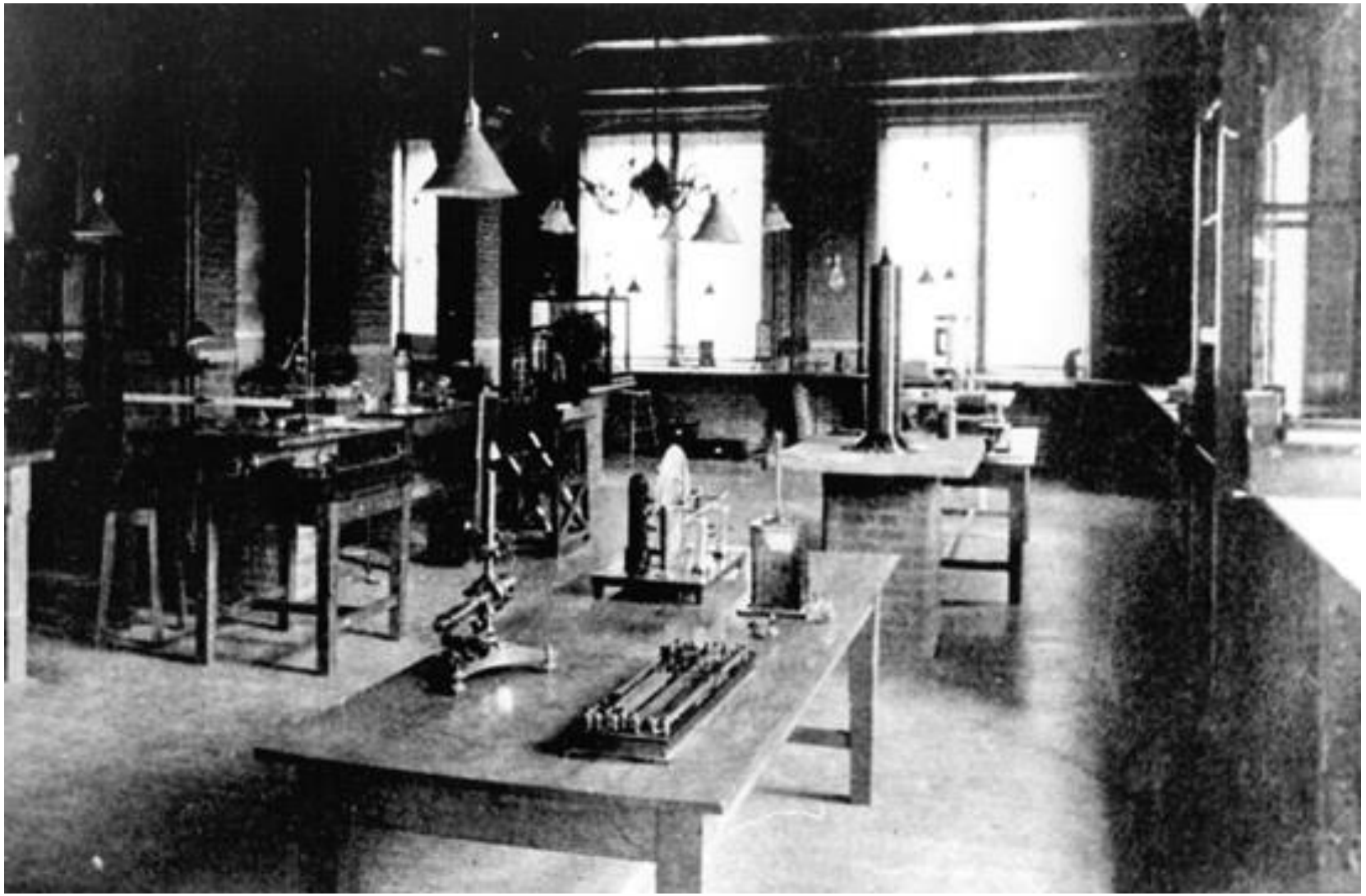
2. Laboratory medicine

- Until well into the 19th century, medicine depended on practical experience rather than laboratory knowledge.
- The term ‘laboratory’ comes from the Latin ‘labor’ (work); i.e. a place for reflective work (theoretical / practical).
- In their medieval origins, laboratories were associated with alchemy and distillation furnaces.
- Laboratories played a central role in the chemical revolution (18th century).
- In the 19th century, the laboratory became a protected space where experiments and measurements could be carried out under ideal conditions of isolation (humidity control, temperature, noise, vibrations, drafts, microorganisms, etc.).

Wellcome Library, London

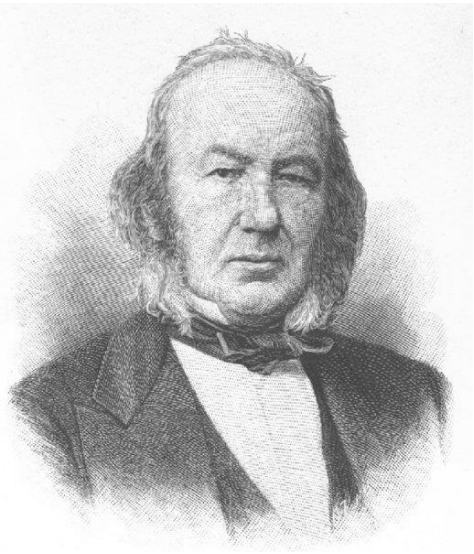


Lavoisier's laboratory converted into a museum (Musée des Arts et Métiers, Paris).



Laboratories, McGill University, Montreal (c.1890).

Introduction à l'étude de la médecine expérimentale (Paris, 1865)



Claude Bernard
(1813-1878)

- Established rules for research method in medicine and biology.
- Established the laboratory as the proper space for medical and biological sciences:

"An experiment is an observation provoked with the purpose of giving rise to the birth of an idea."

"... the hospital wards are only the entrance hall of medicine, but its true sanctuary is the laboratory."

Claude Bernard and his disciples in the laboratory

(L'Hermitte, 1889)

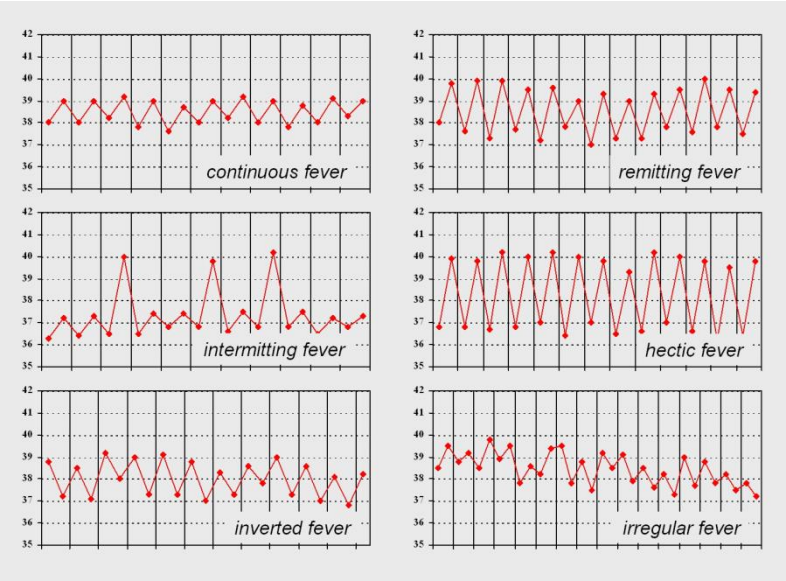
Physiopathology / pathophysiology

- Pathophysiological mentality: disease as a dynamic disorder of functions.
- Development of a scientific explanation of diseases through physics and chemistry.
- Study of diseases as energetic (physical) or material (chemicals) processes.

Clinical thermometry

Systematic study of the evolution of temperature in different diseases:

- Fever curves.
- 'Physiological signs': objective signs of a functional disorder.

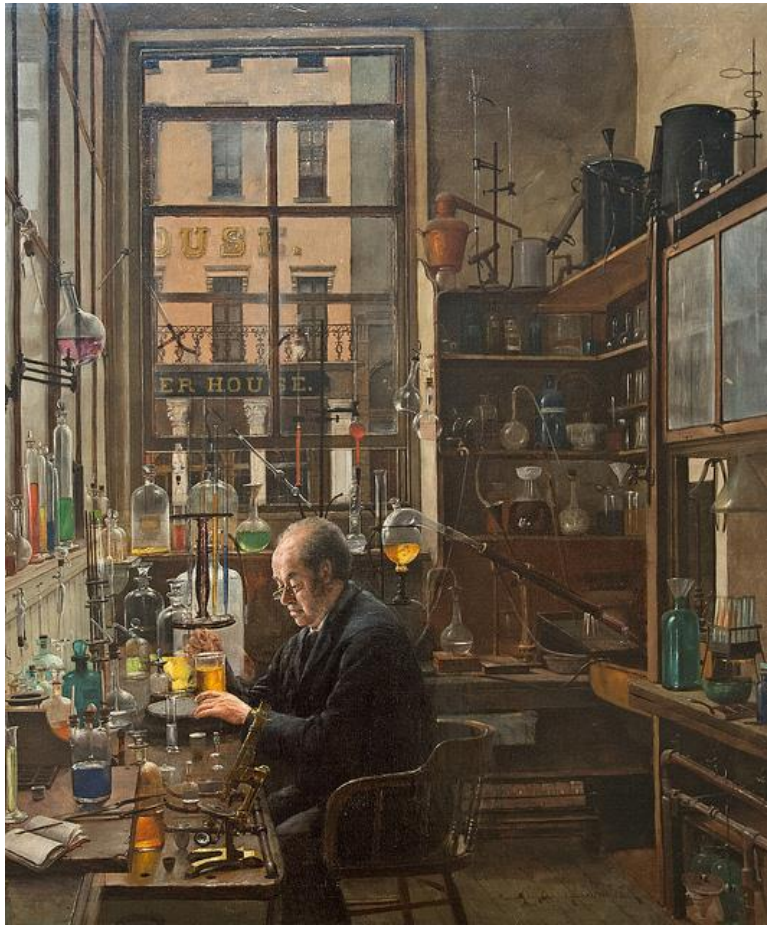


Carl Wunderlich
(1815-1877)

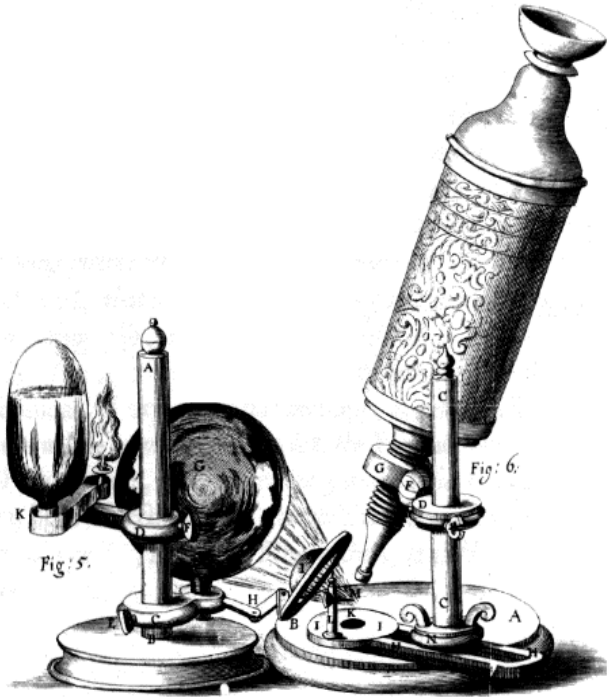
Chemical pathology

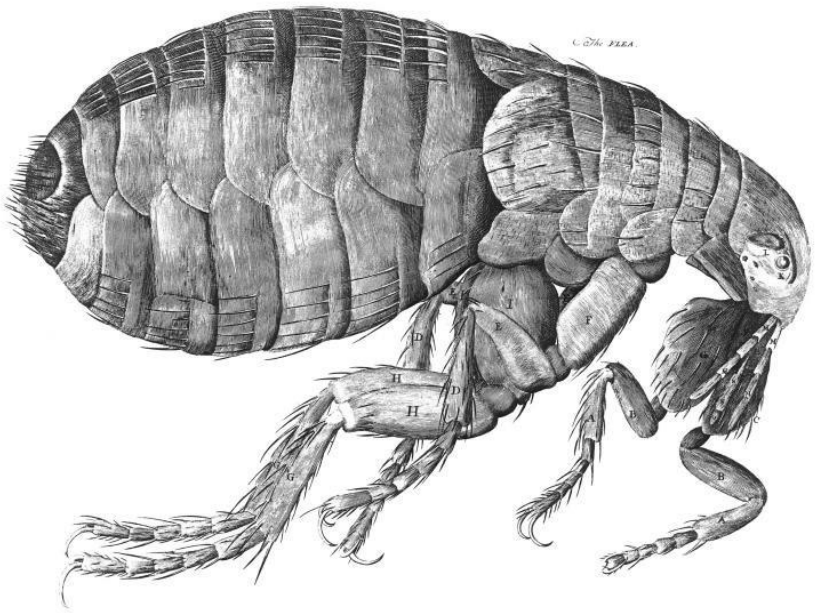
- Albuminuria as a sign of renal pathology (Richard Bright, 1827).

- Detection of leucine and tyrosine in the urine of people affected by yellow atrophy of the liver (Friedrich T. Frerichs, 1858).



In the Laboratory,
Henry Alexander (1860–1894)





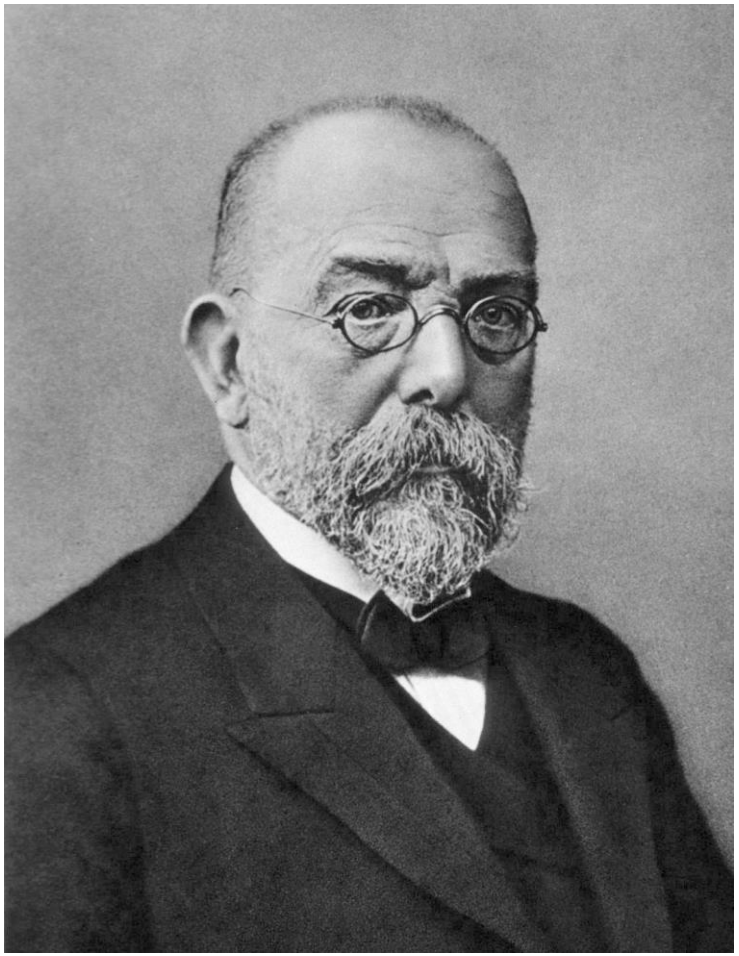
Robert Hooke, *Micrographia* (1665)

Bacteriology

- First description of bacteria (1838).
- Emergence of the term ‘microbe’ (1849).
- First classifications of bacteria.
- Discovery of spores and their role in spontaneous generation.
- Institutionalisation of the discipline.

Ferdinand Cohn (1828-1898)

Louis Pasteur (1822-1895)

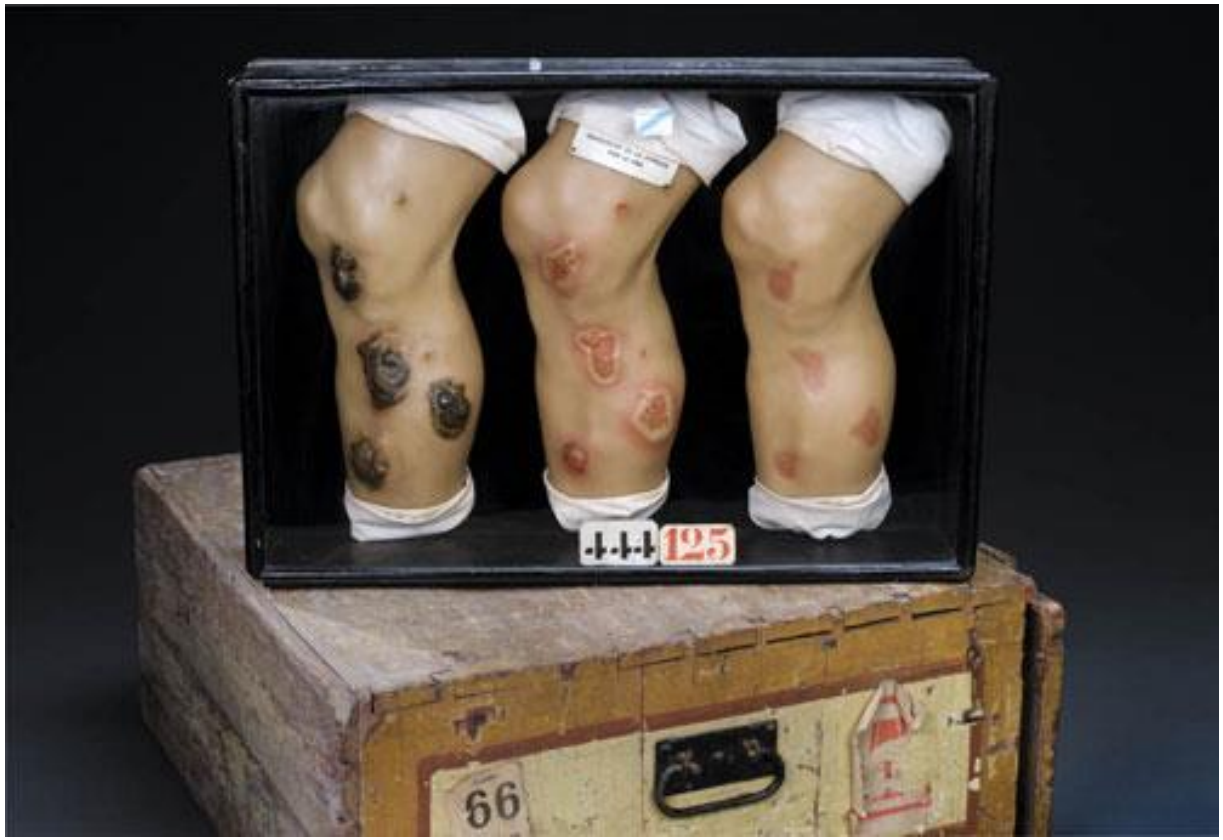


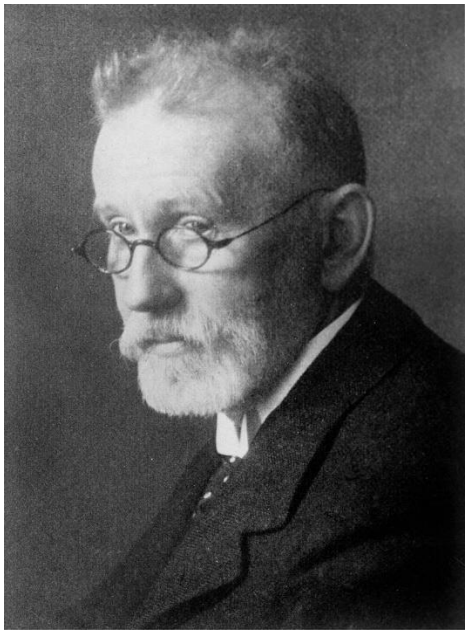
Robert Koch (1843-1910)

Medical microbiology

- The etiopathological approach: disease as external aggression by microorganisms.
- Precedents in antiquity and in the doctrine of 'living contagion' (Girolamo Fracastoro, 16th century).
- General theory of infectious disease. Koch postulated that:
  1. The microorganism must be found in abundance in all organisms that suffer the disease but not in healthy organisms.
  2. The microorganism must be able to be isolated in a diseased organism and cultivated *in vitro*.
  3. The microorganism produced *in vitro* must cause the disease when introduced into a healthy organism.
  4. The microorganism must be isolated from the inoculated experimental host and identified as identical to the original.

- Medical microbiology had a strong sanitary and social impact:
  - It provided a scientific explanation for the mechanism of contagion and encouraged the development of contemporary epidemiology.
  - It led to a marked change of focus in therapeutics.
  - It encouraged the adoption of antisepsis measures, the discovery of drugs (antiseptics and antibiotics), and the development of effective biological resources for preventing infectious diseases: vaccines or active immunisation.





Paul Ehrlich (1854-1915) and Salvarsán 606

Prontosil, Josef Klarer (1932-35)

BRITISH MEDICAL JOURNAL

LONDON SATURDAY JULY 17 1937

PRONTOSIL IN THE TREATMENT OF ERYSIPELAS

A CONTROLLED SERIES OF 312 CASES*

BY

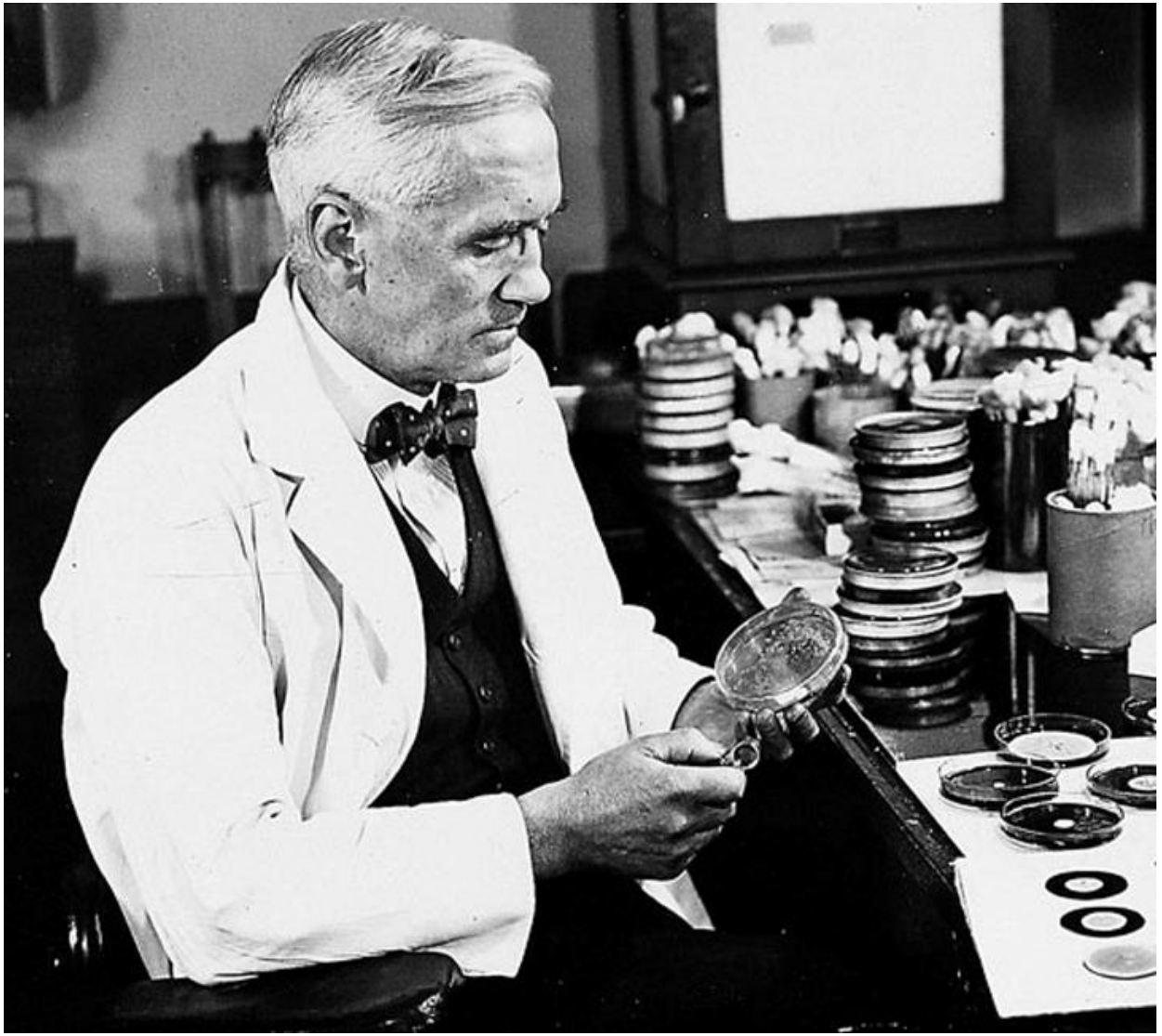
W. R. SNODGRASS, M.A., B.Sc., M.D., F.R.F.P.S.G.

Assistant Physician, Western Infirmary, Glasgow

AND

T. ANDERSON, M.B., Ch.B., M.R.C.P.Ed.

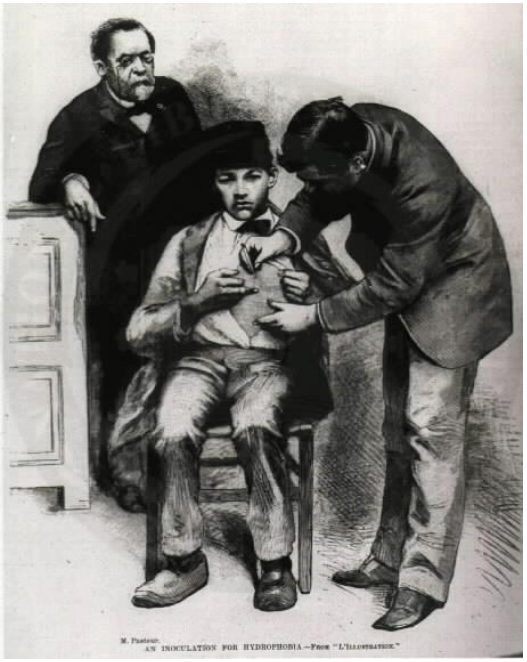
Deputy Superintendent, Rochill Hospital, Glasgow

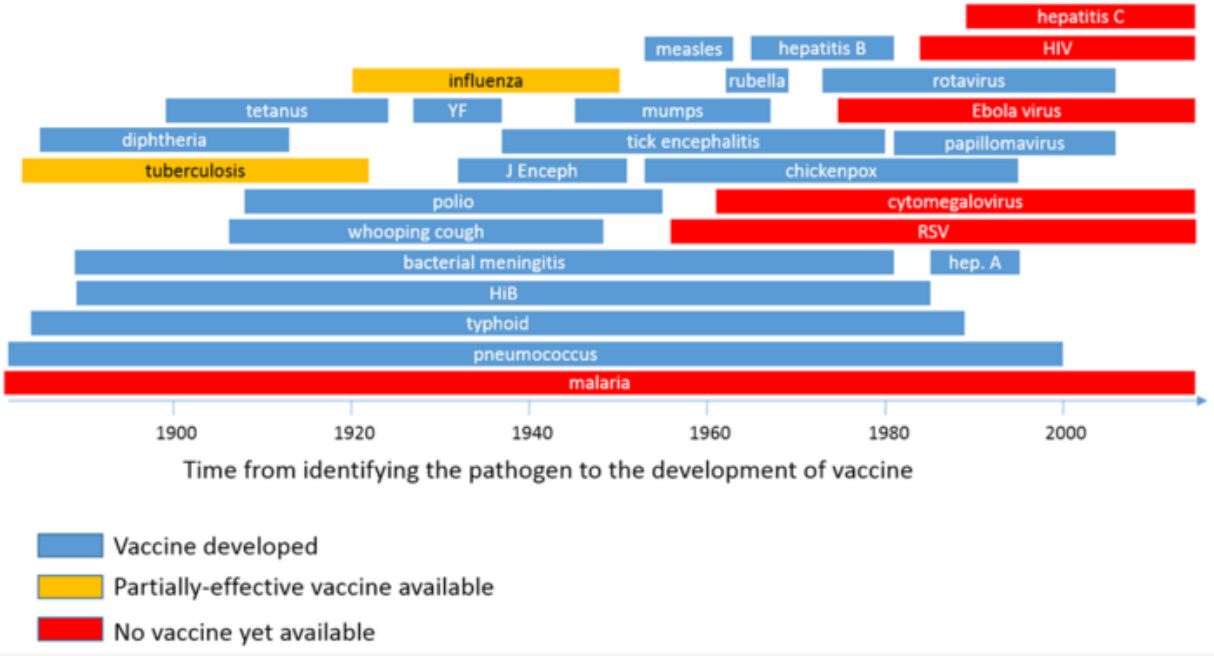


Alexander Fleming (1881-1955)

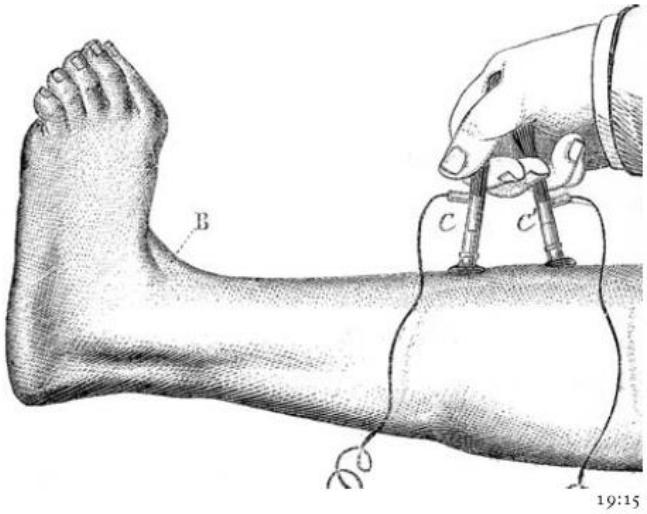
- Fleming departed from earlier research on bacteria-eating organisms. August 1928: penicillin.
- Penicillin could not be initially developed because of the difficulty of producing it in large quantities (unstable).
- Ernst Chain and Howard Florey (Oxford) reproduced Fleming's experiments. With help from the US, penicillin was produced in large quantities. It had great success when applied during World War II
- Chain and Florey shared the Nobel Prize with Fleming in 1945.
- Other antibiotics were sought. Microbes were progressively isolated (Waksman, Dubos, Duggar).
- The search for the panacea has limitations: resistance to antibiotics (new strains of resistant microbes).

José Ramón Alonso, "La verdadera historia de la penicilina", *Jot Down Magazine*

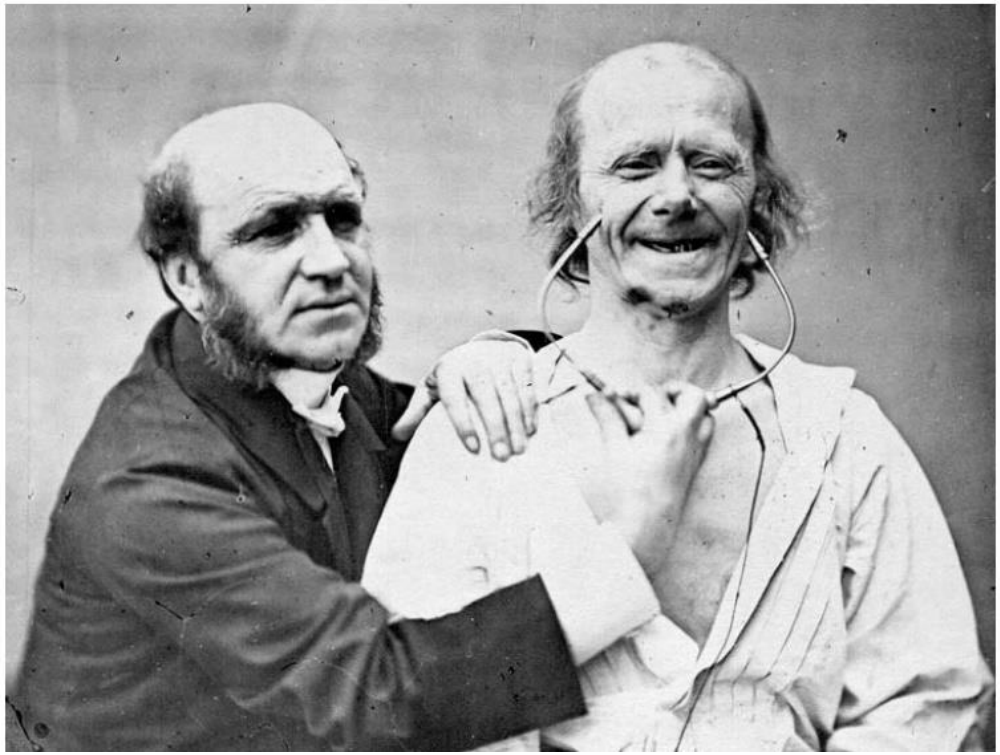

M. Pasteur.
AN INOCULATION FOR HYDROPHOBIA.—From "L'Illustration."

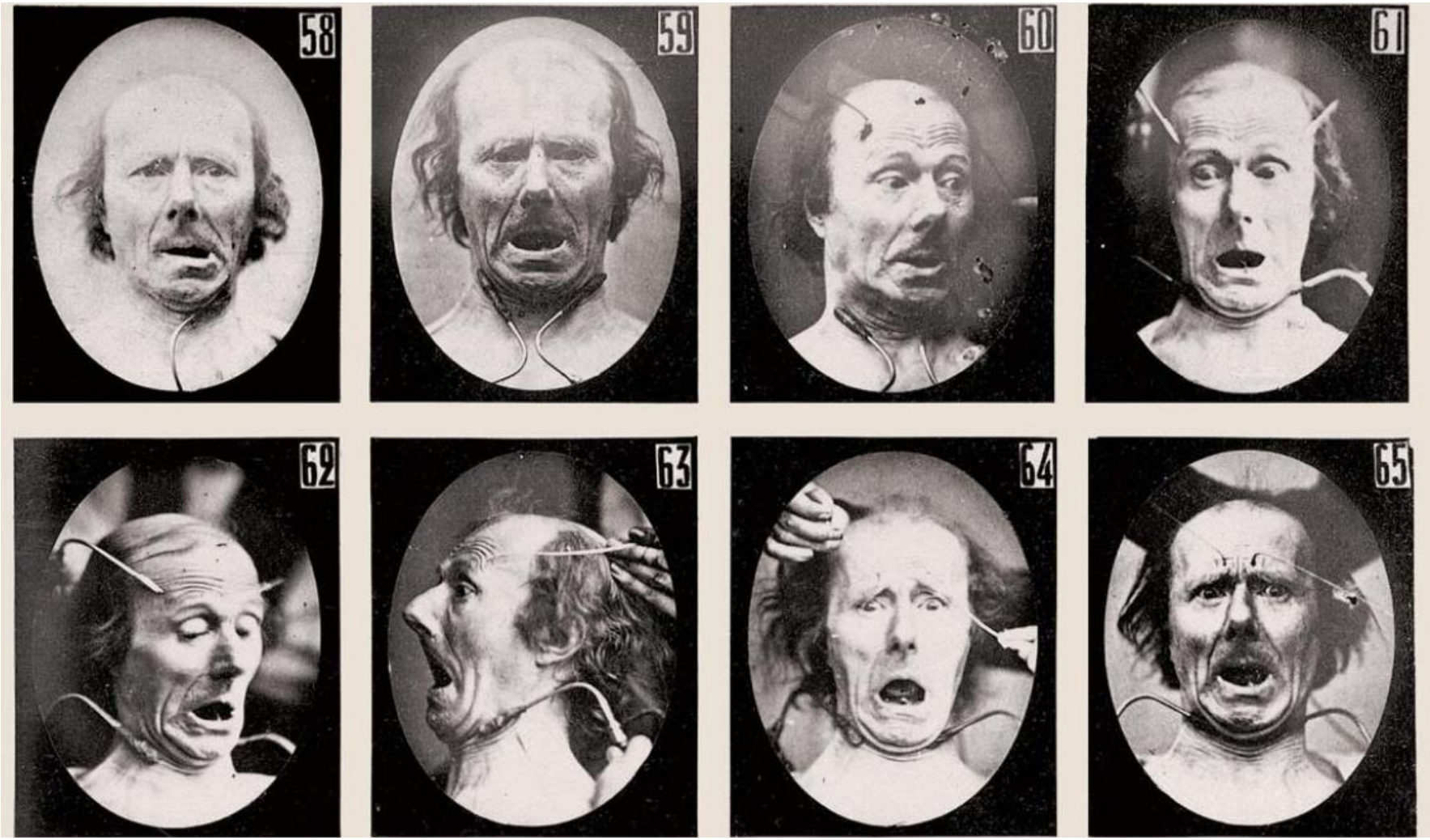

hepatitis C
measles
hepatitis B
HIV
influenza
rubella
rotavirus
tetanus
YF
mumps
Ebola virus
diphtheria
tick encephalitis
papillomavirus
tuberculosis
J Enceph
chickenpox
polio
cytomegalovirus
whooping cough
RSV
bacterial meningitis
hep. A
HiB
typhoid
pneumococcus
malaria
1900
1920
1940
1960
1980
2000
Time from identifying the pathogen to the development of vaccine
Vaccine developed
Partially-effective vaccine available
No vaccine yet available

3. Physics and medicine

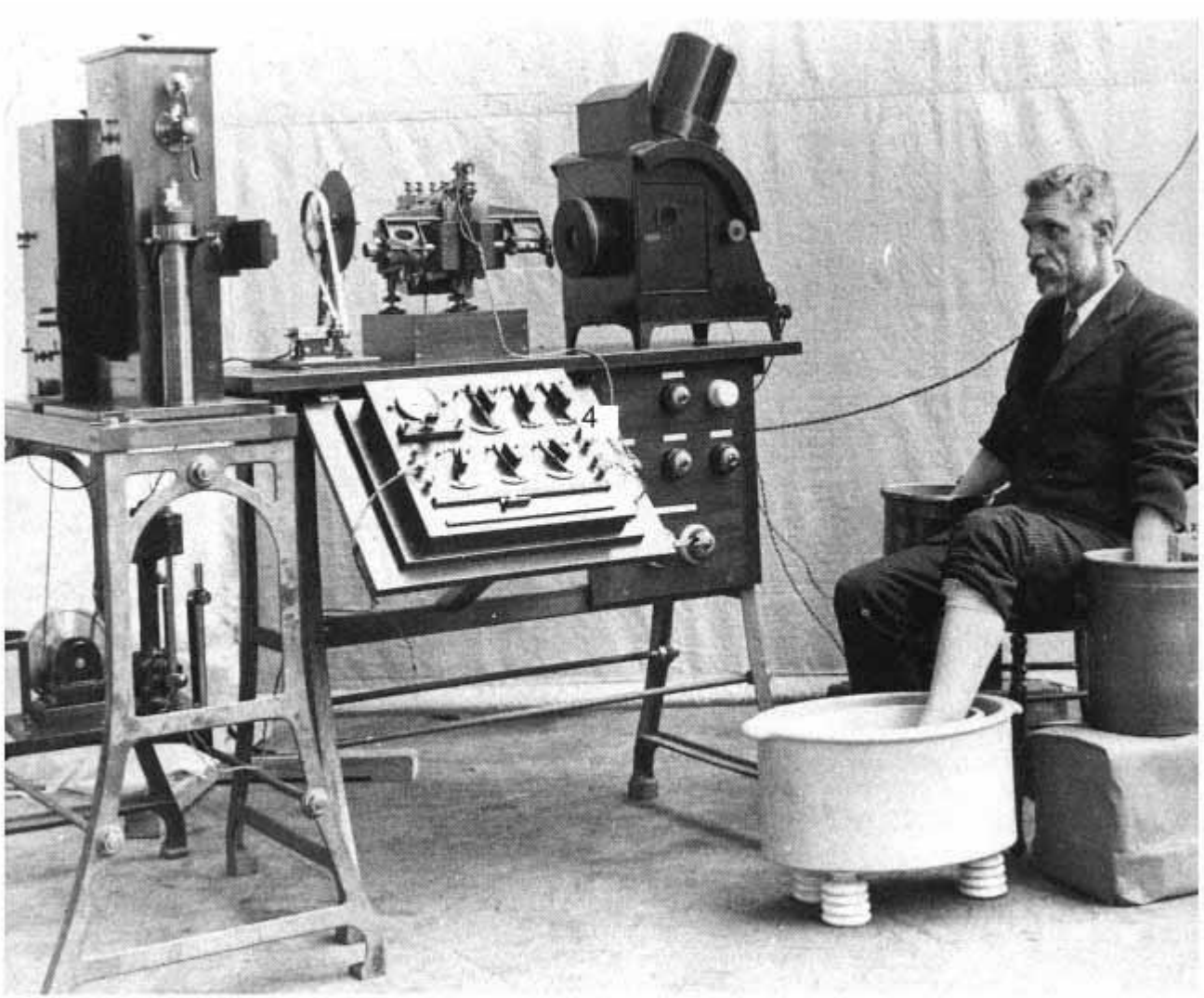


From galvanism to electrotherapy

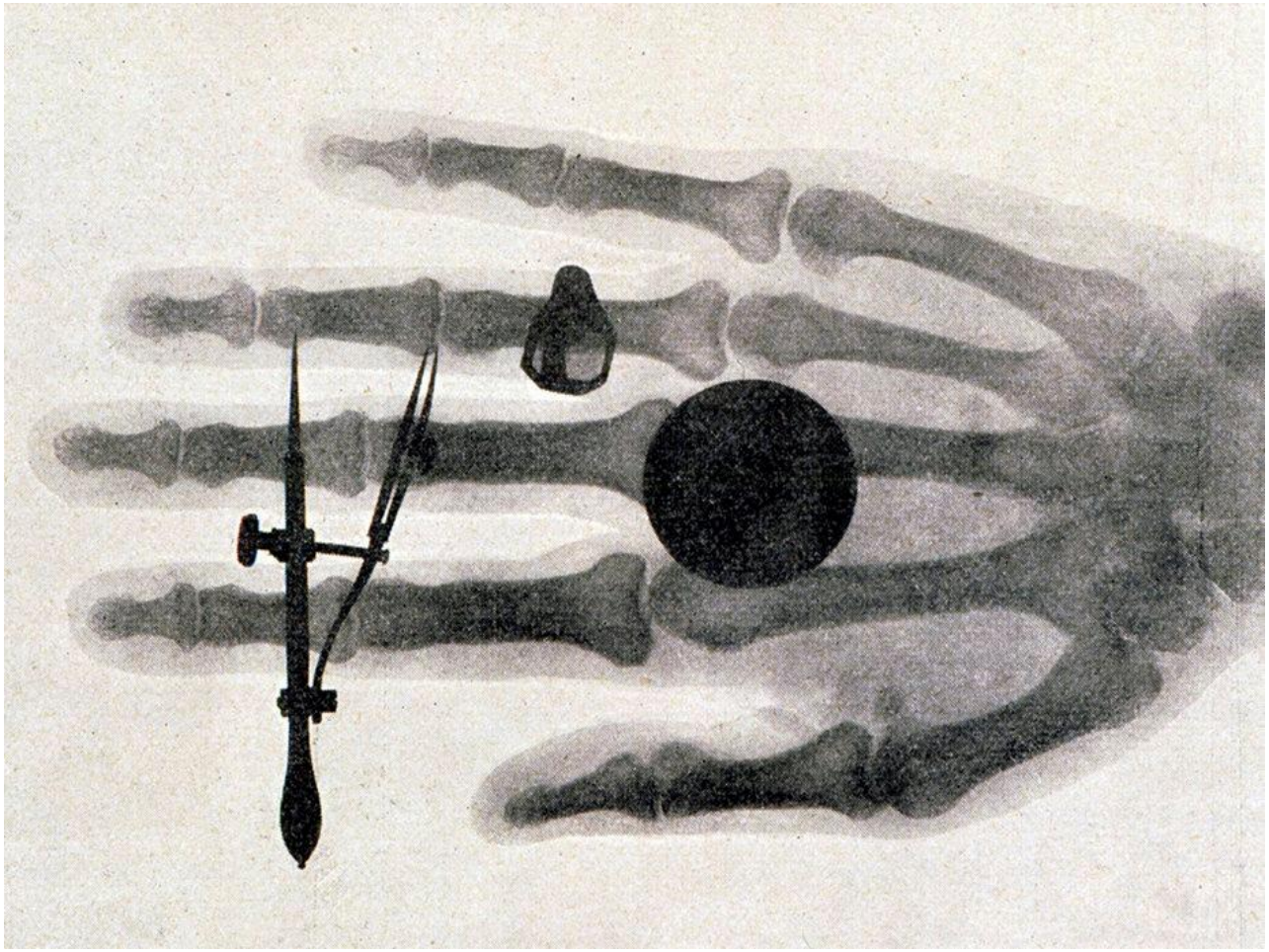




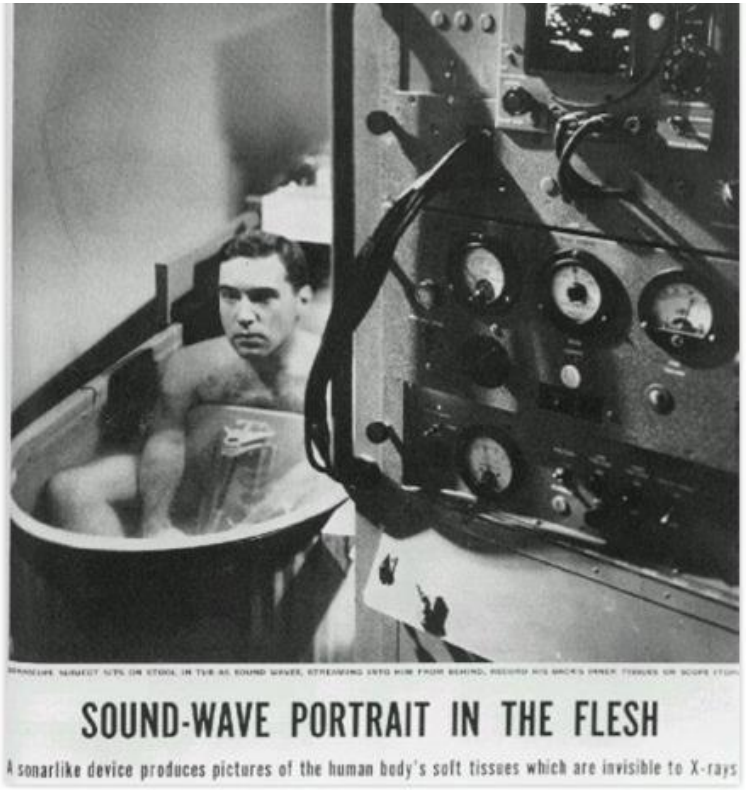
G.B. Duchenne (de Boulogne), *Mécanisme de la physionomie humaine* (1862).



Cambridge Scientific Instruments in association with Willem Einthoven (1912).

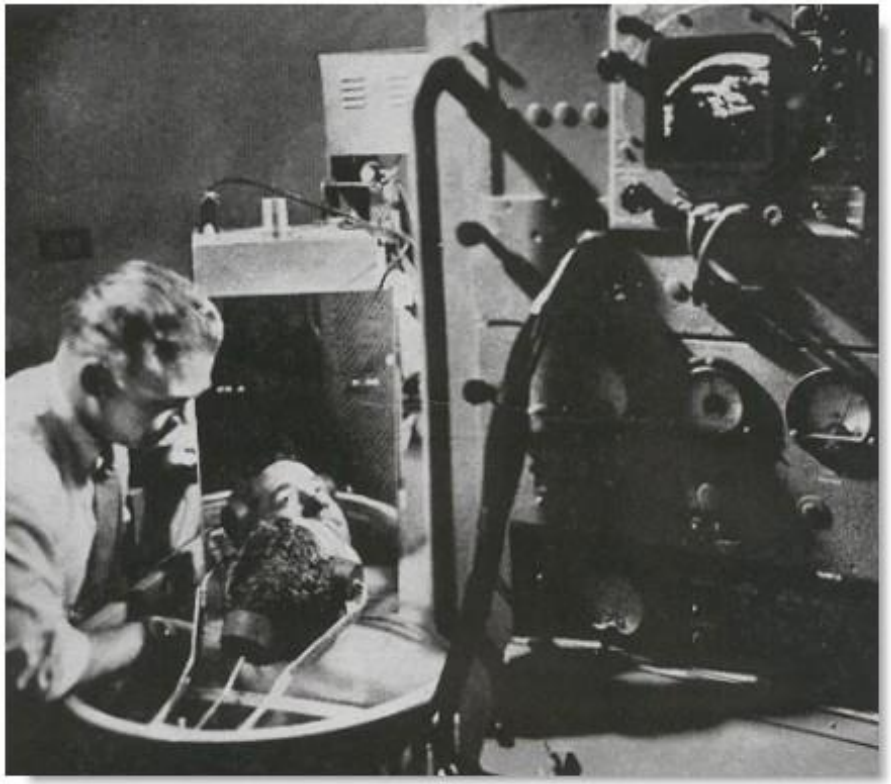


Radiography taken by Wilhelm Roentgen in 1896.



SOUND-WAVE PORTRAIT IN THE FLESH

A sonarlike device produces pictures of the human body's soft tissues which are invisible to X-rays



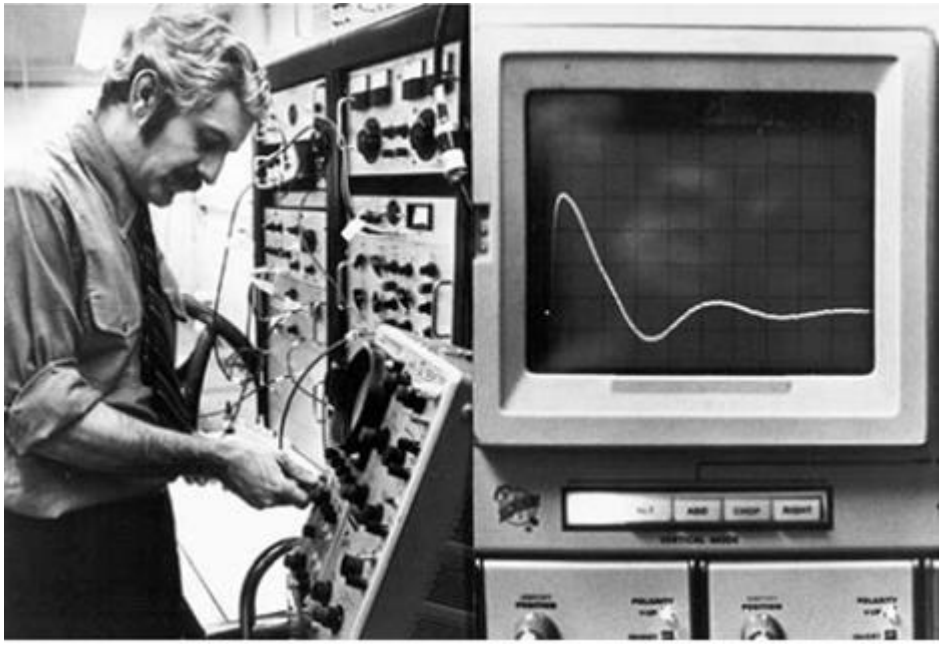
First investigations by Douglass Howry in the 1940s with the use of an ultrasound transducer whose echo generated two-dimensional images of soft tissues (*somascope*).

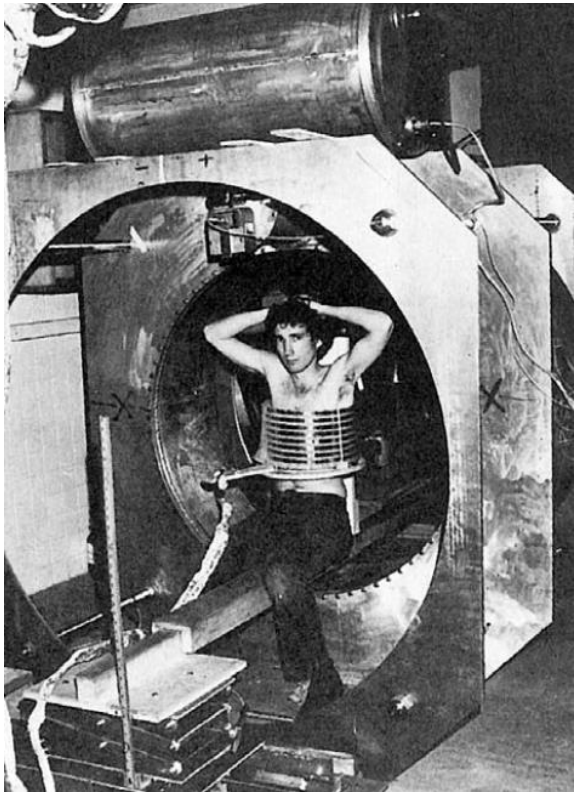
Tumor Detection by Nuclear Magnetic Resonance

Raymond Damadian

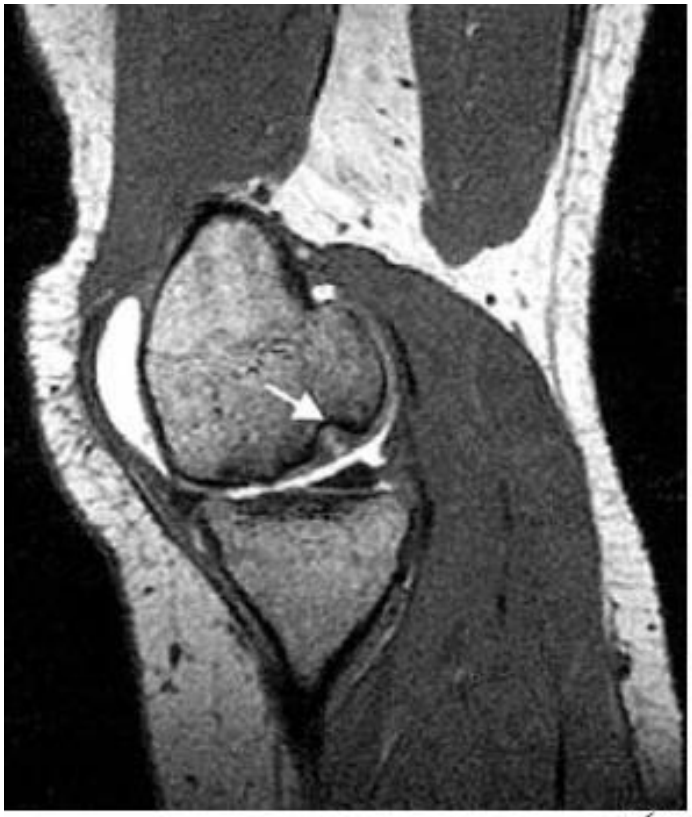
Abstract. *Spin echo nuclear magnetic resonance measurement*

SCIENCE 1971; 171:1151.

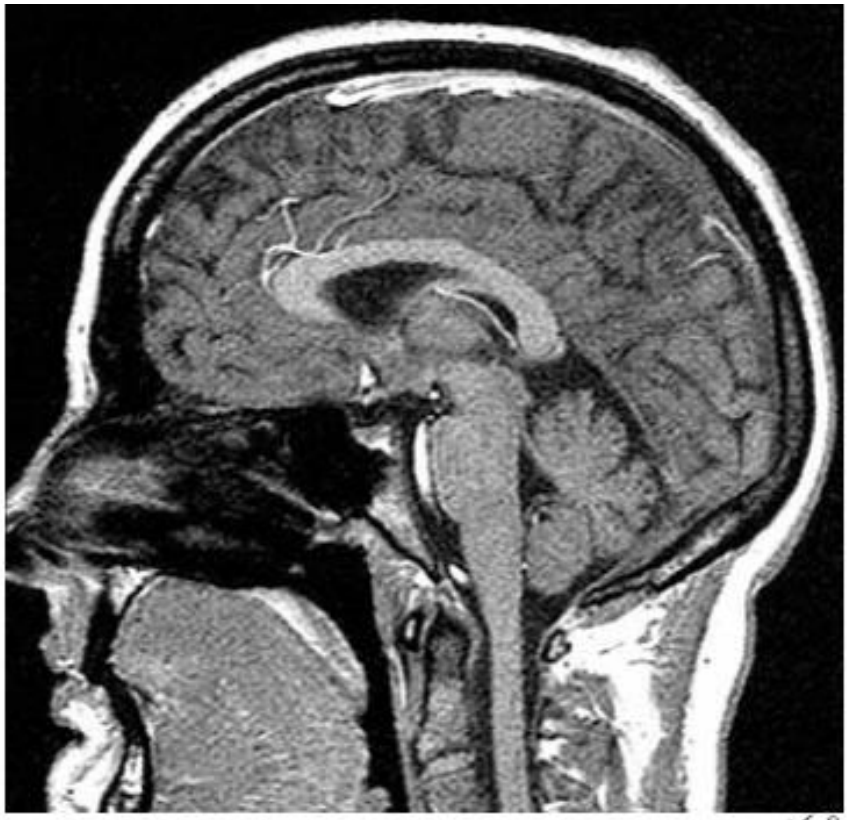




Raymond Vahan Damadian (n. 1936).



96:7



96:8

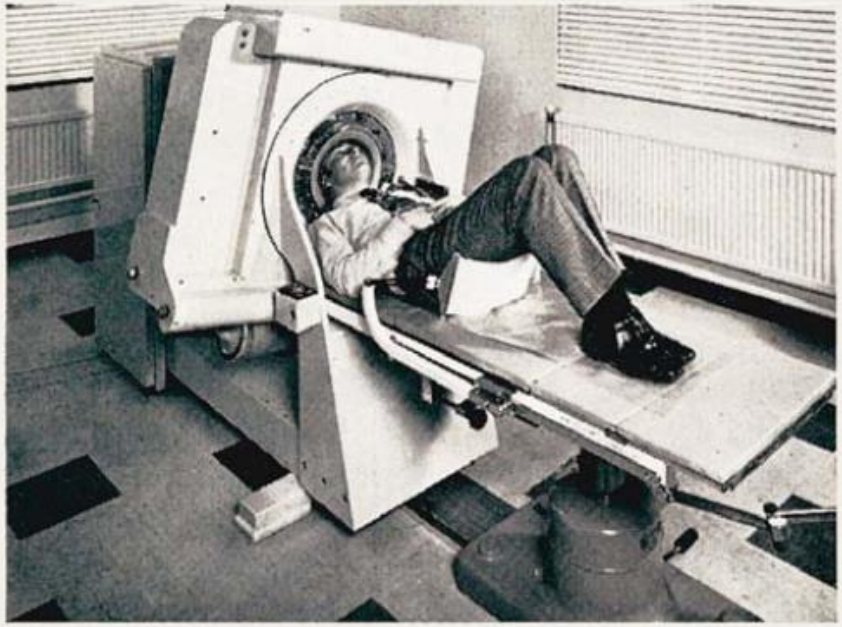


FIG. 5.
Illustration of the patient in position.

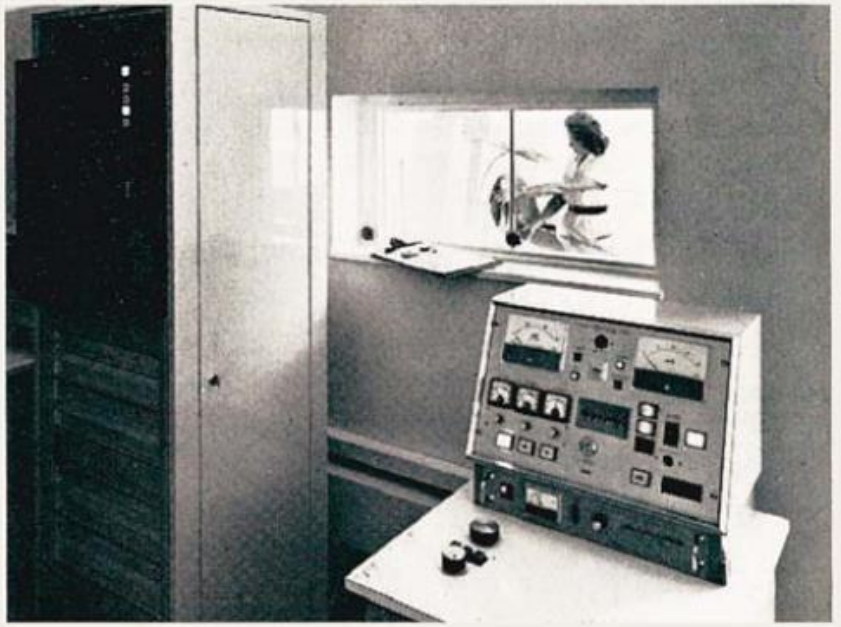
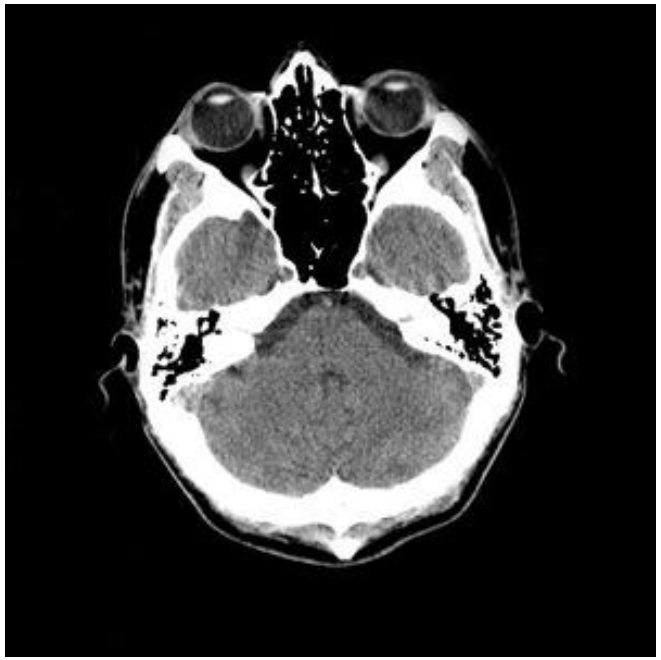
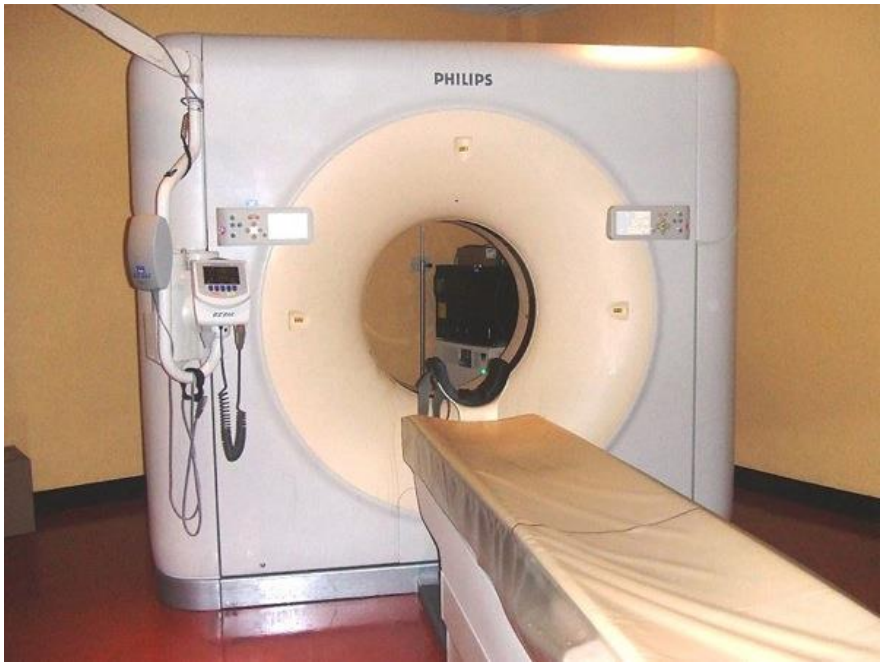


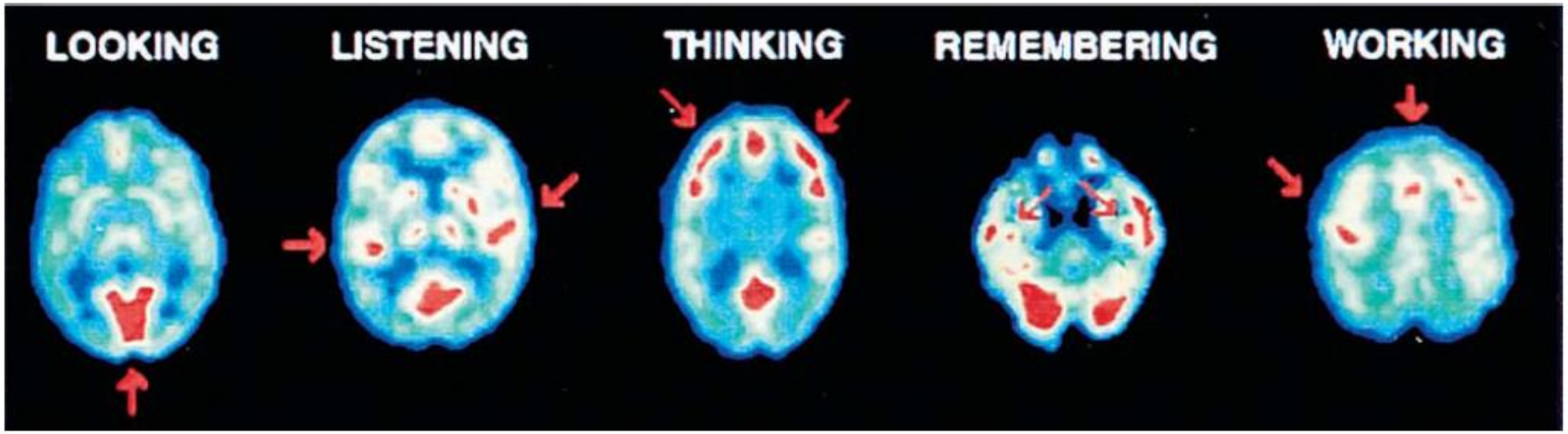
FIG. 6.
X-ray control console.

95:7

Godfrey Hounsfield (1919-2004) won the Nobel Prize in 1979 for the development of computerized axial tomography (CAT).




PHILIPS



Positron emission tomography (PET): brain activity (glucose consumption) when different activities are performed.


SIEMENS
UFC

6. The technification of medicine

- Growing subordination of the patient to health technologies and medicalisation of natural phenomena such as pregnancy, childbirth, sexuality, menopause, and ageing.
- Tendency to over-diagnosis.
- Reification: manipulation, alienation, fragmentation and commodification of the body.
- Medical knowledge and technology are never politically or culturally neutral; they have a huge influence on how people feel and understand their bodies.

- The indiscriminate use of diagnostic and therapeutic technologies is having an obvious impact on health costs and the sustainability of public health care systems.
- An expropriation of health has taken place. This has been driven by economic interests and health professionals (Illich, 1975).
- 'Introduction of the subject in medicine' (Lain) or 'disappearance of the sick man of medical cosmology' (Jewson)?

Theme 14. The pharmaceutical industry

Introduction

In the late 19th century the pharmaceutical industry changed the main function of the traditional apothecary and in the 20th century it asserted its predominance. By the mid-1990s the estimated volume of business for this industry was roughly 200 billion dollars a year, while the figure exceeded 300 billion in the first decade of this century. This progress has continued and now all statistical measures for the volume of investment and business in the sector have taken on gigantic proportions. Numerous circumstances, events, economic factors, laws, regulations, institutions and scientists have contributed to the development of the international pharmaceutical industry. In this topic we analyse the implementation and success of this model worldwide and examine its positive and negative aspects.

Contents

1. A cottage industry
2. The first companies
3. The second half of the 19th century
4. Growth and expansion (1890-1914)
5. The First World War and the interwar period
6. The Second World War
7. Developments since 1950
8. The current situation

Objectives

- To study the historical process that led to the beginning and development of the pharmaceutical industry.
- To analyse tables of statistics to assess what the characteristic features of the industry are today.
- To consider how, in science, the most unexpected research and ideas can lead to discoveries that mark the future – as occurred, for example, with the colorants and pharmaceutical industries.
- To learn about the first industrially produced drugs (alkaloids, vitamins, hormones and antibiotics) and analyse their associations with research and the needs of society.
- To examine the trend in the concentration of pharmaceutical laboratories and understand its repercussions.

- To observe the current situation of the pharmaceutical industry and examine the challenges it will face in the future.
- To know what generic drugs are and understand their importance for healthcare spending and access to drugs around the world.
- To understand the concept of orphan drug (and orphan disease); to analyse the implications of the industry's lack of interest in products that are unprofitable from the financial perspective but have huge repercussions from the healthcare perspective.

Preliminary activity

Read pages 247 and 248 of the Handbook to understand the importance of the drugs industry. Also review topics 17 and 18 to better understand what we will be discussing here.

Points to consider

- What picture do you have of the pharmaceutical industry? Many of you would probably like to work in these laboratories. What do you know about them?

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14. Pharmaceutical Industry

Carmel Ferragud, Rafaela Domínguez, Mar Cuenca
History of Science

Documentation and Scientific Methodology
Degree in Pharmacy

1. A cottage industry
2. The first companies
3. The second half of the 19th century
4. Growth and expansion (1890-1914)
5. The First World War and the interwar period
6. The Second World War
7. Developments since 1950
8. The current situation

1. A cottage industry

- Pharmacy was a craft activity, regulated by guilds, until the 19th century.
- Drugs were produced in the pharmacy. This was a small business that required few staff, was marketed locally, and produced enough profit to maintain a family. It did not require large capital investment.

2. First industries

- Discovery of alkaloids in the early nineteenth century.
- Merck, created in 1668, began producing alkaloids in 1872.
- Schering, created in 1851, also specialised in alkaloids

- Secondary metabolites of plants were generally synthesised from amino acids.
- Most had intense physiological actions with psychoactive effects, so were widely used in medicine to treat mental problems and soothe pain.
- Examples include cocaine, morphine, atropine, colchicine, quinine, caffeine, strychnine, and nicotine.

3. Second half of the 19th century

- Creation of a synthetic organic chemical industry.
- Synthesis of first dyes: malva-aniline (William Perkin, 1856).
- Relationship between the dye industry and the pharmaceutical industry: biologically active substances capable of selectively acting on biological tissues or components.
- Development of molecules and prediction of their behaviour.
- CIBA (Switzerland, 1884): production of medicines and dyes.

Two decisive decades (1880-1890)

- Mass production of medicines
- Pills
- Digitised capsules
- Marketing

Burroughs, Wellcome & Co. Head Office, Snow Hill, London, 1880.

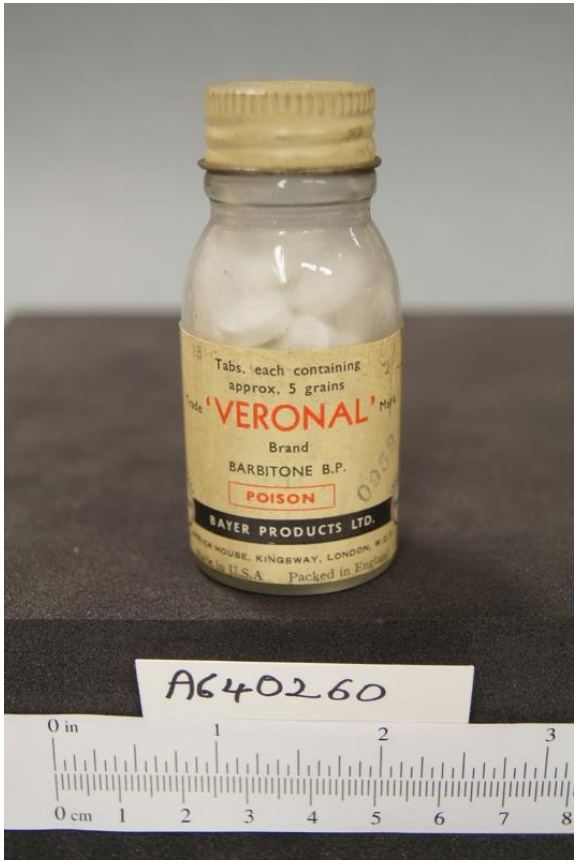
Product exhibition of Burroughs, Wellcome & Co. at the International Medical and Sanitary Exhibition (1881)

4. Growth and expansion (1890-1914)

- Increase in specialised personnel associated with industries.
- Creation of research centres associated with industries.
  - Wellcome: Physiological Research Laboratories (1894).
- Market expansion.
  - Merck was active from 1891 in the USA; by 1913 it already had more than 2,000 employees.

Wellcome Chemical Works, Dartford (1909)

Aspirina, Felix Hoffmann (1897)

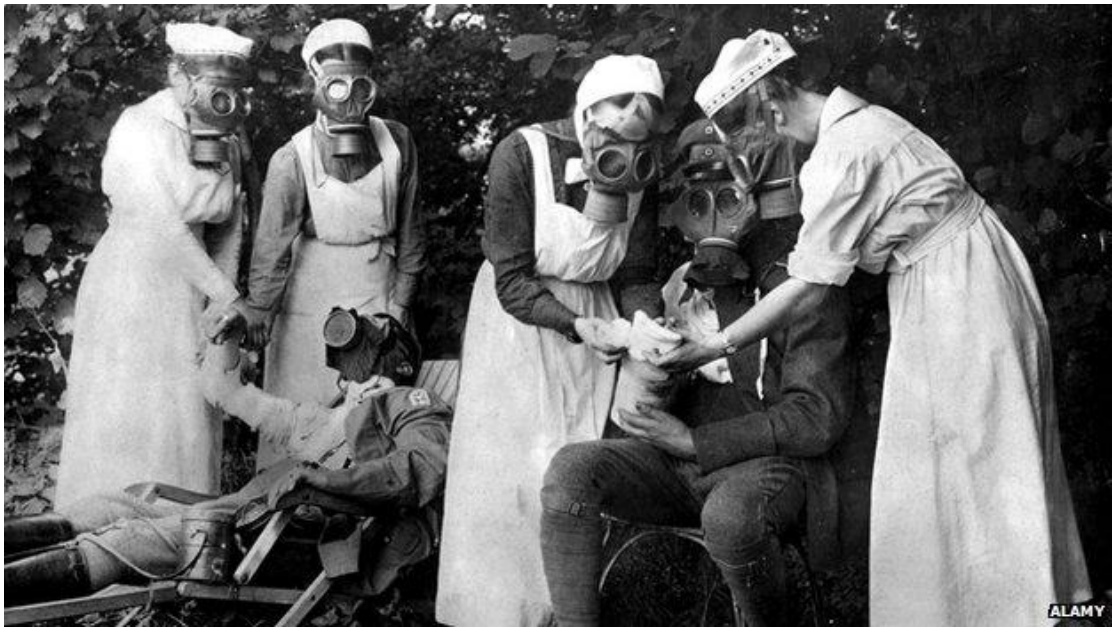


Veronal, Emil Fischer and Josef von Mering (1902)

Salvarsan, Paul Ehrlich (1910)

5. First World War and the interwar period

- 1914-1918:
  - World trade crisis.
  - US seized German patents and gained a reputation in the pharmaceutical industry.



Vitamins

- Concept of deficiency disease (1900-1920).
- Casimir Funk (1884-1967): notion of vitamin (*vita*/amine) (1912). Studies on *beriberi* and vitamin B. Obtained crystallised B1 in the 1930s.
- Studies on scurvy (suffered by sailors).
- In 1933 Albert Szent-Györgyi isolated ascorbic acid (vitamin C) and received the Nobel prize in 1937.
- Rickets: cod liver oil (vitamin D).

Insulin

- Studies on the cause of diabetes and the function of the pancreas (1886-1890).
- Isolation of insulin as an internal secretion of the pancreas: Frederick Grant Banting and Charles Best (1921).
- First trials in 1922: self-experimentation and a 12-year-old diabetic child.
- Pure insulin obtained in 1923-1926 and first therapeutic trials.
- Determination of the chemical structure (1945-1955).
- Development of synthetic forms (1966-1978).

Other hormones

- Adrenaline (1901), thyroxine (1915-1916), and androsterone (1927, synthesised in 1934).
- 1930: Synthesis of other hormones (testosterone, 1935).
- 1960: Contraceptives.

Jokichi Takamine (1854-1922)

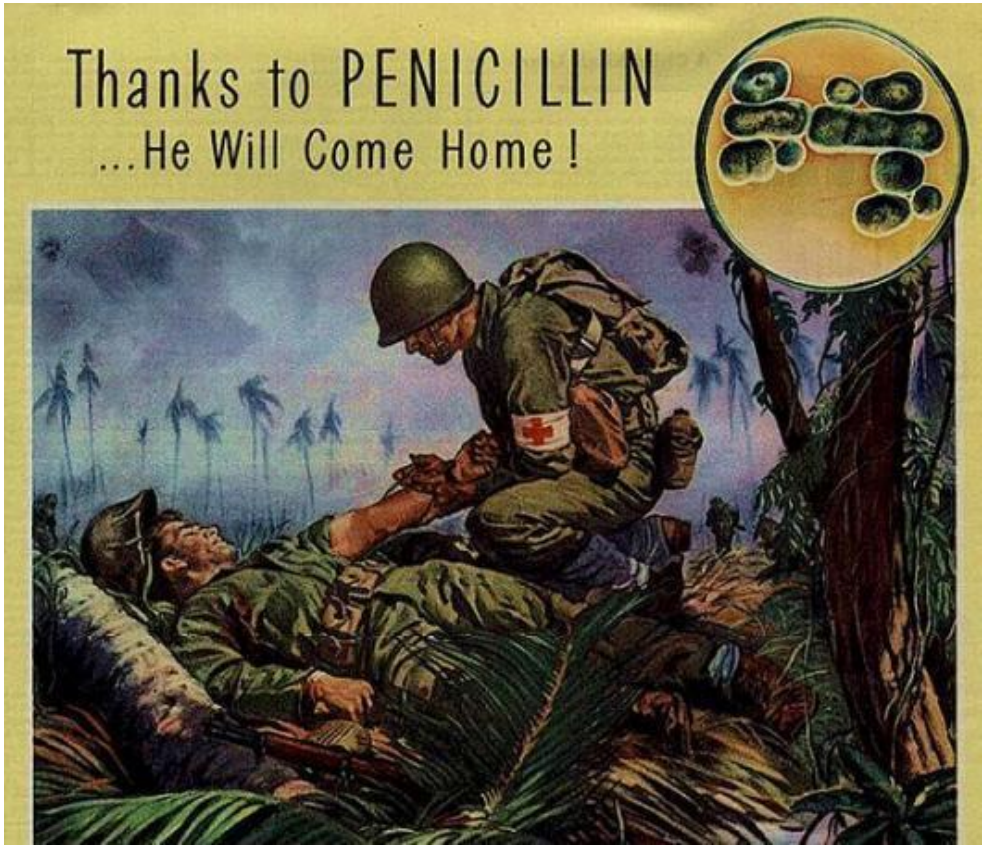
The pharmaceutical market 1918-1939

- Concentration of industries: creation of IG Farben (1925) in Germany and Imperial Chemical Industries (1926) in the United Kingdom.
- Market dominance by Germany (39%), US (13%) and the United Kingdom (12%).

IG Farben's Board of Directors, Hermann Groeber (1926)

6. Second World War

- The age of antibiotics:
  - Sulfamides.
  - Penicillin.
  - Streptomycin (Selman Waksman and Albert Schatz, 1943).
  - Tetracyclines (1948-1952).



7. Developments since 1950

- Expansion of the world market with American predominance and intense concentration of business (multinationals with huge investments in marketing and advertising).
- Consolidation of the system of patents and trademarks.
- Facultative prescription system: national health systems (greater access), population growth, and longer life expectancy (higher pharmaceutical costs).
- New products: cortisone (Merck), psychoactive drugs, biotech products (*discovery by design*).
- Greater regulation of pharmaceuticals.

The thalidomide affair (1957-1963)

Novartis (founded in 1996 from the fusion of CIBA Geigy and Sandoz)

Ranking de empresas farmacéuticas en España

En millones de euros

Mercado farmacéutico total

	Ventas en 2014	Variación en % 2014/2013	Cuota de mercado (%)
Novartis	**1.075**	4,2	6,8
Pfizer	**1.025**	1,8	6,5
Johnson & Johnson	**867**	5,8	5,5
Merck & Co.	**823**	0,9	5,2
Roche	**641**	-6,8	4,1
Sanofi	**638**	3,6	4,0
GlaxoSmithKline	**610**	1,3	3,9
Gilead Sciences	**477**	11,2	3,0
Abbvie	**427**	1,9	2,7
Teva	**381**	-4,3	2,4
Otros (274)	**8.828**	2,2	55,9
TOTAL	**15.792**	2,1	100,0

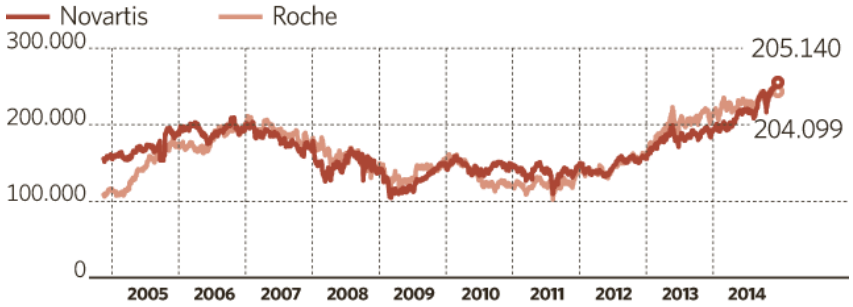
NOVARTIS: Listado de los fármacos principales

		Nuevos dd 2007	Tratamiento	Mn USD 2T15 (ex FX)	
1	Gleevec/Glivec		Leucemia	1.184	6%
2	Gilenya	x	Sclerosis	700	26%
3	Lucentis	x	Macular	537	2%
4	Afinitor	x	Renal carcinoma	423	19%
5	Sandostatin		Acromegaly	413	9%
6	Tasinga	x	Leucemia	412	21%
7	Diovan / +HTC		Hipertensión	333	-52%
8	Galvus		Diabetes	273	-1%
9	Exforge		Hipertensión	272	-16%
10	Exjade		Iron Chelator	262	17%
11	Exelon/ExelonPatch		Alzheimer	208	-8%
12	Xolair		Asma	194	18%
13	Votrient (GSK)		Renal carcinoma	165	ns
14	Neoral/Sandimmun		Transplantes	145	-7%
15	Voltaren		Antinflamatorio	136	4%
16	Tafinlar/Mekinist (GSK)		Melanoma	131	ns
17	Ritalin/Focalin		Déficit atención	108	-13%
18	Myfortic		Transplantes	100	-6%
19	Jakavi	x	Myelofibrosis	98	68%
20	Femara		Pecho	80	-1%
	Top 20			6.174	
	Resto			1.673	
	TOTAL			**7.847**	

Oncología
Específicos
General

Los dos gigantes que valen más de 200.000 millones

Se revaloriza un 30% en 2014



Sólo tres recomendaciones de compra

	COMPAÑÍA	PUESTO	CAPITALIZACIÓN (MILL. €)	EVOLUCIÓN (%)	REC.*
NOVARTIS	Novartis	4	205.140	30,5	M
Roche	Roche	1	204.099	16,5	C
Nestlé	Nestle	2	191.917	11,7	M
	Royal Dutch Shell	3	183.286	8,4	C
HSBC	HSBC	5	153.822	2,6	M
	Anheuser-Busch	6	148.666	19,7	M
TOTAL	Total	8	113.411	7,2	M
bp	BP	7	101.720	−7,0	M
sanofi aventis	Sanofi	9	101.116	−1,0	M
BAYER	Bayer	10	97.414	15,5	C

(*) Recomendación del consenso de mercado: C Comprar M Mantener V Vender

Pipeline has exciting near-term milestones

1 2 3 4 5

Strengthen **Innovation**

Molecule	Indication	MoA	Expected Readout	Potential blockbuster?
LEE011 (ribociclib)	HR+ HER2- advanced breast cancer	CDK4/6 inhibitor	Q4 2016 (PIII)	✓
OAP030 (Fovista®)	Neovascular AMD	Aptamer anti-PDGF	Q4 2016 (PIII)	✓
AMG 334[1]	Prophylaxis of migraine	CGRP receptor antagonist	H2 2016 (PIIb, PIII)[2]	✓
RLX030 (serelaxin)	Acute heart failure	Relaxin receptor agonist	H1 2017 (PIII)	✓

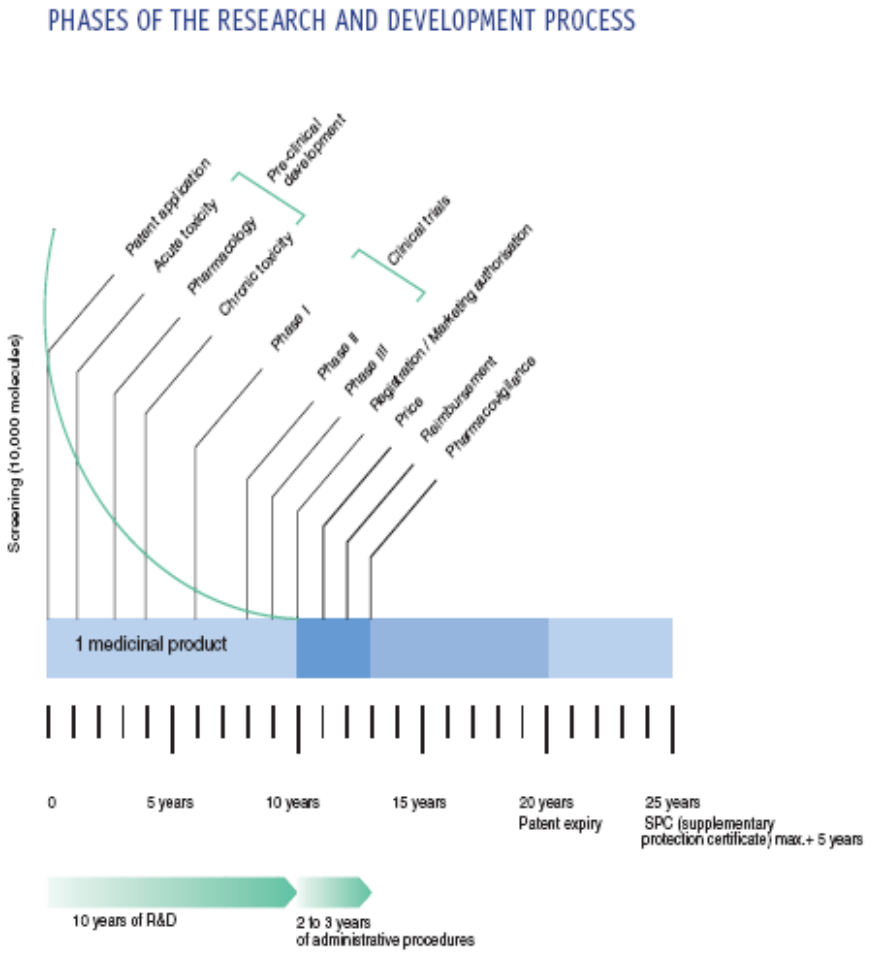
[1] *In collaboration with Amgen; Novartis has AMG 334 rights outside of US, Canada and Japan*
[2] *PIIb for chronic migraine, PIII for episodic migraine*

NOVARTIS

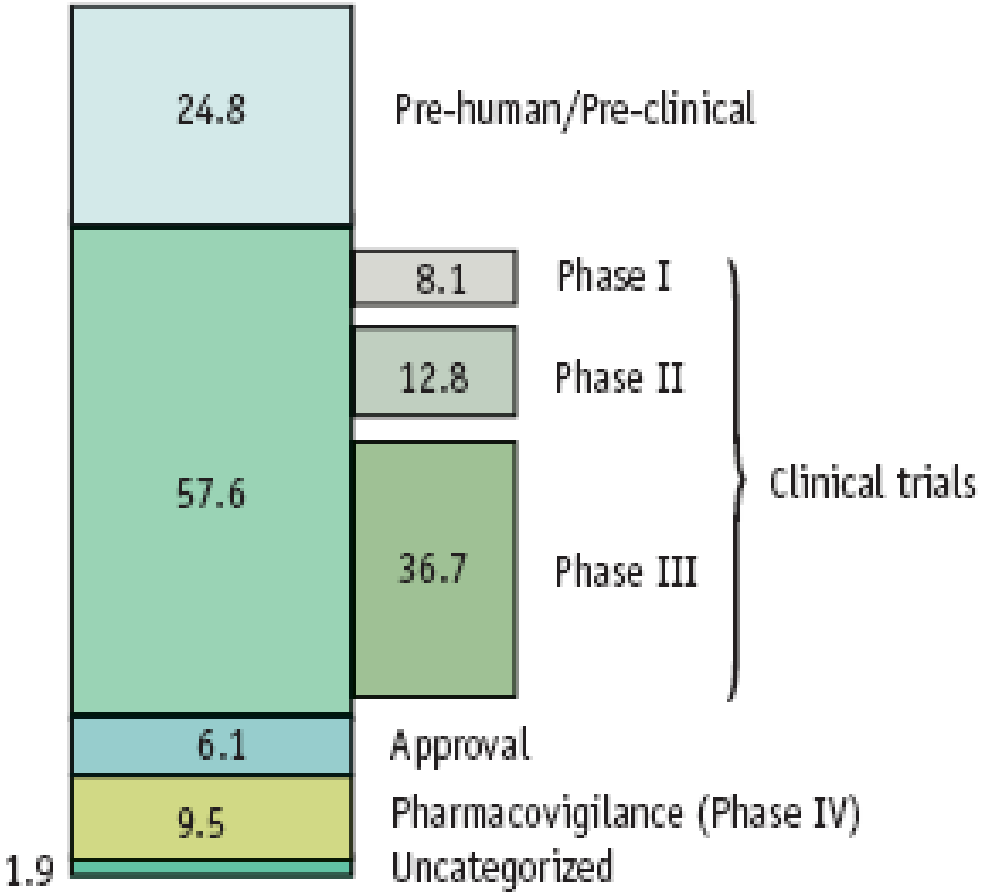
8. The current situation

- Concentration of large multinationals.
- High cost of producing drugs.
- Large investment in research and development.
- United States and Europe lead production and spending.
- Generic drugs.
- Orphan drugs.

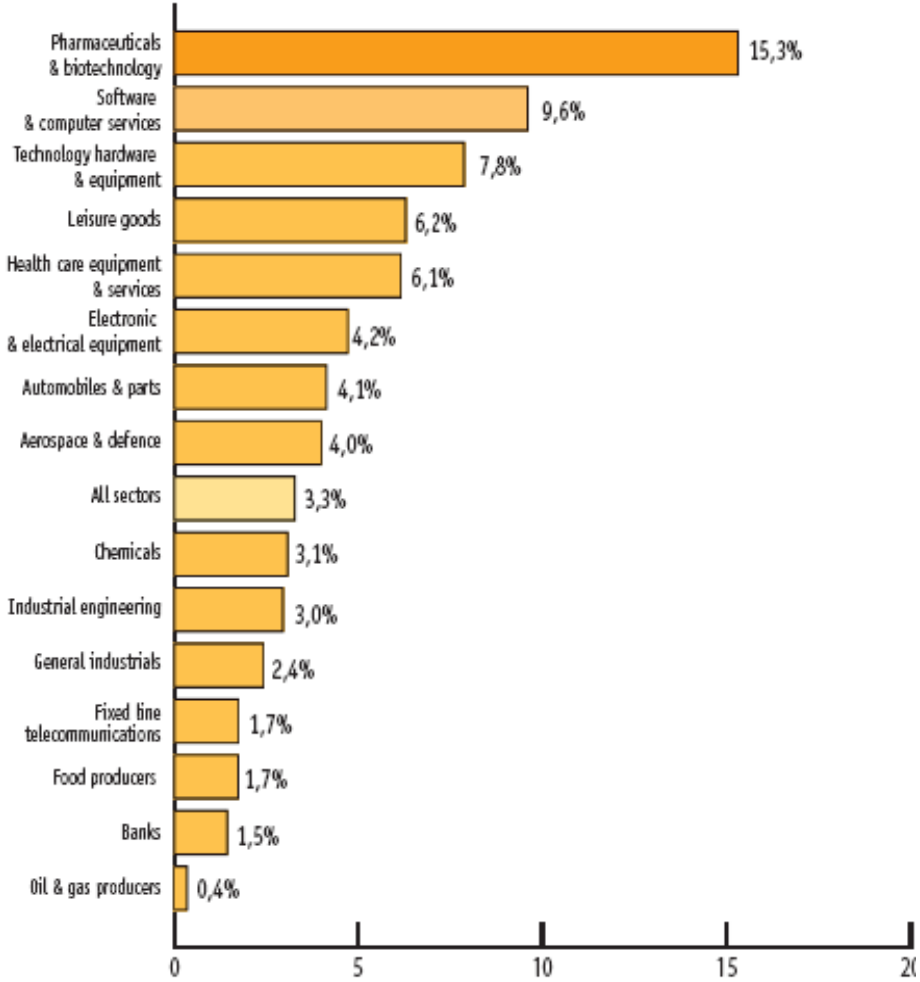
- New medicines take a considerable amount of time and cost a considerable amount of money to produce.
- The average time from first synthesis to arrival on the market is 12-13 years.
- The cost of development was estimated at an average at roughly €1 billion per drug in 2005.
- Only one or two of every 10,000 substances synthesised in the laboratory end up being marketed as drugs.



ALLOCATION OF R&D INVESTMENTS BY FUNCTION (%)



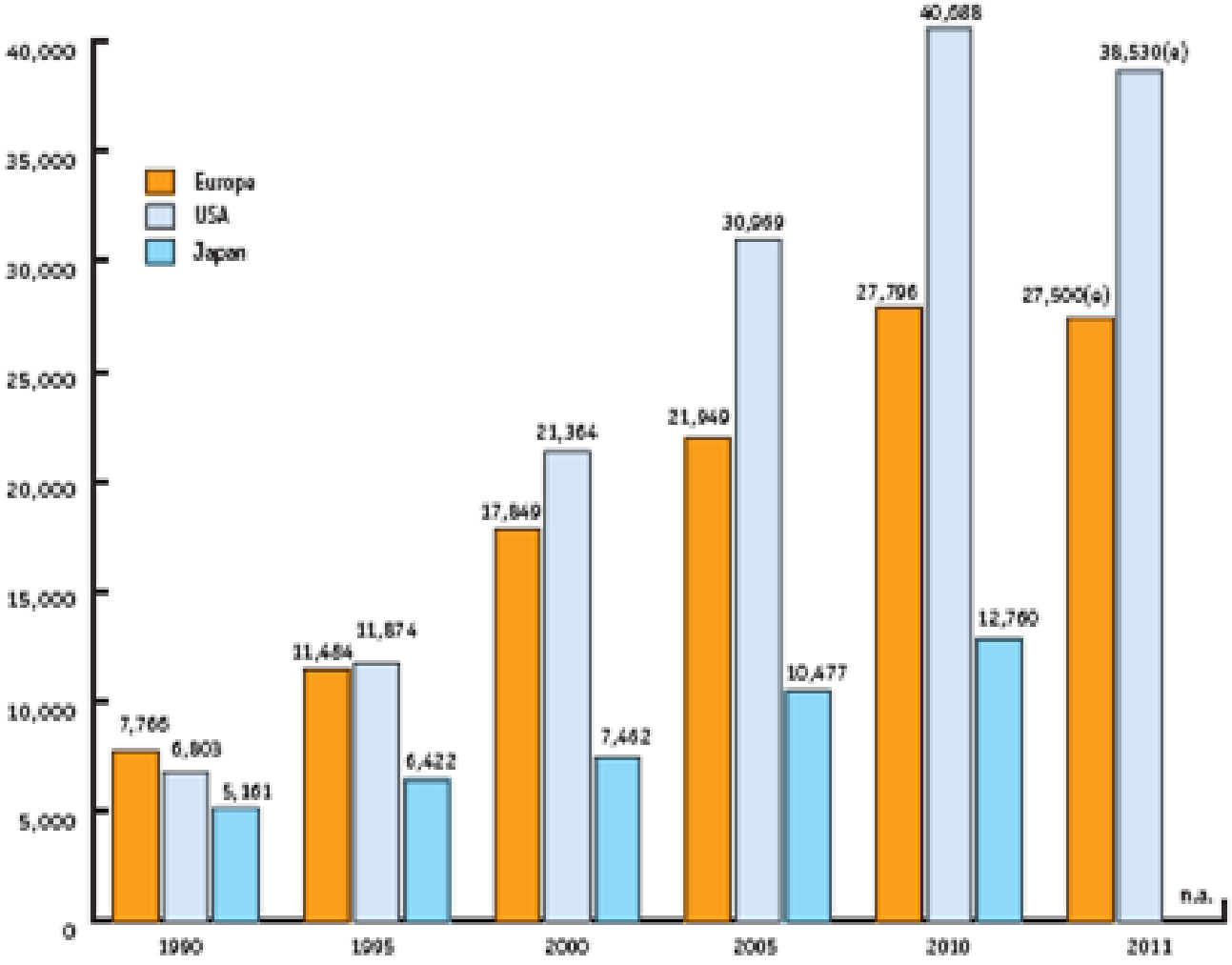
RANKING OF INDUSTRIAL SECTORS BY OVERALL SECTOR R&D INTENSITY (R&D AS PERCENTAGE OF NET SALES – 2010)



Note: Data relate to the top 1,400 companies with registered offices in the EU, Japan, the USA and the Rest of the World, ranked by total worldwide R&D investment

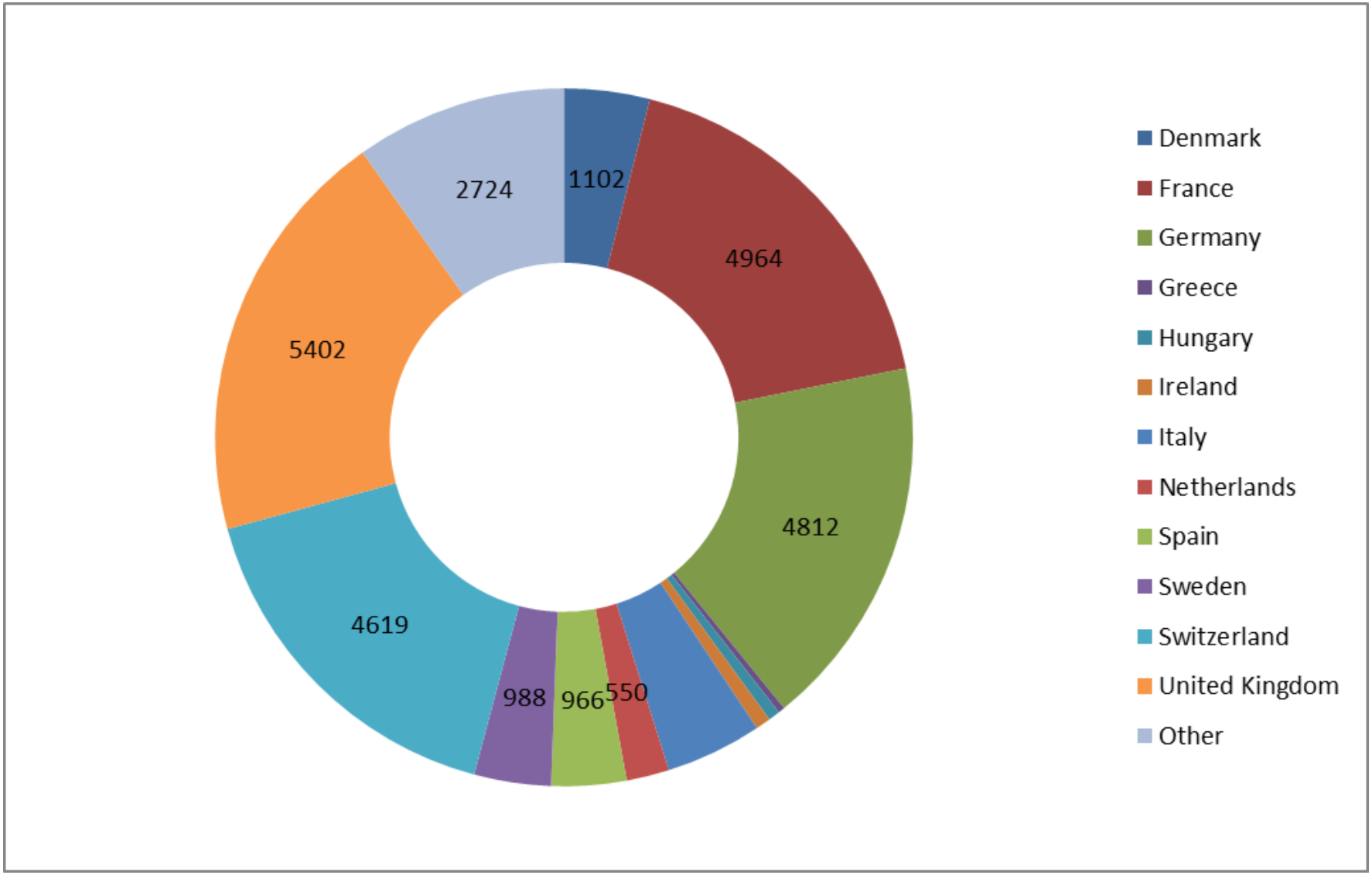
Source: The 2011 EU Industrial R&D Investment Scoreboard, European Commission, JRC/DG Research & Innovation

PHARMACEUTICAL R&D EXPENDITURE IN EUROPE, USA AND JAPAN (MILLION OF NATIONAL CURRENCY UNITS*), 1990-2011



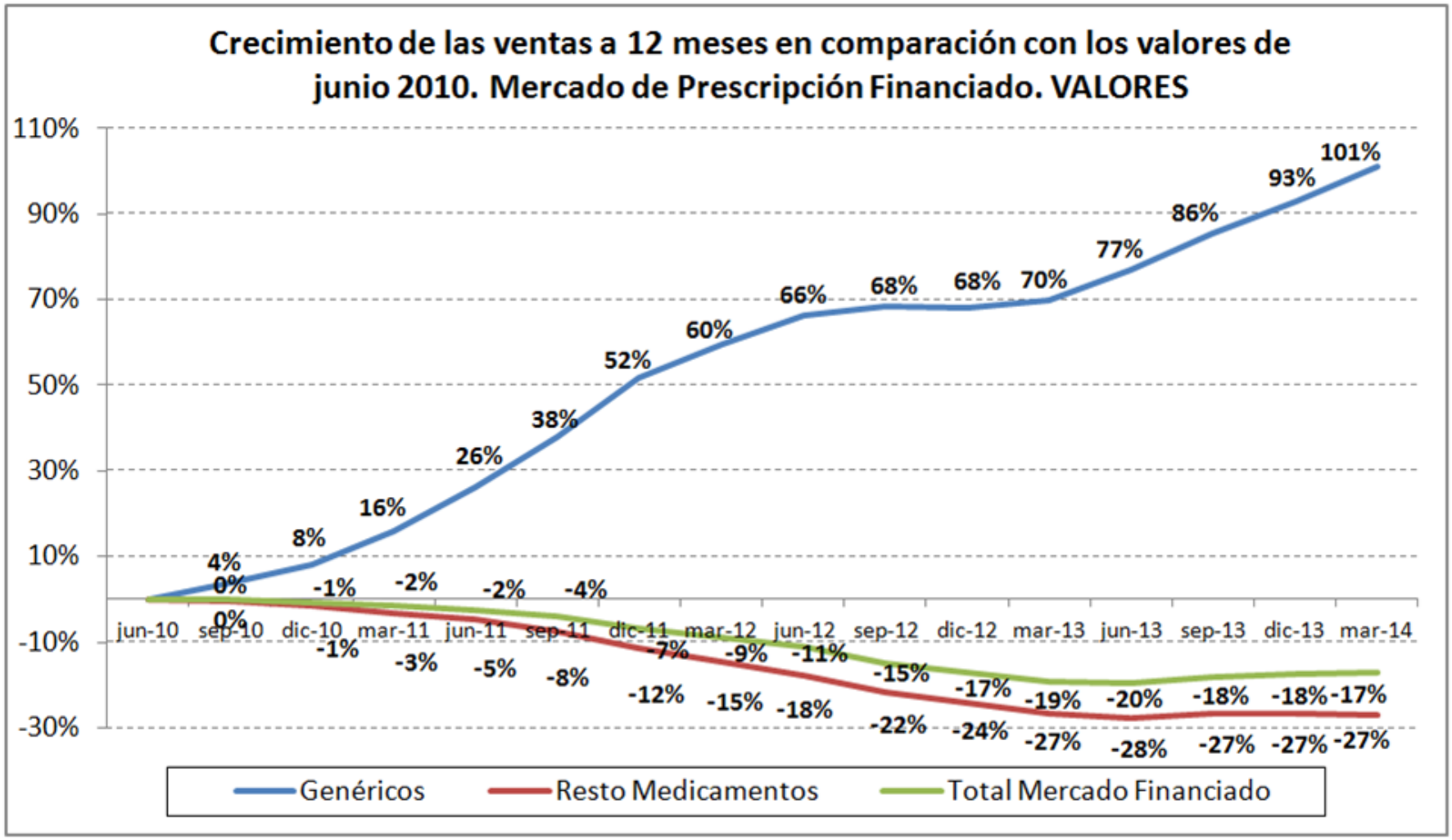
R & D EXPENDITURE OF THE EUROPEAN PHARMACEUTICAL INDUSTRY 2010 (€ million)

efpia
European Federation of Pharmaceutical Industries and Associations

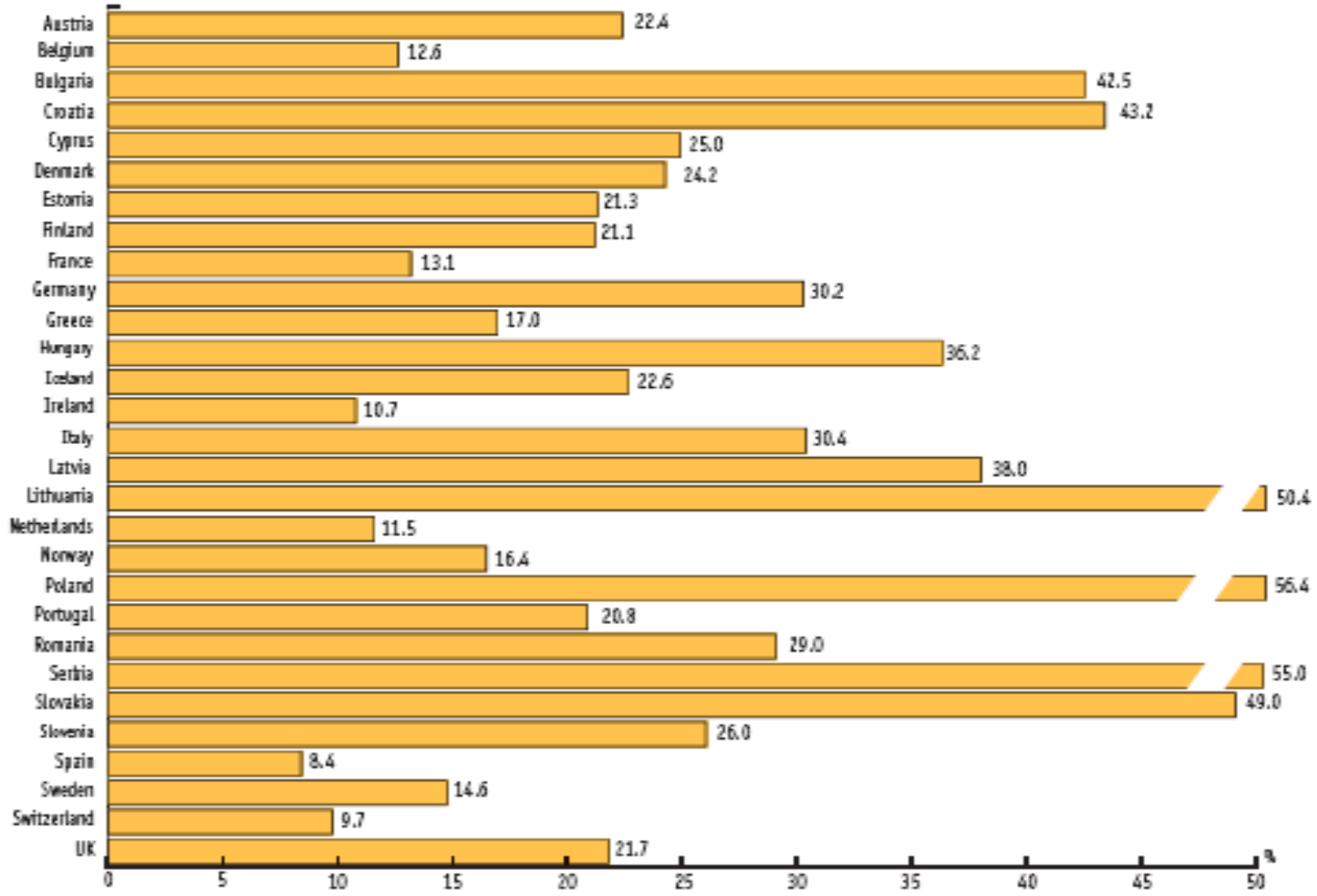


Generic drugs

- Generic drugs have the same pharmacokinetic, pharmacodynamic, and therapeutic characteristics as another drug whose patent has expired and is referred to as the 'reference drug'.
- According to the Law of Guarantees and Rational Use of Medicines and Health Products of 2006 (LGURMPS), a generic drug is "any drug that has the same qualitative and quantitative composition of active principles and the same pharmaceutical form as the reference drug and whose bioequivalence with it has been demonstrated by suitable studies of bioavailability".
- In Spain the percentage of generic drugs used, though increasing, is lower than in other countries.


Crecimiento de las ventas a 12 meses en comparación con los valores de junio 2010. Mercado de Prescripción Financiado. VALORES
110%
90%
70%
50%
30%
10%
-10%
-30%
jun-10
sep-10
dic-10
mar-11
jun-11
sep-11
dic-11
mar-12
jun-12
sep-12
dic-12
mar-13
jun-13
sep-13
dic-13
mar-14
0%
4%
8%
16%
26%
38%
52%
60%
66%
68%
68%
70%
77%
86%
93%
101%
0%
-1%
-2%
-2%
-4%
-7%
-9%
-11%
-15%
-17%
-19%
-20%
-18%
-18%
-17%
0%
-1%
-3%
-5%
-8%
-12%
-15%
-18%
-22%
-24%
-27%
-28%
-27%
-27%
-27%
Genéricos
Resto Medicamentos
Total Mercado Financiado

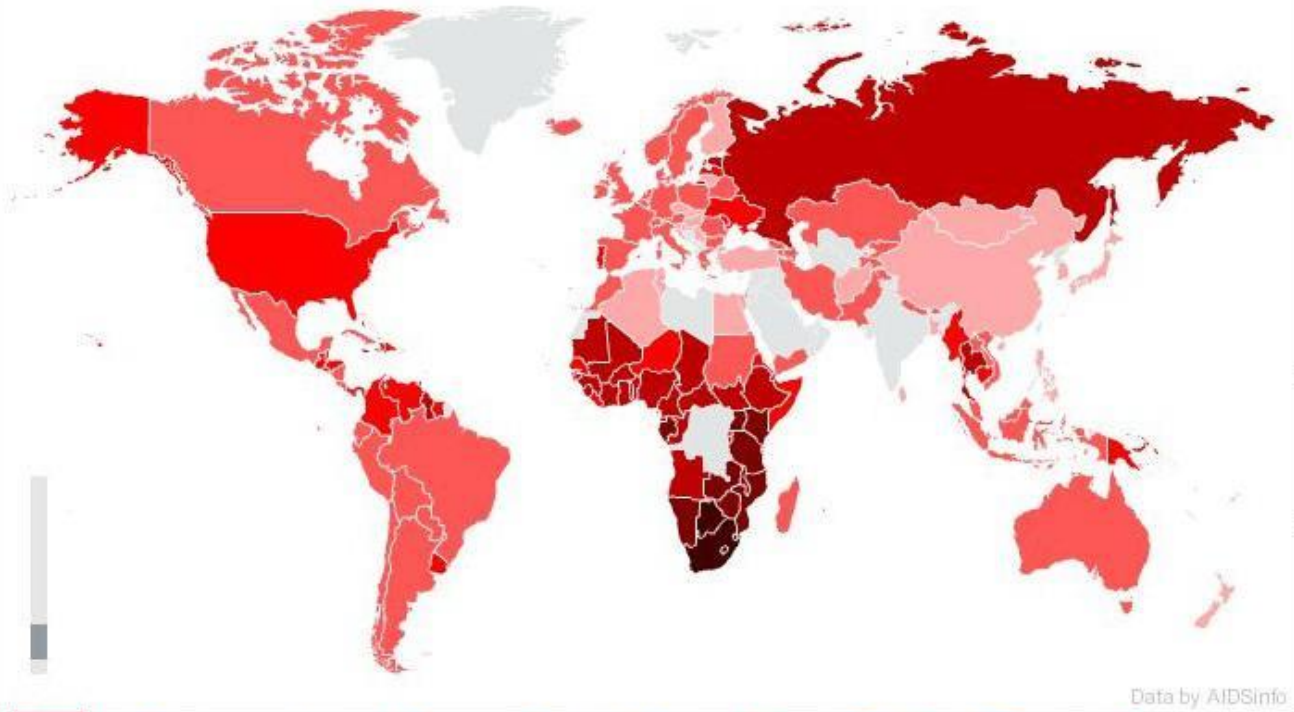
SHARE (ESTIMATE - IN %) ACCOUNTED FOR BY GENERICS IN PHARMACEUTICAL MARKET SALES VALUE (AT EX-FACTORY PRICES), 2010



AIDSinfo

subjects | country profiles

EPIDEMIOLOGICAL STATUS



legend

Estimated HIV Prevalence

- 15.0% - 28.0%
- 5.0% - <15.0%
- 1.0% - <5.0%
- 0.5% - <1.0%
- 0.1% - <0.5%
- <0.1%
- No data

People living with HIV

time 2011

1990 — 2011

ranking 123 ABC

1	Swaziland
2	Botswana
3	Lesotho
4	South Africa
5	Zimbabwe
6	Namibia
7	Zambia

World Overview

- In 2000 the South African government, led by President Thabo Mbeki and the African National Congress, said it could not afford medicines and accused multinational drug companies of trying to benefit from the AIDS crisis in Africa.
- In 2001 the South African Association of Pharmaceutical Laboratories (PMA) began a legal battle against the government by appealing against a 1997 law that attempted to make AIDS drugs less expensive.
- Authorities sought to obtain drugs to combat disease through importation or local production. However, the PMA, which comprises 42 national and multinational companies, opposed the law due to an 'infringement' of international patent rights.

Treatment Action Campaign (founded in 1998 to demand free treatment)

Orphan drugs

- Orphan drugs are products that serve to diagnose, prevent, or treat very serious and rare diseases or disorders.
- They are called 'orphans' because the pharmaceutical industry has little interest, under normal market conditions, in developing and marketing them.
- The criteria for a drug to be declared an 'orphan' are:
  - In the United States: it is useful for treating a disease with less than 200,000 patients/year and a prevalence of 7.5/10,000 inhabitants.
  - In Japan: less than 50,000 patients/year; 4/10,000 inhabitants
  - In Australia: less than 2,000 patients/year; 1.1/10,000 inhabitants
  - In the EU: less than 185,000 patients/year; 5.0/10,000 inhabitants

Las mordeduras de serpiente, la nueva epidemia de África

- Se agotan las existencias del antiveneno más eficaz, que dejará de fabricarse en 2016
- El ébola sobrevive escondido en el ojo de un médico

GUILLERMO ALTARES | Madrid | 8 SEP 2015 - 18:53 CEST

Archivado en: Venenos Sustancias tóxicas Intoxicación Farmacia Investigación científica África Enfermedades Animales Medicina Sanidad Fauna Salud Ciencia Especies

Mamba negra, una de las serpientes más venenosas de África. / C.J. LONIDES

Parece una de las plagas de Egipto, pero es una realidad a la que se enfrentan cada día miles de seres humanos: 100.000 personas mueren cada año en el mundo por picaduras de serpiente, 30.000 de ellas en África. Según ha difundido hoy la organización Médicos sin Fronteras, la situación podría empeorar radicalmente en los próximos años ya que las existencias del antiveneno más eficaz de África subsahariana, Fav-Afrique, se agotan en 2016 y ya ha dejado de fabricarse.

Sanofi dejó de producir este antiveneno en 2014 y las últimas existencias caducarán en 2016. Preguntado sobre el motivo por el que esta antitoxina dejará de fabricarse, Alain Bernal, director de Comunicación de Sanofi Pasteur, explica que se abandonó su producción "en un contexto en el que existían otros productores capaces de responder a las necesidades mundiales". "Desde 2006, los productores que competían con Fav-Afrique se han multiplicado con unas condiciones de precios con las que Sanofi no podía alinearse", prosigue Bernal.

> Sanofi explica que abandonó la producción "en un contexto en el que existían otros productores capaces de responder a las necesidades mundiales"

MSF sostiene, en cambio, que ningún otro remedio es tan eficaz y, aunque se venden otros antivenenos en África, "su seguridad y su eficacia no han sido establecidas apropiadamente". Según los datos de la organización humanitaria, en total cinco millones de personas son mordidas por serpientes en el mundo cada año. Además de los muertos, 400.000 personas quedan incapacitadas o desfiguradas y unas 8.000 sufren amputaciones.

El producto cuesta entre 250 y 300 euros, un precio desorbitado en la inmensa mayoría de los países que sufren esta plaga, cuyos habitantes solo pueden acceder al medicamento si cuentan con la ayuda de una ONG o, como ocurre en el caso de Suráfrica, si está subvencionado por el Gobierno. Para Alcoba, "la solución pasa por inversiones". "Hay que subvencionarlo, como ocurre con otros medicamentos, o facilitar la producción de genéricos", explica este experto en medicina tropical.

Theme 15. Intellectual property: patents

Introduction

The intellectual property system offers incentives to inventors and creators by acknowledging and rewarding their efforts while stimulating research and the development of new products and services. It thus helps to strike a balance between the rights of inventors and public interest, creating a mechanism for guaranteeing society's access to the results of innovation.

The World Intellectual Property Organization (WIPO), based in Geneva (Switzerland), oversees the protection of intellectual property in its 182 member states.

In the sphere of public health, WIPO has implemented important agreements for the availability and accessibility of essential medicines. However, the combination of inventors' rights and World Trade Organization rules may lead to decisions that have adverse consequences on public health. One example is found in relation to generic drugs for preventing or treating endemic diseases and epidemics in low-income countries (e.g. AIDS in Africa). Another example are the exorbitant prices for certain drugs for national health systems, which could endanger the health system if the aim is to treat the entire sick population (e.g. Sovaldi for treating hepatitis C).

The law stipulates that intellectual property rights (invention patents) should generally be protected for 20 years. This could prevent the transfer of technology to low-income countries that need it, increase the cost of treatments in developed countries, and endanger national health systems, especially in times of economic crisis.

The current global pricing system encourages the industry to set the price of new patent-protected medicines at levels the market can bear in order to obtain maximum profit. Moreover, the system enables prices to first be negotiated in countries such as the USA, thus guaranteeing a high starting price that does not need governmental agreement, before negotiations are held in each country individually. This strategy leads to the sequential launch of new drugs, which are sold first in the main markets while their entry into smaller countries at lower prices is delayed. The prices for these drugs may therefore differ among high-income countries, with variations that can fluctuate between 28% and 388%.

Contents

Objectives

- To learn how the intellectual property system works and understand the role of pharmaceutical patent rights in access to drugs.
- To consider whether setting the prices of drugs in open markets with competitive trading is the right way forward with oligopolies, states as the main purchasers, and products that are vital for people's survival.

Preliminary activity

The World Intellectual Property Organization (WIPO) has a Standing Committee on the Law of Patents, which deals with issues related to patent law. From 21 to 25 May 2012, members and observers of this committee met in Geneva to discuss the issue of patents and health. Acting as observer was Knowledge Ecology International (KEI), a non-profit non-governmental organisation focused on social justice, especially for the most vulnerable sectors including the poor and marginalised. In 2006, KEI won the MacArthur Award for Creative and Effective Institutions for its work in advancing the public interest in intellectual property policy.

Durante la decimosexta sesión del Comité Permanente sobre el Derecho de Patentes (SCP), Sudáfrica, haciendo uso de la palabra en nombre del Grupo Africano y del Grupo de la Agenda para el Desarrollo (DAG), presentó una propuesta sobre el tema de las patentes y la salud (SCP/16/7). En respuesta a dicha propuesta, los Estados Unidos presentaron su propia propuesta (SCP/17/11), durante la decimoséptima sesión, celebrada del 5 al 9 de diciembre de 2011. KEI reitera su apoyo a la propuesta del Grupo Africano y el DAG, tal como lo expresara en su comentario del 12 de septiembre de 2011, enviado al SCP.1 KEI también señala su preocupación por los intentos del Gobierno de los Estados Unidos de restar peso a los retos y las barreras con los que se enfrentan los pacientes a la hora de acceder a medicamentos a causa de las patentes relativas a tecnologías médicas.

Las propuestas presentadas en el SCP deben situarse en el contexto de los instrumentos internacionales existentes, en los que se estipulan los compromisos y las obligaciones en la materia. **El Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (Acuerdo sobre los ADPIC) crea una norma mundial en materia de protección de la propiedad intelectual**. Tras la entrada en vigor de los ADPIC, se formularon otros compromisos internacionales igualmente importantes en lo que respecta a la salud pública.

La Declaración de Doha relativa al Acuerdo sobre los ADPIC **y la Salud Pública** (en adelante, la Declaración de Doha) señala que el Acuerdo sobre los ADPIC "***puede y deberá ser interpretado y aplicado de una manera que apoye el derecho de los Miembros de la OMC de proteger la salud pública y, en particular, de promover el acceso a los medicamentos para todos***." Del mismo modo, en la Estrategia mundial y el plan de acción sobre salud pública, innovación y propiedad intelectual de la Organización Mundial de la Salud, adoptados en 2008, ***se hace un llamamiento a los Estados miembros para que promuevan el acceso a los medicamentos para todos*** (párrafo 15.e).

En su propuesta, los Estados Unidos señalan que es necesario realizar estudios y ponencias sobre las barreras distintas de las patentes, y desean documentar la incidencia positiva del sistema de patentes y los factores que influyen en el acceso a los medicamentos distintos de las patentes con miras a determinar "***qué efecto, si lo hubiere, tienen las patentes en la disponibilidad de los medicamentos***". **Es bien sabido y esta sobradamente documentado que el sistema de patentes ofrece derechos monopolísticos sobre medicamentos que salvan vidas, y dichos monopolios provocan un auge de los precios**. Al pedir al SCP que se centre exclusivamente en pruebas exculpatorias a fin de ofrecer una imagen halagüeña de un sistema de patentes basado en derechos fuertes, **los Estados Unidos intentan menoscabar la atención que se está prestando a aquellos cambios cuya introducción es necesaria para lograr el "acceso a la medicina para todos".**

La Lista de Medicamentos Esenciales (LME) de la Organización Mundial de la Salud

Para respaldar su propuesta, los Estados Unidos señalan que solo el 4% de los medicamentos que se encuentran en la Lista de Medicamentos Esenciales (LME) de la OMS están actualmente protegidos por patentes, y sugiere que la escasez de medicamentos patentados en la lista de la OMS significa que las patentes sobre medicamentos no son importantes para los pacientes. Los comentarios sobre la LME

ilustran, en el mejor de los casos, los escasos conocimientos del Gobierno estadounidense sobre la cuestión del acceso a los medicamentos. **Exceptuando los medicamentos para tratar el VIH/SIDA, que solo fueron añadidos a la LME a raíz de las amplias campañas desplegadas por los activistas de la lucha contra el SIDA, prácticamente no se han incluido medicamentos patentados en la LME**. ¿A qué se debe? ¿Acaso cree el Gobierno de los Estados Unidos que las personas pobres de los países en desarrollo no usarían los medicamentos patentados si fueran asequibles? Cabe recordar ciertos datos en relación con la medicación contra el cáncer.

En 2011, Paul Miano examinó los 100 medicamentos contra el cáncer que los Institutos Nacionales de Salud (NIH) de los Estados Unidos consideran importantes (véase Cancer: Approval, ownership, market structure, and placement on WHO Model Essential Medicamentos List, for 100 new molecular entities (NMEs) on the NCI alpha list of cancer drugs and vaccines, Nota de investigación KEI 2011:1). **Según Miano, más de la mitad de esos 100 medicamentos importantes contra el cáncer fueron registrados por primera vez en la FDA para su venta en los Estados Unidos después de enero de 2000, y aproximadamente los dos tercios son productos del mismo proveedor, lo cual sugiere que se han protegido contra la competencia por medio de patentes u otros derechos de propiedad intelectual. Si alguno de los autores de la propuesta estadounidense o alguno de sus familiares tuvieran cáncer, ¿desearían tener acceso a todos los medicamentos de la lista, o solo a un tercio de ellos**?

La Lista Modelo de Medicamentos Esenciales de la OMS para 2011 no incluye ningún fármaco contra el cáncer en la lista principal, y 20 en la lista complementaria. El producto más reciente de la LME de la OMS incluido también por los NIH de Estados Unidos entre los 100 productos más importantes fue registrado por la FDA en 1996, y todos los medicamentos contra el cáncer incluidos en la LME están libres de patentes**. Insinuar que ningún fármaco patentado contra el cáncer es "esencial" equivale a decir que las vidas de las personas pobres que sufren algún cáncer tampoco son esenciales, o que esos productos son sencillamente demasiado costosos para justificar su uso en entornos con escasos recursos. Pero cuando los productos dejan de estar protegidos por patente, suelen incluirse en la lista. Lo que dicen los Estados Unidos es que las personas pobres pueden esperar hasta que sus patentes dejen de estar vigentes para usar esos productos. Para muchos pacientes con cáncer, eso significa morir.**

Si los Estados Unidos hubieran celebrado consultas más amplias con los grupos de defensa de la salud, jamás habrían afirmado en la propuesta presentada al SCP de la OMPI que la falta de medicamentos patentados en la LME demuestra más que el hecho de que las patentes encarecen excesivamente esos medicamentos. **El hecho de que no se incluyan medicamentos patentados contra el cáncer en la LME no significa que los pobres no sufren cáncer, ni que los nuevos medicamentos no funcionan. Significa que las patentes disparan los precios de tal manera que las personas pobres no tienen acceso a esos fármacos.**

En otra parte de su propuesta, los Estados Unidos afirman que la expedición de licencias obligatorias sobre patentes "no propiciará la colaboración del propietario de la patente", y al beneficiario de la licencia obligatoria "quizá no le resulte fácil fabricar con éxito el medicamento". No cabe duda de que así es, pero todo lo señalado también es aplicable cuando ha vencido la patente. En ambos casos, la ley autoriza la libre fabricación de versiones genéricas y la libre competencia. Está amplia e indudablemente probado que la eliminación de los obstáculos jurídicos permite promover eficazmente la competencia y reducir los precios. No cabe duda de que así ocurre en los Estados Unidos, donde, según la GphA, 10.072 de los 12.751 medicamentos incluidos en el Libro Naranja de la FDA cuentan con equivalentes genéricos, y los genéricos aparecen en el 69% de todas las recetas, pero solo representan el 16% de la inversión en medicamentos bajo receta. **Los Estados Unidos podrían preguntar cuántos medicamentos contra el cáncer incluidos en la lista de medicamentos importantes para tratar el cáncer de los NIH están disponibles en versión genérica, y preguntar qué se debe hacer para elevar su número, en lugar de sugerir que resulta imposible acceder a ellos en forma de genéricos.**

[...]

La propuesta de los Estados Unidos parece minimizar las barreras creadas por las patentes, y cita varios programas humanitarios y actividades voluntarias relacionados con el SIDA en guisa de sustitutos de las políticas gubernamentales para garantizar el acceso a los medicamentos. **La propuesta de los Estados Unidos se hace eco del punto de vista de las grandes empresas farmacéuticas y pasa por alto el de los grupos de defensa de la salud pública, el desarrollo y el consumidor, expertos en la problemática del acceso a los medicamentos.** KEI se siente sumamente decepcionada por la propuesta presentada por los Estados Unidos al SCP.

Además, a pesar de expresar su preocupación con respecto a las barreras distintas de las patentes que impiden el acceso a los medicamentos, los Estados Unidos hacen caso omiso de los mecanismos distintos de las patentes que conceden derechos adicionales a los titulares de derechos. Por ejemplo, **la propuesta de los Estados Unidos no tiene en cuenta los derechos exclusivos sobre los resultados de ensayos, una práctica que en realidad amplía el poder de monopolio sobre los medicamentos**. La propuesta de los Estados Unidos no plantea una justificación ni aborda las consecuencias de sus esfuerzos por cambiar las normas mundiales sobre la propiedad intelectual fuera de instituciones multilaterales como la OMPI y la OMC. Los Estados Unidos han ofrecido a los países con mercados más reducidos el acceso preferencial a su mercado a cambio de un grado de protección y observancia en materia de patentes superior al que exigen sus obligaciones internacionales. El ejemplo más reciente de lo anterior es la negociación secreta del Acuerdo Estratégico Transpacífico de Asociación Económica. **Los Estados Unidos también elaboran, para su Informe Especial 301, una clasificación anual unilateral de países que no suelen aplicar las normas en materia de propiedad intelectual sobre los resultados de ensayos farmacéuticos y la patentabilidad de los medicamentos que van más allá de los requisitos de los acuerdos internacionales, tales como los ADPIC, y que violan la ética médica y encarecen los medicamentos.**

Font: Document: LAS PATENTES Y LA SALUD: COMENTARIOS RECIBIDOS DE LOS MIEMBROS Y OBSERVADORES DEL COMITÉ PERMANENTE SOBRE EL DERECHO DE PATENTES (SCP). Accessible online a: https://www.wipo.int/edocs/mdocs/scp/es/scp_18/scp_18_inf_3.pdf

List of Essential Medicines (LEM) is an inventory of medicines used to treat urgent world health problems. The medicines are identified via a process based on scientific tests, in the context of quality, safety, effectiveness and cost-efficiency, which are fundamental selection criteria. The World Health Organization (WHO) has been publishing the List of Essential Medicines since 1977 to combat the global burden of disease. The list is revised every two years to reflect new healthcare challenges, thus providing member states with a reference that they can adapt to their national needs. The first list, created in 1977, included 208 essential medicines. The list for 2019 included 460 medicines for treating priority diseases such as malaria, HIV/AIDS, tuberculosis, and reproductive health disorders, new antibiotics, and medicines for treating the increasingly common chronic diseases such as cancer, diabetes and cerebrovascular diseases (see the latest list at: https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf).

In Spain, in December 2018, Marta Sibina Campos, a member of the Spanish parliament for Girona during the 12th Legislature (2016 to 2019), published a video in which she denounced both the extortionate prices pharmaceutical companies set for certain patent-protected medicines and the policy that is followed in this area: https://www.youtube.com/watch?v=RjNnyJ_c2MU&feature=youtu.be

Points to consider

Read the official proposal by Knowledge Ecology International to the WIPO's Standing Committee on the Law of Patents and watch the video by the former Spanish member of parliament. Then answer the following questions:

1. How many people infected by HIV/AIDS died in developing countries before the WHO agreed to include certain patented anti-AIDS drugs in the LEM?
2. What would WHO's LEM be like if it included a new category of "products that are inexpensive if obtained through generics suppliers"?

3. Would Herceptin or Sovaldi appear in WHO's LEM if they cost a lot less? (Note: Herceptin is a drug for treating HER2-positive breast cancer.)
4. Should WHO have pre-classified generic and biosimilar anti-cancer drugs?
5. What can Spain do to bring down the cost of drugs such as Herceptin that are subject to intellectual property rights? Can the pricing issue mentioned by Marta Sibina be resolved? Or do you think the problem is far more complex and requires the involvement of governmental actors, international bodies such as WHO, WIPO's Standing Committee on the Law of Patents, international trade treaties, and the companies who actually hold the patent rights, etc.?

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WHO. (2019). Model List of Essential Medicines. 21st List. Geneva: World Health Organization. Licence: CC BY-NC-SA 3.0 IGO. Online document. Accessible from: https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf

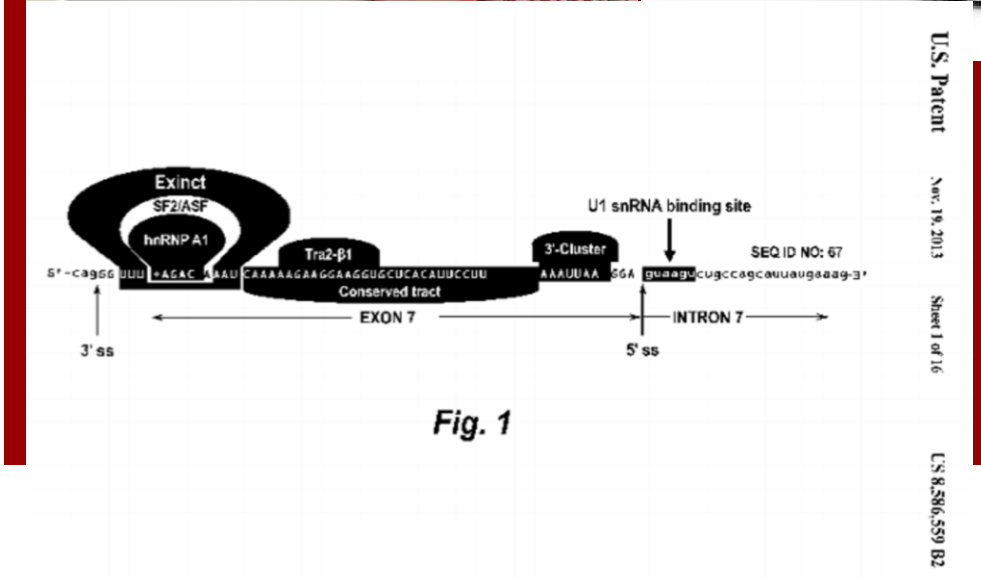

Fig. 1

Theme 15. Intellectual property: patents

Carmel Ferragud, Rafaela Domínguez, Mar Cuenca **Documentation and Scientific Methodology**
History of Science
Degree in Pharmacy

Contents

1. Definition
2. History
3. Patents and the pharmaceutical industry
4. From blockbuster drugs to personalised medicine
5. High prices and inequality

1. Definition

- Intellectual property (IP) is associated with **creations of the mind** e.g. inventions, artistic and literary works, symbols, names and images used in commerce.

- IP is divided into two categories:

- copyright (from books, music, paintings, sculptures and films to computer programs, databases, advertisements, maps and technical drawings).

- industrial property (patents for inventions, trademarks, industrial designs and geographical indications).

For more information, vist:
https://www.wipo.int/edocs/pubdocs/es/intproperty/450/wipo_pub_450.pdf

1. Definition

What is a patent for an invention?

- **a legal title granted by a governmental body that protects a technological invention for a limited period of time** (normally for a maximum of 20 years).
- It grants the holder **the right to prevent third parties** from exploiting the invention in the countries for which it has been granted.
- **Applicants must disclose the details of how their invention works.**
- **All patents are published**; everyone can benefit from the information contained in them and generate knowledge.

1. Definition

(19) OFICINA ESPAÑOLA DE PATENTES Y MARCAS

ESPAÑA

(11) Número de publicación: **2 713 240**

(51) Int. Cl.:

G01N 33/574 (2006.01)

(12) TRADUCCIÓN DE PATENTE EUROPEA T3

(86) Fecha de presentación y número de la solicitud internacional: **16.02.2015 PCT/EP2015/053196**

(87) Fecha y número de publicación internacional: **20.08.2015 WO15121465**

(96) Fecha de presentación y número de la solicitud europea: **16.02.2015 E 15704319 (1)**

(97) Fecha y número de publicación de la concesión europea: **12.12.2018 EP 3108254**

(54) Título: **Proteína asociada a vesícula que interacciona con G-alfa (GIV) como marcador predictivo en cáncer colorrectal de estadio II**

(30) Prioridad:

17.02.2014 US 201461940705 P

(45) Fecha de publicación y mención en BOPI de la traducción de la patente:
20.05.2019

(73) Titular/es:

VENTANA MEDICAL SYSTEMS, INC. (25.0%)
1910 E. Innovation Park Drive
Tucson, Arizona 85755, US;
THE REGENTS OF THE UNIVERSITY OF CALIFORNIA (25.0%);
THE UNITED STATES OF AMERICA AS REPRESENTED BY THE DEPARTMENT OF VETERANS AFFAIRS (25.0%) y
F. HOFFMANN-LA ROCHE AG (25.0%)

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HU, SONG;
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MURANYI, ANDREA y
SHANMUGAM, KANDAVEL

A European patent, granted for all the countries of the European Union. In Spain the patent document is translated into Castilian and published in the BOPI. Source: Espacenet database of the European Patent Office, https://worldwide.espacenet.com

1. Definition

Requirements for patenting

IT IS NOT POSSIBLE TO PATENT:

- Discoveries, scientific theories or mathematical methods.
- Artistic creations.
- Diagrams, rules or methods for carrying out intellectual activities.
- Ways of presenting information.
- Methods for the medical treatment of people or animals (as opposed to medical products).
- Varieties of plants or animals, or essentially biological processes for the production of plants or animals.

1. Definition

Requirements for patenting

- The invention must be **novel**. The application may be rejected if an identical product or process has already been unveiled.
- The details of its invention must have been **published.**
- The invention must involve **inventive activity**. This involves solutions to specific problems that are not obvious for those with an average knowledge of the technical field in question.
- The invention must be suitable for **industrial use.** It cannot be purely theoretical.
- The invention **must not be contrary to public order or morality.**

(http://www.madrimasd.org/blogs/patentesymarcas/2016/las-patentes-el-orden-publico-y-las-buenas-costumbres-primera-parte)

2. History

- Late Middle Ages and Renaissance: monopoly of privileges (patents) granted by the Crown (on the whims and wishes of a monarch).
- The right to make a profit through control of a consumer product, exploration of a new territory or development of an invention.
- The **oldest** known **privilege for an invention** dates back to **1421** (granted by the Republic of Florence to architect Filippo Brunelleschi (1337-1446) for a boat with a crane for carrying marble).
- The **earliest precedent**, the basis for the subsequent **patent law**, was the **Venetian Patent Statute (1474)**: legal protection was granted to inventors for ten years.
- In Spain, the **first privilege for an invention** was **granted for life** in **1522** by King Charles I via Royal Decree to the Catalan inventor Guillén Cabier for an instrument for navigating ships in calm seas.
- The 17th century saw specific legislation on patents for inventions: e.g. the English Statute of Monopolies (1623), which granted exclusive rights, to the first inventor only, for a period of 14 years.

2. History of the WIPO

- The origins of the WIPO date back to 1873 and the International Exhibition of Inventions in Vienna (some inventors and exhibitors did not attend).

- **The first international treaty, signed in 1883, was the Paris Convention** for the **Protection of Industrial Property.** The treaty granted rights to people from one country to have their creations protected in other countries.

- Under the Convention, **intellectual property rights were created for patents, trademarks and industrial designs**. The Convention came into effect in 1884 in just over ten countries (including Spain). https://www.wipo.int/treaties/es/remarks.jsp?cnty_id=313C, an **International Bureau,** was created for administrative purposes.

For more information, visit:
https://www.wipo.int/treaties/es/ip/paris/summary_paris.html ;

https://www.wipo.int/treaties/es/text.jsp?file_id=288515

2. History of the WIPO

- In **1886** the **Berne Convention** was held for the Protection of Artistic and Literary Works, i.e. **the birth of copyright**. An International Bureau was created for administrative purposes.

- In **1893 the United International Bureaux for the Protection of Intellectual Property** (BIRPI) were created in Berne (Switzerland). These were the precursor to the present-day World Intellectual Property Organization. In 1960, the Bureaux were moved from Berne to Geneva in order to be closer to the United Nations.

- In 1970 the International Bureau was created, established by the WIPO Convention. A Secretariat was also set up to take charge of coordination.

- In 1974 the WIPO joined the United Nations.

- In **1978** the International Patent System (IPS) was set up.

- In 1996, the WIPO signed a **cooperation agreement** with the **World Trade Organization** (WTO), which is responsible for the laws that govern trade between countries.

2. History of the OEPM

Source: http://historico.oepm.es/historia_oepm/default.html

HISTORIA DE LA OEPM

LA REAL JUNTA GENERAL DE COMERCIO (1679-1835)

REAL GABINETE DE MÁQUINAS (1788-1808)

EL CONSERVATORIO DE ARTES Y OFICIOS (1810-1814) Y LA DIRECCIÓN DE FOMENTO GENERAL DEL REINO (1820-1823)

REAL CONSERVATORIO DE ARTES (1824-1887)

DE LA DIRECCIÓN ESPECIAL (1887) A LA OEPM (1992)

LA EXISTENCIA LEGAL DE LA OEPM SE REMONTA A TRES REALES DECRETOS DE 1810, 1820 Y 1824, AÑO ESTE ÚLTIMO EN EL QUE, DEFINITIVAMENTE, SE CREA LA INSTITUCIÓN BAJO EL NOMBRE DE REAL CONSERVATORIO DE ARTES Y OFICIOS. NO OBSTANTE, ES POSIBLE ENCONTRAR INTERESANTES ANTECEDENTES DURANTE LOS SIGLOS ANTERIORES Y SEGUIR SU EVOLUCIÓN HASTA LA ACTUALIDAD.

Academia de Bellas Artes, en la calle de Alcalá

Bartolomé Sureda

Francisco Antonio Zea

Ordenanza XII de la Junta de Comercio de Burgos (1766)

Marca nº 575, solicitada por José Bosch y Hermano, de Badalona (Barcelona)

Felipe Bauzá

Luis Mariano de Larra, primer director del BOPI

Oficina Española de Patentes y Marcas

UAM UNIVERSIDAD AUTONOMA DE MADRID

GOBIERNO DE ESPAÑA MINISTERIO DE INDUSTRIA, COMERCIO Y TURISMO

3. Patents and the pharmaceutical industry

- Any new drug, especially for a common disorder, will probably have a world market.
- The profits from a single new drug may be huge and may have an enormous influence on a company's prospects.
- The **profits depend** largely **on patent laws, the competence of competitors, and good fortune** in a company's own research.

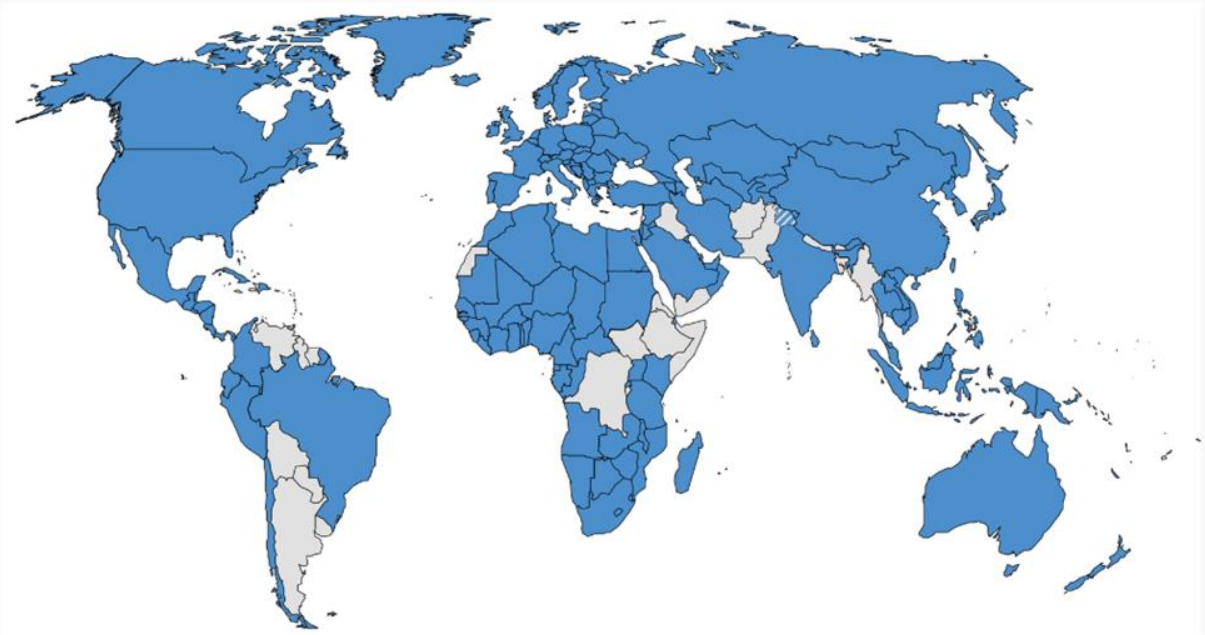
- ***Boehringer*** registered strong growth in its largest business segment with prescription drugs. *Jardiance (diabetes) was* the main driver of growth, increasing sales by almost 45% (roughly 1 billion euros).

- Its competitor ***Sanofi*** has suffered weaknesses in this area. The patent for its most important diabetes medicine, *Lantus*, has expired, and it registered a fall in sales of almost 17% (1.5 billion euros in the first half of 2019). In general, sales of Sanofi in the diabetes business fell by 7%.

3. Patents and the pharmaceutical industry

International Patent System. PCT Treaty. Without the patent system to protect innovations in the field of chemistry and pharmacy, the pharmaceutical industry as we know it today would not exist.

El PCT cuenta actualmente con 153 Estados contratantes



Adhesiones y ratificaciones recientes

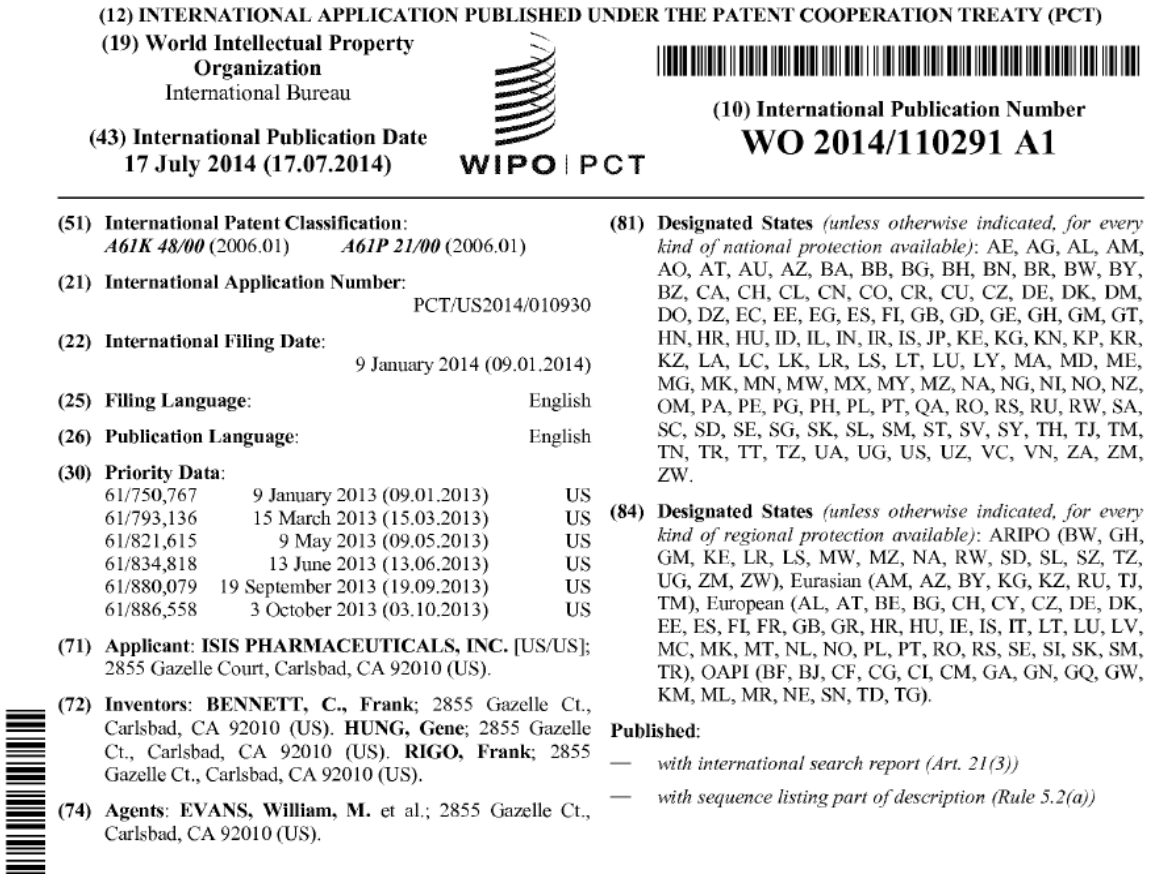
- Samoa, 2 de octubre de 2019 (en inglés) New (quedará obligado el 2 de enero de 2020)
- Jordania, 9 de marzo de 2017(en inglés)
- Camboya, 8 de septiembre de 2016 (en inglés)
- Djibouti, 23 de junio de 2016 (en inglés)
- Kuwait, 9 de junio de 2016 (en inglés)
- Estados que son parte en el Convenio de París, pero no en el PCT (en inglés)

Reducciones en las tasas

https://www.wipo.int/pct/es/pct_contracting_states.html

3. Patents and the pharmaceutical industry

One of the patents that protects *Spinraza* has applied for a grant in roughly 118 countries around the world, invoking the international Patent Cooperation Treaty, PCT System.



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
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WIPO | PCT

(10) International Publication Number
WO 2014/110291 A1

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A61K 48/00 (2006.01) *A61P 21/00* (2006.01)

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PCT/US2014/010930

(22) International Filing Date:
9 January 2014 (09.01.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/750,767	9 January 2013 (09.01.2013)	US
61/793,136	15 March 2013 (15.03.2013)	US
61/821,615	9 May 2013 (09.05.2013)	US
61/834,818	13 June 2013 (13.06.2013)	US
61/880,079	19 September 2013 (19.09.2013)	US
61/886,558	3 October 2013 (03.10.2013)	US

(71) Applicant: **ISIS PHARMACEUTICALS, INC.** [US/US]; 2855 Gazelle Court, Carlsbad, CA 92010 (US).

(72) Inventors: **BENNETT, C., Frank**; 2855 Gazelle Ct., Carlsbad, CA 92010 (US). **HUNG, Gene**; 2855 Gazelle Ct., Carlsbad, CA 92010 (US). **RIGO, Frank**; 2855 Gazelle Ct., Carlsbad, CA 92010 (US).

(74) Agents: **EVANS, William, M.** et al.; 2855 Gazelle Ct., Carlsbad, CA 92010 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *with sequence listing part of description (Rule 5.2(a))*

Source:

https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2014110291

3. Patents and the pharmaceutical industry

- Is technological and scientific progress aided or hindered by patent systems?

- For: **the process stimulates innovation**. Patents incorporate an information system and a legal publication process from the moment the invention and its material expression are made public after a patent is granted. An alternative to protection by patent is the trade secret.

- Against: **patents restrict access to all the knowledge** that provides support for **future innovation**. The free flow of innovation helps technological innovation and scientific progress.

4. From blockbuster drugs to personalised medicine

Biotechnological drugs initiated by the American companies *Genentech* and *Eli Lilly*; genetic engineering used to produce synthetic insulin. Since then, pharmaceutical companies have launched more than three dozen similar drugs.

Several of these products, such as *Humira,* were very successful commercially (blockbusters).

When the patent for H*umira* passes into the public domain, manufacturers will have to demonstrate the effectiveness and safety of their biosimilars in their own studies; development and the manufacturing of the product are much more expensive than with traditional generics.

4. From blockbuster drugs to personalised medicine

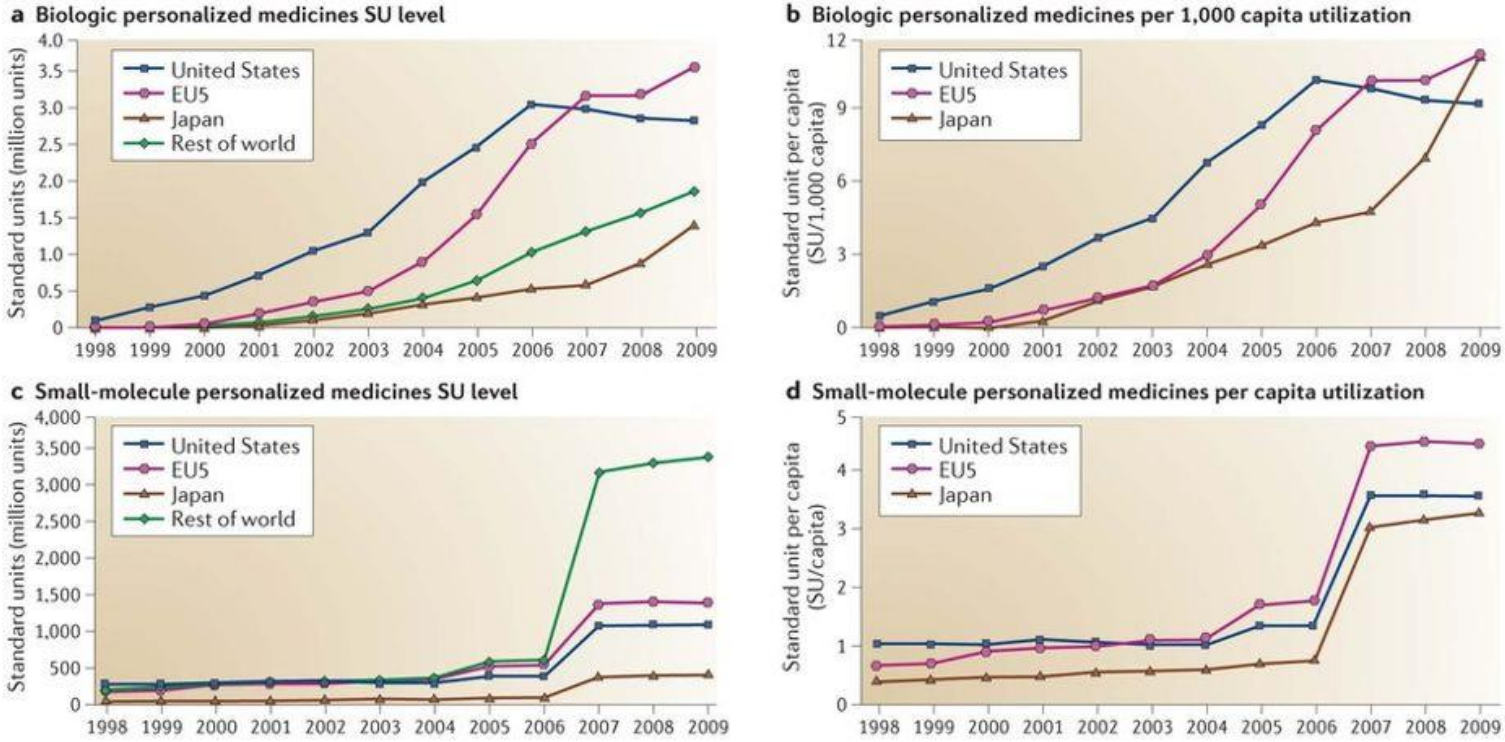
Personalised medicine is a growing new approach to preventing and treating illnesses that adapts to individual patients, taking into account their genetic make-up, environment and lifestyle.

Personalised medicine is becoming a real possibility thanks to scientists' ability to use new DNA technology to collect data about a person's complete genome (all the genetic information about a person) quickly and cheaply.

On 30 January 2015, the president of the United States, Barack Obama, launched **The Precision Medicine Initiative** https://obamawhitehouse.archives.gov/precision-medicine

4. From blockbuster drugs to personalised medicine

Despite the enormous attention paid to personalised medicines, the rate at which they are adopted in clinical practice has been limited.



Level of standard unit and use per capita of personalised medicines: 1998-2009.
Source: https://www.nature.com/articles/nrd4177 *Nature* (2013).

4. From blockbuster drugs to personalised medicine

The FDA has approved **20-25 new drugs** per year over the last two decades. However, annual approvals **in the last five years** (except for fall 2016) have ranged from **40-50 new drugs.** This uptake has been driven by the progress made in oncology, immunology and gene therapy.

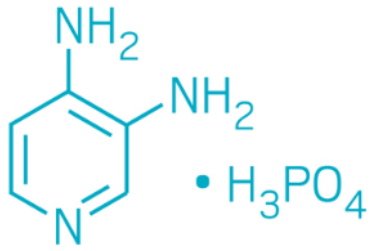
In 2018 the FDA approved a record number of 59 new drugs.

34 approvals were given for drugs to treat **rare diseases** and 16 approvals were given for orphan drugs to treat cancer and extremely rare diseases (with just a few dozen patients).

5. High prices and inequality

CASE: **Jacobus/Catalyst**
This plan involved executing an old generic compound (Amifampridine) through the FDA's modern approvals process, which, according to the agency's rules, would grant them market exclusive.

FIRDAPSE



Before Catalyst's Firdapse was sanctioned for use by the FDA, hundreds of patients had been able to access a similar drug from compounding pharmacies for a fraction of the cost, or Jacobus' for free, as part of an FDA-ratified compassionate use program. But the approval of the Catalyst drug, accompanied by market exclusivity spanning seven years — effectively precluded Jacobus and compounding pharmacies from selling their versions.

Dosing for any of these treatments is based on the patient's weight and disease severity. Catalyst's Firdapse, which is approved with a maximum dose of 80 mg, carries an average list price of $375,000 a year. The company does not disclose a per pill number, a Catalyst spokesperson told *Endpoints News*.

Firdapse

Approval date: Nov. 28

Active ingredient: Amifampridine

Marketer: Catalyst Pharmaceuticals

Indication: Lambert-Eaton myasthenic syndrome

Mechanism of action: Unknown

Modality: small molecule

Wholesale acquisition cost: n/a

Special Feature: Orphan drug, breakthrough status

Notes: first FDA approval of a treatment for LEMS

Read More: https://cen.acs.org/articles/87/i44/Biotech-Companies-Make-Merger-Deals.html

5. High prices and inequality

TRIBUNA:

Las patentes y los pobres

JEFFREY SACHS

6 MAY 2001

La mayoría de los fármacos que ayudan a salvar vidas se fabrican con patente de empresas farmacéuticas occidentales. Sin embargo, los precios protegidos por las patentes a menudo dejan estos medicamentos fuera del alcance de los habitantes de los países pobres. Así, mientras que muchos pacientes de sida de los países ricos se mantienen vivos gracias a los fármacos, en los países pobres mueren millones antes de tiempo.

El tratamiento típico contra el sida cuesta unos 10.000 dólares anuales (casi dos millones de pesetas) por paciente en los países ricos. Pero producir algunas de las combinaciones de tres fármacos utilizadas para tratar el sida cuesta sólo entre 350 y 500 dólares anuales (entre 64.000 y 92.000 pesetas). Algunos fabricantes de productos genéricos, como Cipla de India, se han ofrecido a proporcionar estos fármacos a precios cercanos al coste de producción. Merck, Abbott Laboratories y Bristol Myers Squibb, tres grandes empresas con patente, están dispuestas a suministrar a África con 'beneficio cero', es decir, aproximadamente a un precio de 500 dólares por paciente y año.

FONDO COMÚN | En favor de los países en desarrollo

EEUU cede sus patentes de fármacos contra el sida

- **EEUU se convierte en el primero en unirse al fondo común de patentes**
- **Los países pobres ahorrarán 1.000 millones de dólares anuales gracias a él**

Reuters | Londres

Actualizado jueves 30/09/2010 **17:22 horas**

Los Institutos Nacionales de Salud (NIH) de EEUU han anunciado que compartirán los derechos de propiedad intelectual de algunos fármacos para el VIH/sida con un fondo común de patentes diseñado para que los tratamientos sean accesibles para los más pobres.

Los NIH son la **primera institución dedicada en la investigación que se une a este grupo** de patentes de medicinas para el VIH lanzado por UNITAID, un sistema de financiación sanitaria sufragado mediante una **tasa** impuesta a los billetes de avión fundado por Brasil, Reino Unido, Chiles, Francia y Noruega en 2006

5. High prices and inequality

Enfermos de hepatitis C llevan su protesta frente a la farmacéutica que se lucra con el Sovaldi

Las declaraciones de una ex directiva de Gilead, que justificó el precio del tratamiento, desatan la ira de los afectados. La multinacional ganó mas de 21.000 millones de euros en 2014.

Enfermos de hepatitis C se manifiestan frente a laboratorio que fabrica Sovaldi. EFE

MÁS INFORMACIÓN

- Sanidad solo dará el tratamiento contra la hepatitis C al 1% de los 300.000 enfermos
- Enfermos de hepatitis C denuncian que sus expedientes no llegan a quienes dan el fármaco
- Diario de un enfermo de hepatitis C encerrado
- Gran despliegue policial en la #MarchaAMoncloa para exigir tratamiento contra la hepatitis C

5. High prices and inequality

- The Doha Declaration (2002) represented significant progress in stimulating access to drugs for many WHO member countries.
- The unaffordable cost of many new drugs continues to affect citizens' right to health; one example is the high cost of drugs against cancer and hepatitis C.
- A clear contradiction exists between proposing progress "towards universal health coverage and the achievement of the Millennium Development Goals for Health" and what happens in practice in relation to access to medicines.
- Proposals were made in relation to the urgent need for coherent and coordinated answers to face the "determinants of access to essential medicines to improve their availability, accessibility, quality and rational use."

5. High prices and inequality

- A new treatment for hepatitis C costs 25,000 euros per patient in Europe, whereas in the USA it costs 84,000 dollars (roughly 63,000 euros). Egypt produces the same generic drug for 900 dollars (roughly 675 euros) and India has an identical product for 200 dollars (roughly 150 euros).
- The poorest countries encourage their pharmaceutical companies to produce cheaper generic alternatives, make branded products expensive, and use other tools to bring down the price of medicines to more affordable levels.
- These countries are under enormous pressure from international institutions and multinational pharmaceutical companies despite the fact that the production of generic medicines and other options are legitimate according to international rules.

5. High prices and inequality

- Multinational drug manufacturers profit from the current patent system.
- Pharmaceutical companies spend more money on advertising and marketing than on research.
- Their research is also biased because it focuses on lifestyle drugs rather than medicines that save lives.

Conclusions

- The challenge in public health is to find the **optimum balance** between the rights of patent holders (the inventors of technological innovations that improve health conditions) and the needs of the general public.
- An imbalance exists between developed and developing countries in relation to control of patent rights. Developing countries want economic access to advanced technology. Some of those countries (with R+D skills) obtained a certain amount of redress by threatening to ignore patents if the prices of the medicines were not reduced (e.g. for AIDS).