Advocacy for appropriate regulation of biological tests sold directly to consumers

La relation entre tests IVD conventionnels et DTCT : une source d'inquiétude pour les biologistes médicaux français

Dr Michel Vaubourdolle, Pharm.D., Ph.D.

Head of Department of Biochemistry – Hormonology – DMU BioGeM*
University Hospitals Sorbonne Université, Saint-Antoine, AP-HP
Member of Healthcare Committee COFRAC – Technical assessor
SFBC Accreditation and Stat biology WGs chairman
A/ISO EFLM WG - IFCC POCT Committee member
Member of the French Pharmacy National Academy

* laboratory accredited by COFRAC with NF EN ISO 15189, 17025 and 22870 standards

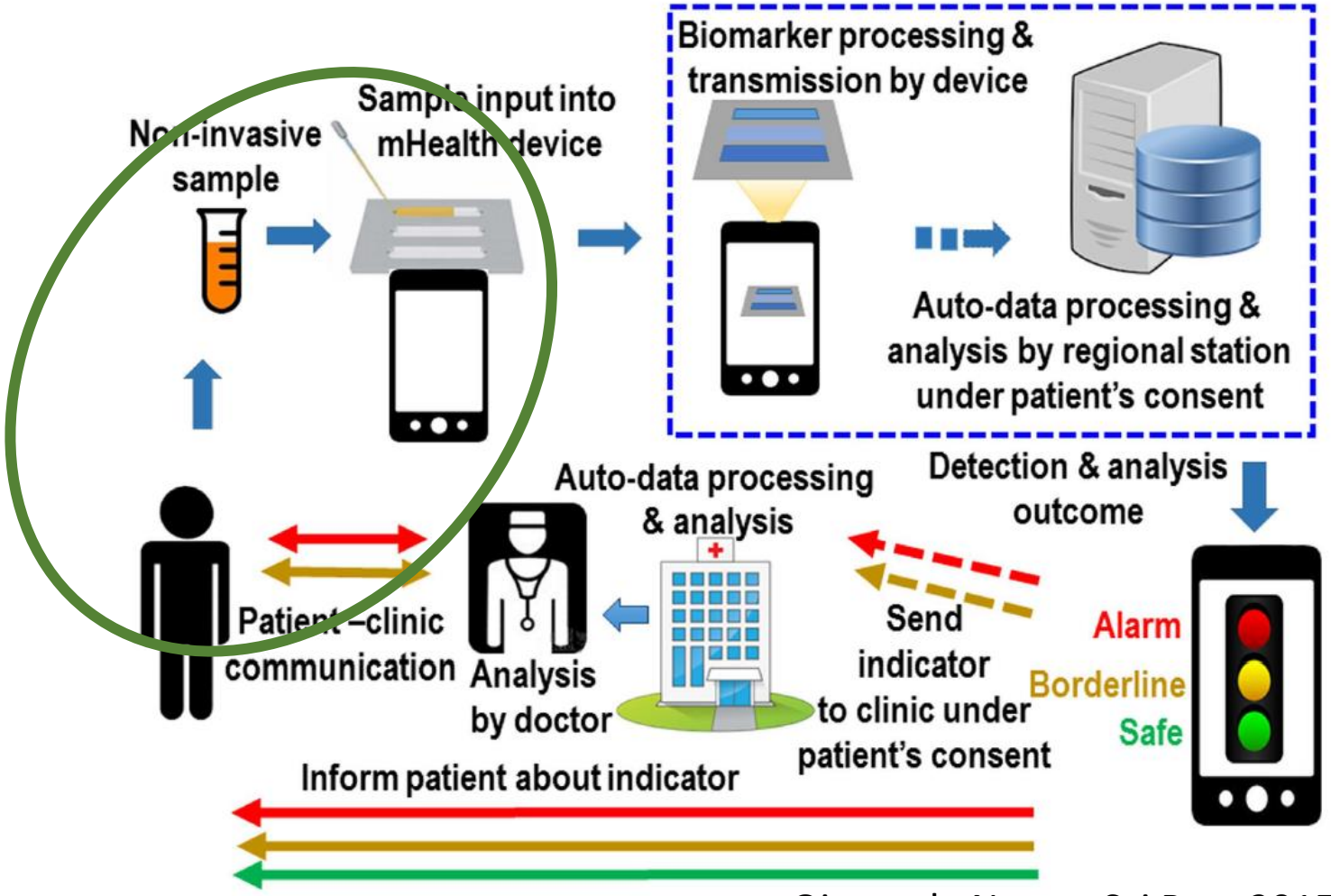
Session internationale – 17/11/2023
LE POURQUOI ET LE COMMENT DES TESTS EN ACCÈS LIBRE AUX CONSOMMATEURS (DTCT)

In the context of the e-m-health development: a promising path for DTCT

A role for healthcare professionals and Laboratory Medicine specialists ?

“DTCT” is theoretically outside of healthcare system
But m-health connected medical devices include the healthcare system

DTCT will be probably more efficient if linked to the national healthcare system



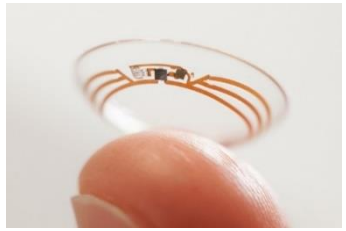
Qin et al., Nature Sci Rep. 2015

m-health main target = chronic diseases (diabetes)
Some examples of connected medical devices
Also including healthcare system via medical prescription

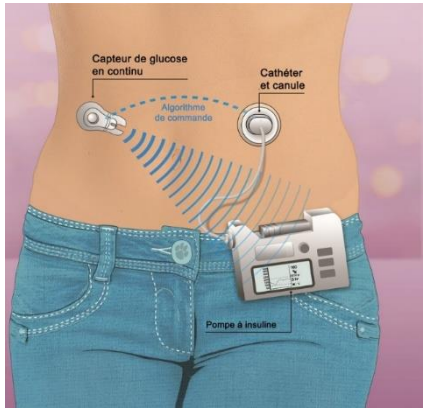
From connected glucose… **….to artificial pancreas**

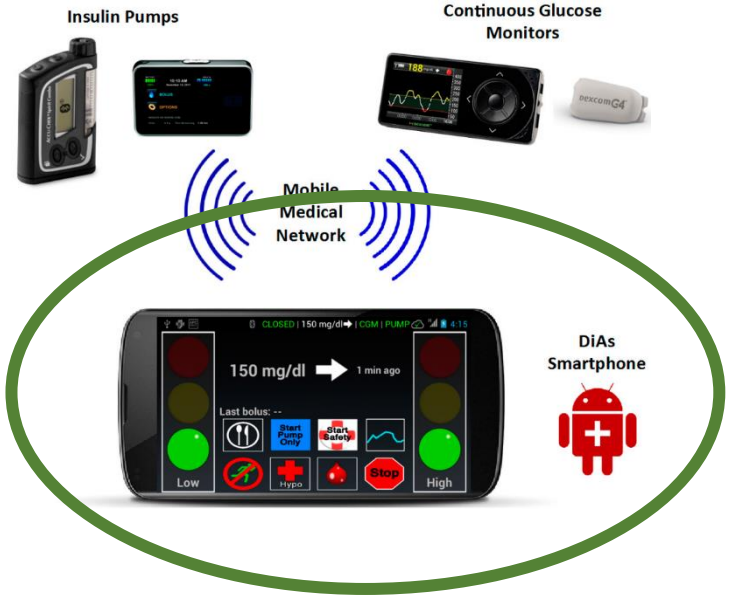
DTCT will be probably more efficient if supervised by an healthcare worker not on Internet

***Via* patch**



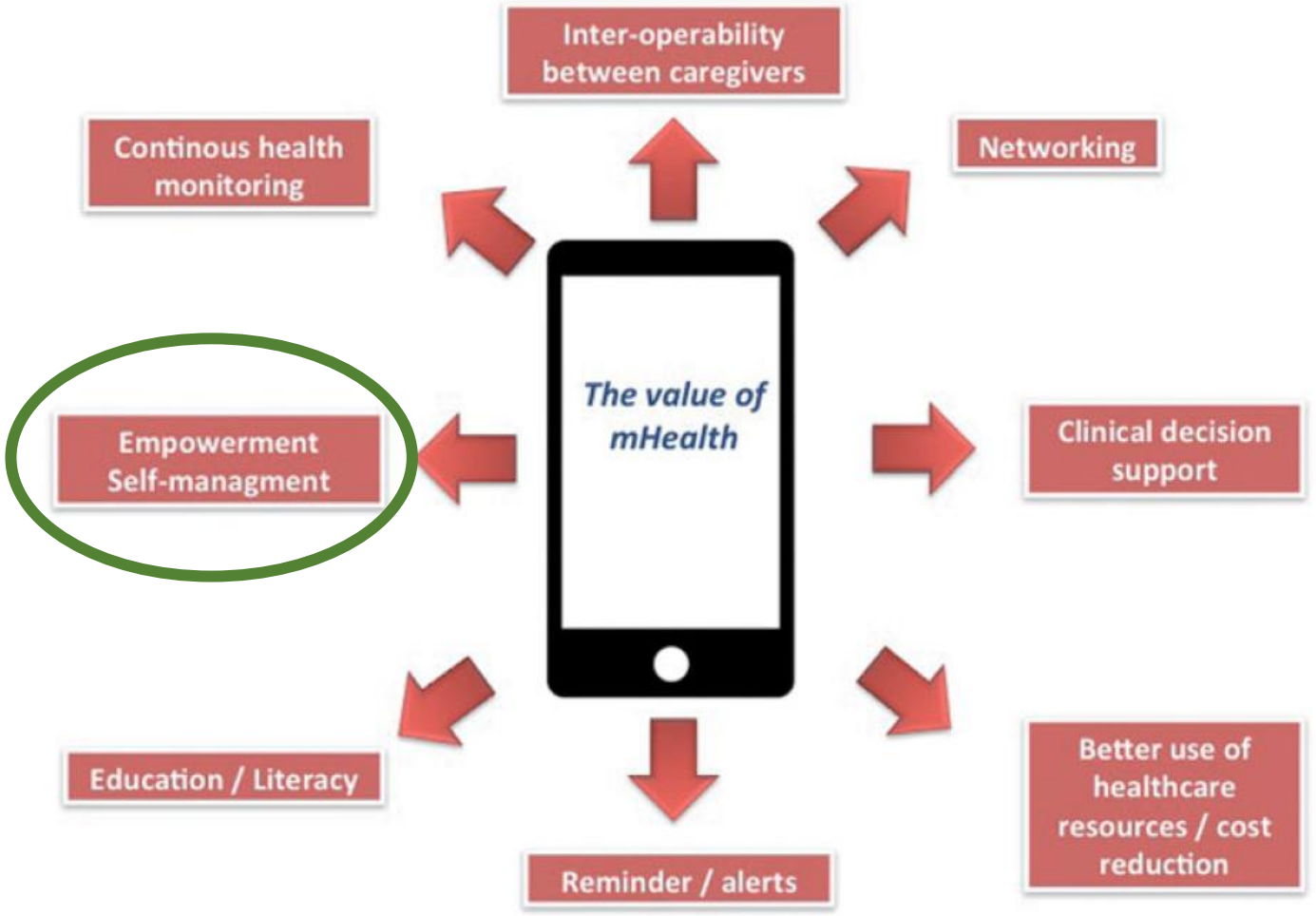
***Via* contact lenses**





m-health added value

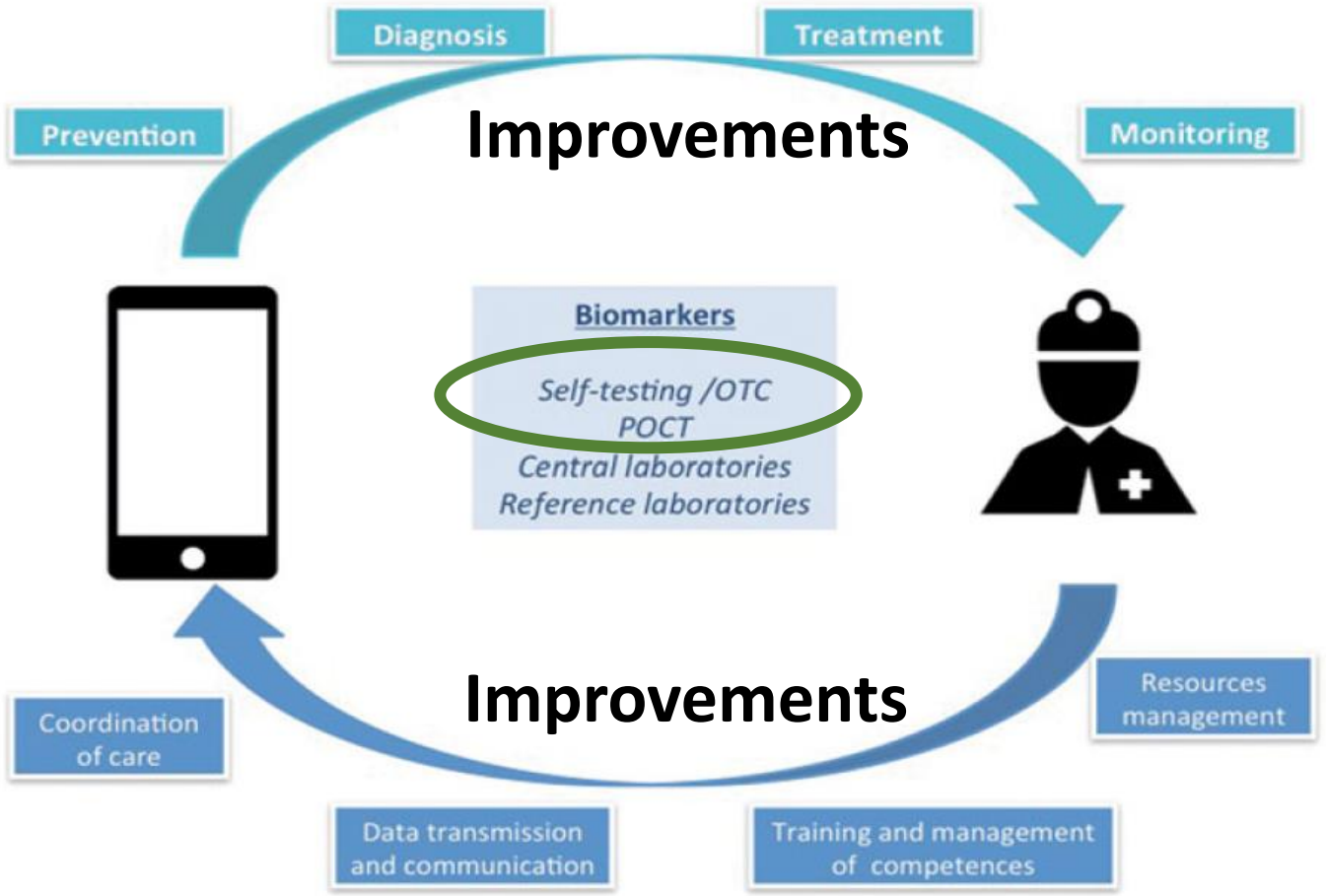
Only item in common with "DTCT" claimed advantages



D'après Gruson and Ko, Critical Reviews in Clinical Laboratory Sciences , 2016

Laboratory medicine
What to expect from e-health worldwide?

All items under regulation in healthcare



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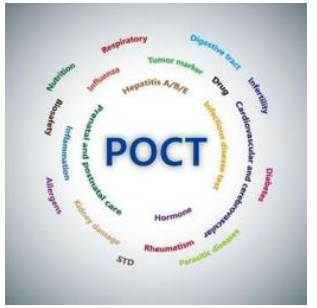
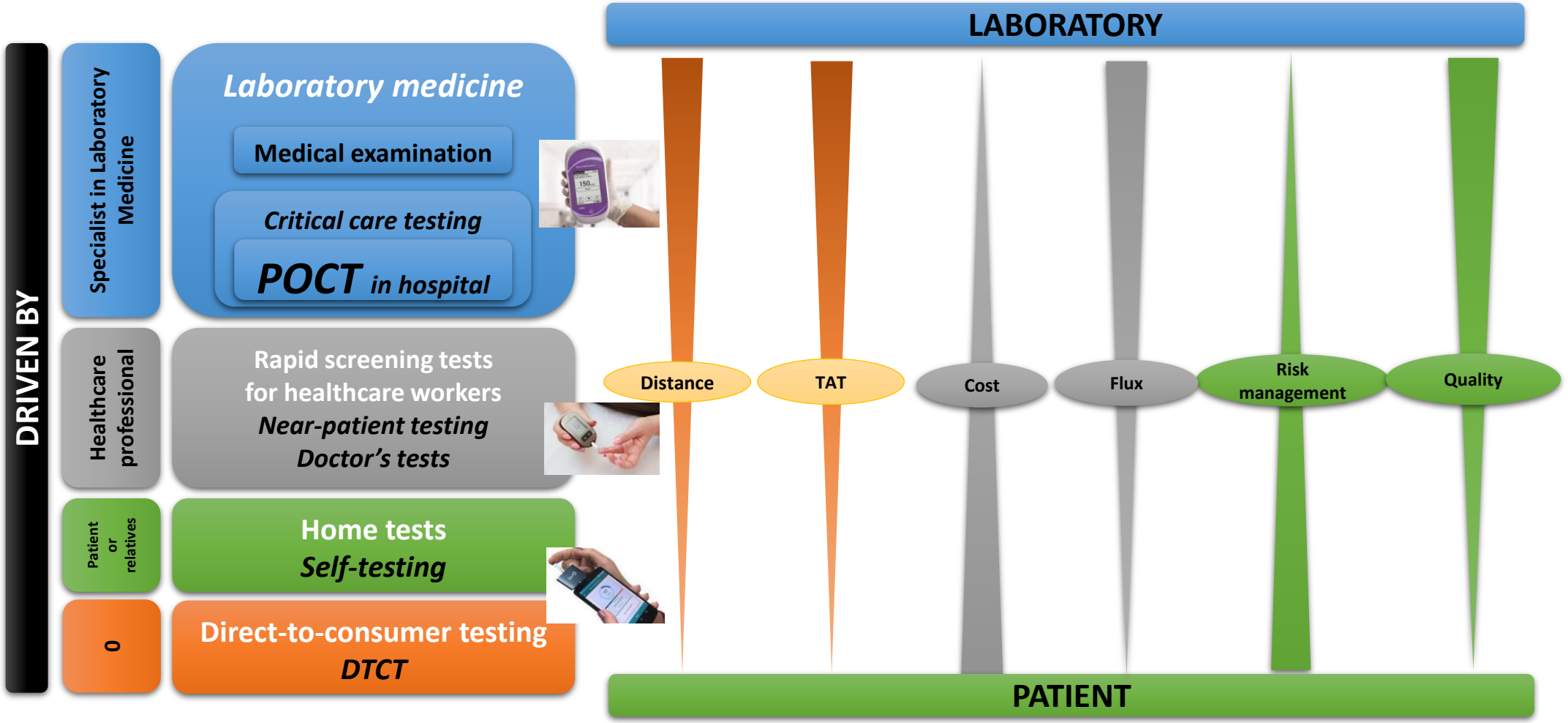


If the goal is to improve healthcare using e-health new features

Why could we add DTCT to existing POCT/self-testing contexts ?

“Testing” outside clinical laboratory: a confusing continuum

4 situations: POCT, rapid screening tests, home tests and DTCT



Is there a real difference between
“self-testing” and “regulated DTCT used by patient with an healthcare goal” ?

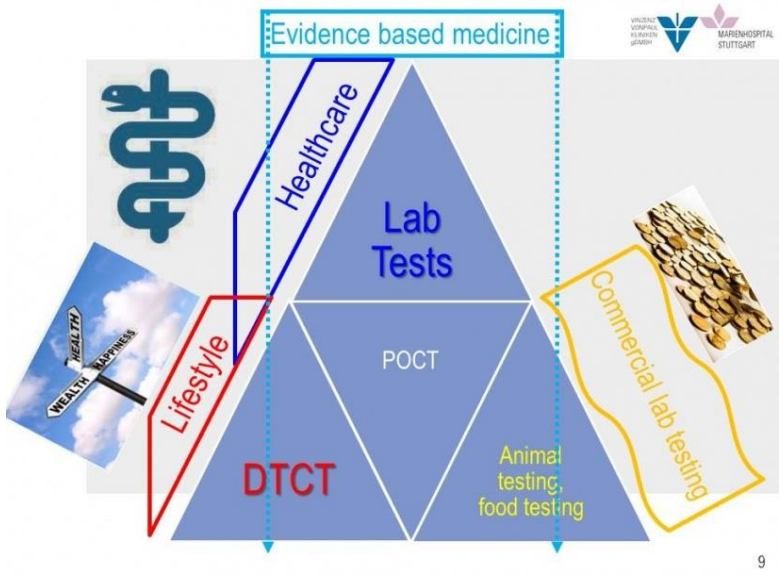
“Testing” outside clinical laboratory: a confusing continuum

A subjective approach from French regulation

	POCT		Self-testing		DTCT	
	POCT in hospital	POCT outside hospital Screening tests	Self-testing under HP supervision	Self-testing without HP supervision	DTCT “Wellbeing” purposes	DTCT Healthcare goals
Guaranteed analytical reliability	++++	+++	+*	Not proven	Not proven	Not proven
Risk management	++++	+++	+	Not proven	Not proven	Not proven
Clinical relevance	++++	+++	++	Not proven	Not proven	Not proven
Main advantage	Critical care testing	Patient care optimization	Continuous health monitoring	Patient self-empowerment	Consumer autonomy	?

*regulation depending on the type of testing (sold in Pharmacies – CE marked – medical prescription)

Where is the good cursor for an acceptable benefit/risk ratio ?



DTCT and benefit/risk ratio

P4 Medicine or O4 Medicine? Hippocrates Provides the Answer

Clare Fiala, Jennifer Taher, Eleftherios P Diamandis

The Journal of Applied Laboratory Medicine, Volume 4, Issue 1, 1 July 2019, Pages 108–119, https://doi.org/10.1373/jalm.2018.028613

The term P4 medicine (predictive, preventative, personalized, participatory) was coined by Dr. Leroy Hood of the Institute for Systems Biology to demonstrate his framework to detect and prevent disease through extensive biomarker testing, close monitoring, deep statistical analysis, and patient health coaching.

Results: Using this study as a basis, we here analyze the Hippocratic roots and the advantages and disadvantages of P4 medicine. We introduce O4 medicine (**overtesting, overdiagnosis, overtreatment, overcharging**) as a counterpoint to P4 medicine to highlight the drawbacks, including possible harms and cost.

Conclusions: We hope this analysis will contribute to the discussion about the **best use of limited health-care resources to produce maximum benefit for all patients**.

Benefits and Risks of Direct-to-Consumer Testing

Nadia Ayala-Lopez, MLS(ASCP), PhD; James H. Nichols, PhD

Arch Pathol Lab Med (2020) 144 (10): 1193–1198.

Convenience, avoidance of doctor's appointments, curiosity, and the desire to take control of one's health are driving interest toward direct-to-consumer (DTC) testing. DTC is laboratory testing that is initiated by the consumer without a physician order. The results are reported back directly to the consumer. DTC testing is an exciting addition to the traditional healthcare model for consumers who want **knowledge of their health status and disease risk, ancestry, and their body's expected response to certain medications** based on their genotype.

DTCT potential benefits viewed from consumers

DTCT in the P4 perspective?
But from healthcare workers and Hippocrate view risk is O4

National Library of Medicine

MedlinePlus
Trusted Health Information for You

What are the benefits and risks of direct-to-consumer genetic testing?

Direct-to-consumer genetic testing has both benefits and limitations, although they are somewhat different than those of genetic testing ordered by a healthcare provider.

Genomics Inform. 2019 Sep; 17(3): e33.
Published online 2019 Sep 26. doi: 10.5808/GI.2019.17.3.e33

Direct-to-consumer genetic testing: advantages and pitfalls

Bermseok Oh*

Many papers enhance the public health risks over the potential benefits due to a lack of regulation

In this issue: POCT – making the point
The Journal of the International Federation of Clinical Chemistry and Laboratory Medicine
eJIFCC

Direct to consumer laboratory testing (DTCT) – opportunities and concerns

Matthias Orth[1,2]

[1] *Vinzenz von Paul Kliniken gGmbH, Institut für Laboratoriumsmedizin, Stuttgart, Germany*
[2] *Medizinische Fakultät Mannheim, Ruprecht Karls Universität, Mannheim, Germany*

Direct to consumer laboratory testing has the potential for self-empowerment of patients. However, the Direct to consumer laboratory testing (DTCT) uses loopholes which are related to the particular situation of healthcare: While advertisements and claims for medical usefulness are very high regulated in healthcare, essentially no regulations safeguard the consumers in DTCT. The same is true for the quality of testing services since quality regulations are only mandatory in healthcare. Another problem is the lack of medical interpretation of test results. Besides being very risky for the consumers, healthcare professionals relying on test results obtained by DTCT must be aware about the risks of these data.

REVIEW ARTICLE

THE INTERNATIONAL JOURNAL OF CLINICAL PRACTICE

Direct-to-consumer testing: more risks than opportunities

G. Lippi,[1] E. J Favaloro,[2] M. Plebani[3]

Int J Clin Pract, December 2011, **65**, 12, 1221–1229

THEORETICAL ADVANTAGES

- ✓ **Claimed possibility of analysis of genetic predispositions** for a variety of health conditions
- ✓ **Personalized genetic risks** can lead patients to more healthful lifestyle choices that should decrease the likelihood or delay the risk of developing certain genetic diseases, through major compliance with health-screening practices
- ✓ **Access testing** without a medical prescription and thereby save time and money otherwise applied for a visit to the general physician or specialists
- ✓ **Greater consumer autonomy** and empowerment, as well as theoretically enhanced privacy of test results.

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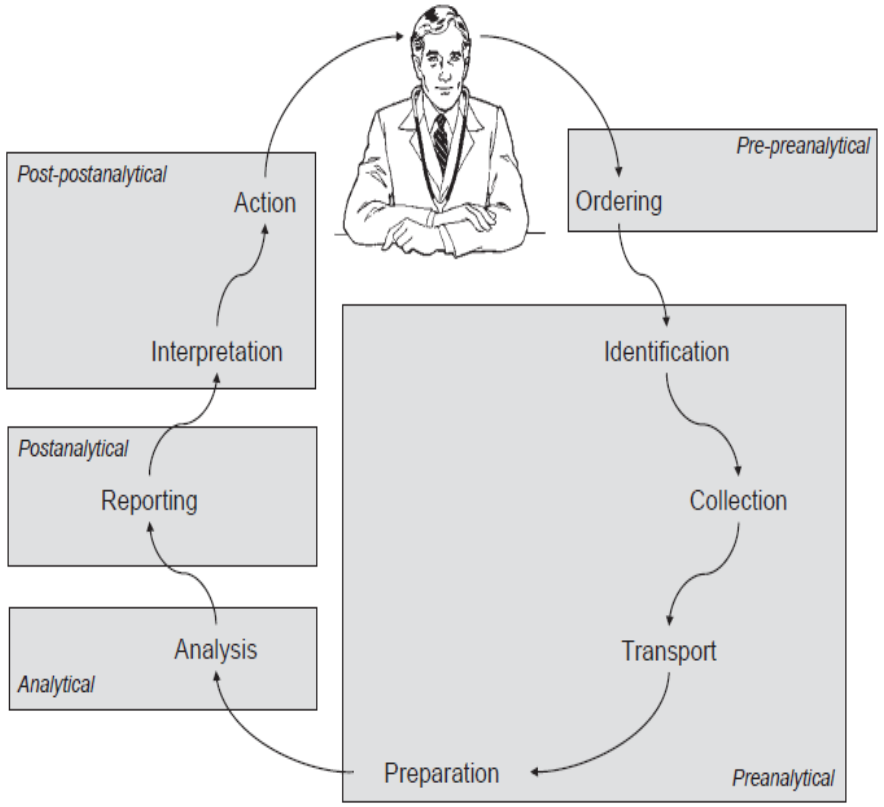

Figure 1 The different phases of the total testing process

From a risk analysis on the examination process

REAL DRAWBACKS

Test ordering

- ✓ **No control on appropriateness**
- ✓ **Incremental costs for the patients**
- ✓ **Potential request for confirmatory testing in institutional laboratories**
- ✓ **Wasteful use of the health care resources**

Patient identification

- ✓ **Impossible to verify the identity of the sample**
- ✓ **Possible to purposely misidentify the sample**

Sample collection, transport and preparation

- ✓ **No evidence that the procedures used for shipping samples fulfil basic requirements of sample stability**
- ✓ **Risk of transfer of materials from DTC testing companies to other entities**

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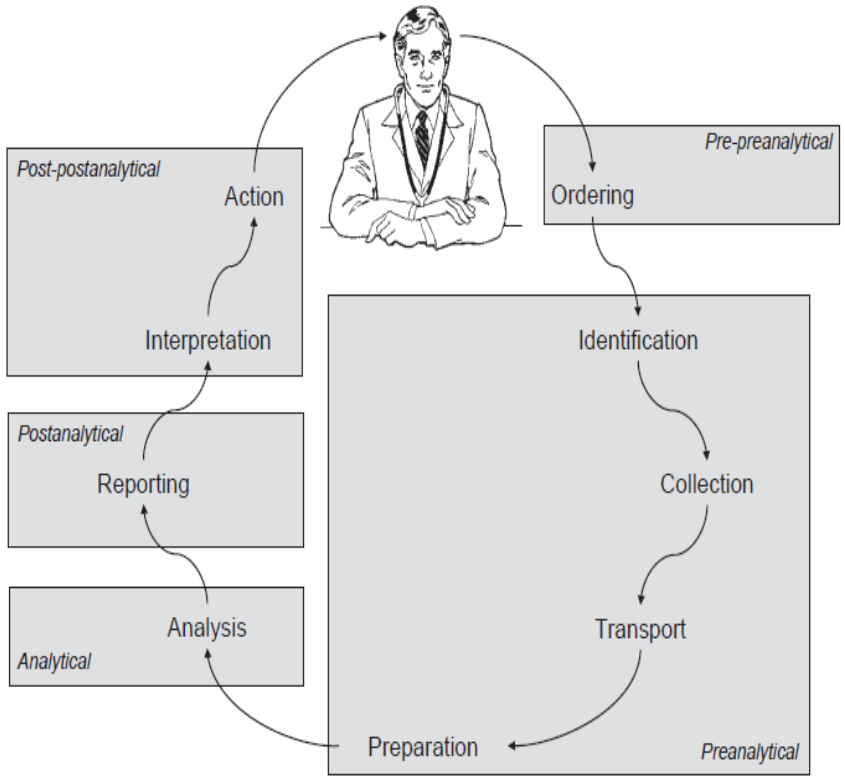


Figure 1 The different phases of the total testing process

From a risk analysis on the examination process

REAL DRAWBACKS

Sample analysis

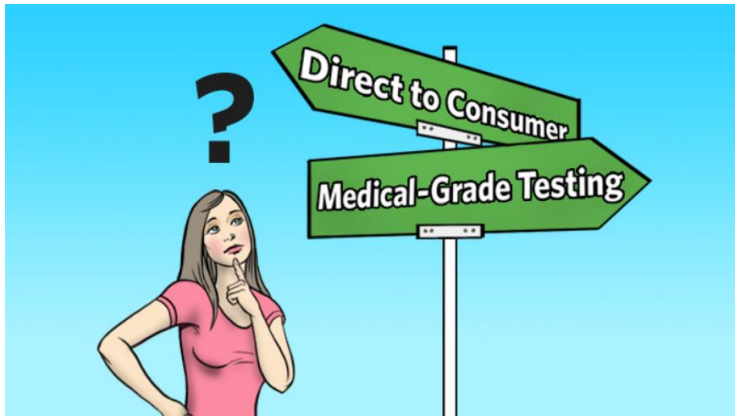
- ✓ **Scarce evidence of quality assessment throughout the testing process, especially in facilities with no certification**
- ✓ **No evidence of adherence to external quality assessment schemes (EQAS) or proficiency testing, which should target both analytical quality and scoring systems**
- ✓ **No need to operate under national of international regulation for IVD**
- ✓ **Competency of the staff working in DTC testing companies is unclear**

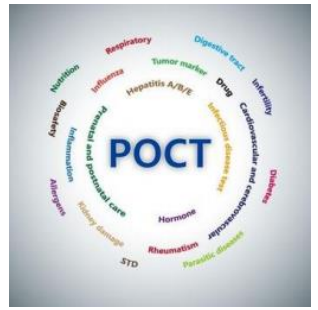
Test reporting and interpretation

- ✓ **Lack of appropriate interpretative comments**
- ✓ **Lack of specific characteristics and limitations of the test**
- ✓ **Uncertain competency of companies' genetic counsellors**
- ✓ **Generation of anxiety or false reassurance for positive and negative results**
- ✓ **Lack of information about procedures for handling and resolving consumer complaints**

Clinical action

- ✓ **Lack of evidence-based information about the clinical effectiveness of testing**





DTCT/home tests: What could we do or suggest to our national/international authorities?

REVIEW ARTICLE

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Table 2 Pathway for the introduction of a genetic test within the clinical practice

Steps	Stakeholders	Competencies
Application (i.e. Health Technology Assessment report)	Geneticists, policy makers, economists, directors of healthcare facilities and trusts.	Familiarity with Health Technology Assessment
Test offer	Geneticists and other clinicians, policy makers	Knowledge of the genetic bases of diseases, pathophysiology and clinics, pathways of interactions between genes and environment, cost-effectiveness analyses
Informed consent	Geneticists and other clinicians, ethical committees, patients and consumers associations	Competency on ethical, juridical, social and clinical implications
Test performance	Genetic laboratories	Medical genetics education.
Test interpretation	Laboratory geneticists, clinical geneticists and other clinicians	Knowledge about genome variability, its influence on diseases and competency on the specific test characteristics
Results reporting	Clinicians, geneticists, laboratory professionals, nurses, psychologists, sociologists, bioethicists	Knowledge about genome variability, its influence on diseases and related therapies, knowledge about the specific test characteristics and limitations, competency on ethical, juridical, social and clinical implications, communication skills
Data protection and safeguard	Geneticists, informatics engineers, policy makers, ethical committees, healthcare facilities	Juridical, informatics and bioinformatics competency
Definition of the clinical pathway	Clinicians, geneticists, laboratory professionals, bioethicists, nurses, psychologists, sociologists, direction of healthcare facilities and trusts, patients and consumers associations	Knowledge about clinical implications of tests results, clinical governance, laboratory organisation, preventive and reproductive medicine, organisational and management competencies
Approach to the family	Clinical geneticists, bioethicists, psychologists, sociologists, patients and consumers associations, general practitioners	Competency on ethical, juridical, social and clinical implications, communication skills

REVIEW ARTICLE

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In 2022, few advances about DTCT regulation

Self-testing control in France?

Potential role of specialists in laboratory medicine

- **Actual role driven by national regulation**
  - When a measuring device is used (glucometers, INR)
    - ✓ Do a control of results consistency compared to lab tests when the patient comes to the lab for examination
    - ✓ Write a report for physician and orientate the patient
  - Not often applied now in France due to lack of control and defect of recognition of this act by social security reimbursement
- **Perspectives (hopes)**
  - To do in real life this job because we know that consequences of inappropriate use of devices by patients lead to important iatrogenic damage
- **Opportunities**
  - To show that medical laboratory is implicated in global patient care outside the walls of laboratory on a big public health operation
  - To contribute to patient therapeutic education with pharmacists who are selling the devices and are closer to the patients
  - To create the conditions of the creation of intellectual acts in laboratory medicine in parallel with technical acts already defined

Screening tests/home tests

Potential role of pharmacies

A proposal from the French National Academy of Pharmacy

Rapport

de l'Académie nationale de Pharmacie

24 Jan

"Autotests-TROD : rôle du pharmacien d'officine"

2018

Ce rapport a été rédigé par l'Académie nationale de Pharmacie, à la demande de la DGS. Il a été adopté par le Conseil le 13 décembre 2017. Il repose sur l'étude des problématiques de santé liées à l'usage des autotests et des TROD et sur le rôle du pharmacien d'officine dans le cadre du parcours de santé de l'usager/patient. Il inclut des recommandations aux pouvoirs publics, à l'ANSM, aux industriels du diagnostic in vitro, aux pharmaciens d'officine, aux professionnels de santé et aux organismes formateurs.

Télécharger

https://www.acadpharm.org/dos_public/Rapport_autotests_TROD_VF9_2018.03.22.pdf

Basic considerations

- Development of e-health and m-health lead to **huge progresses in healthcare process**
- Clinical labs and pharmacies are **essential links** in health chain
- DTCT and self-testing are now inserted in **prevention** process and patient **auto-empowerment**
- **Earliness of patient care** is a critical factor for healthcare quality

- **National regulations** should be adapted quickly to these new technologies
- DTCT or self-tests available for healthcare allegation
  - ✓ must be associated with a **clinical relevance**
  - ✓ **Analytical quality** of tests/devices is not sufficiently validated
  - ✓ **Sale (deliverance) of DTC tests** should be done by healthcare professionals and needs a minimal training for a good patient accompaniment before and after testing

Recommendations to national authorities

- Enhance the **national requirements for quality assurance for DTCT/self-tests and screening tests**
- Organize a **better training for health professionals** about existing guidelines and regulations concerning quality assurance
- Better **secure the use of self-testing using a measurement device** (diabetes and anticoagulation essentially) with an application of existing procedure of devices verification by clinical laboratories - organize a link between pharmacies and clinical labs to optimize diabetic patients care

Recommendations to national organism in charge of health market regulation (ANSM)

- **Proceed now**, without waiting for the application of European IVD regulation, to an independent analytical evaluation of CE marked devices or reagents designed for DTCT/self-testing
- **Contribute** to development of a repository for these tests

Recommendations to IVD companies

- **Restrict the market releases just** to tests whose clinical relevance has been validated in agreement with national repository and clinical needs
- **Improve clearly the quality** of information delivered in testing package and notice

Recommendations to pharmacists

- **For sale/deliverance of self-tests**
  - **To inform**, **advise and orientate** the patient/user to adequate healthcare professionals like physicians or proximity clinical labs
  - **To be aware** about national and international recommendations about tests clinical relevance and interpretation

Recommendations to health professionals

- **To develop and maintain** links between pharmacists, specialists in laboratory medicine, physicians, nurses,… to **regulate and organize** on a coordinated basis, the use of self-testing and screening tests, including reimbursed devices for self-monitoring (diabetes, anticoagulation)

Recommendations to learning programs

- Harmonize and quickly prepare **learning programs** on self-tests and screening tests for pharmacists and concerned healthcare professionals for a better and more accessible patient accompaniment at any point of the national territory
- Implement a mandatory **continuing education** program on these tests, really independent from distributors or IVD companies
- **Involve** as often as possible in learning programs the **laboratory medicine professionals or specialists**

All contexts are now mixed

Hospital POCT, screening tests, self testing/DTCT

DTCT/Home tests: a confusing situation in France

- **3 types**

✓Quantitative results with measure device self monitoring – *CE-marked – sale in pharmacies, medical prescription*

✓Qualitative for orientation or screening – *CE marked – sale in pharmacies (except pregnancy and ovulation tests)*

✓Internet purchase – *“wild” field no regulation but unauthorized labs (genetic testing) not allowed on the territory*

A proposal for clarification?

"Convenience, avoidance of doctor's appointments, curiosity, and the desire to take control of one's health are driving interest toward direct-to-consumer (DTC) testing"

New DTCT proposed online to consumers

Consumer motivation?

"Convenience – Curiosity No fee/visit needed to access to test"	**"Take control of one's health"**
DTCT treated as a common consumer product	**DTCT treated as healthcare product using IVD service and/or device**
Consumer is aware of the limitations of the test and that there is no guarantee to improve health	**Provider must prove and guarantee the effectiveness of claims on healthcare improvement**
No needed regulation No reimbursement	**National regulation needed on:** ✓ Analytical quality (IVD-R) ✓ Process risk management (involvement of specialists in LM) ✓ Clinical relevance (involvement of physicians) ✓ Personalized accompaniment (proximity network of healthcare workers)
Residual risks: privacy, ethics, no possible regulation of the Internet use	**Residual risks: no possible regulation of the Internet use**

"Convenience, avoidance of doctor's appointments, curiosity, and the desire to take control of one's health are driving interest toward direct-to-consumer (DTC) testing"

New DTCT proposed online to consumers

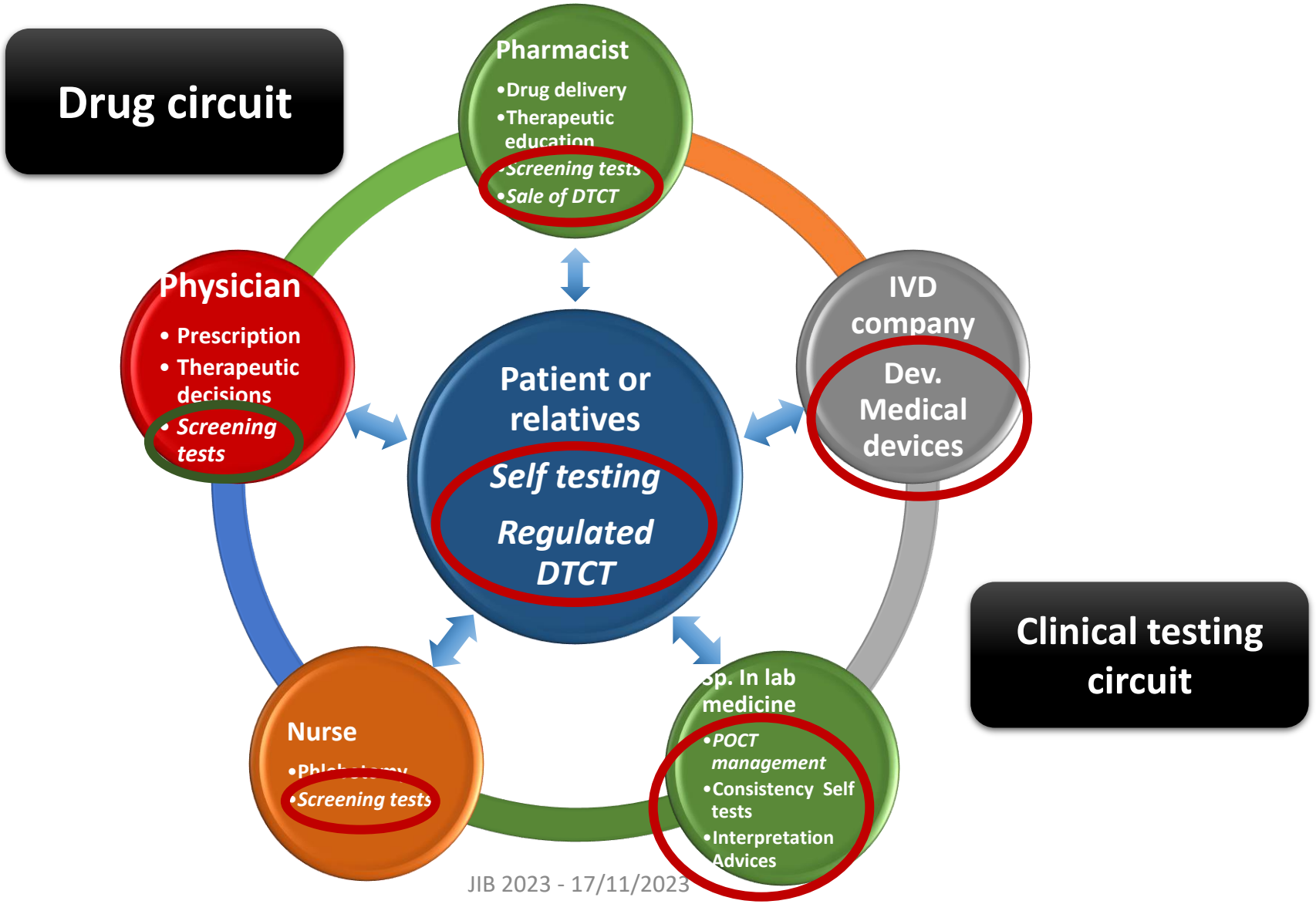
Provider claims?

Wellbeing	Healthcare improvement
DTCT treated as a common consumer product	DTCT treated as healthcare product using IVD service and/or device
Provider informs consumer clearly about the limitations of the test and that there is no guarantee to improve wellbeing	Provider must prove and guarantee the effectiveness of claims on healthcare improvement
Regulation to verify no healthcare claims No reimbursement	National regulation needed on: ✓ Analytical quality (IVD-R) ✓ Process risk management (involvement of specialists in LM) ✓ Clinical relevance (involvement of physicians) ✓ Personalized accompaniment (proximity network of healthcare workers)
Residual risks: privacy, ethics, no possible regulation of the Internet use	Residual risks: no possible regulation of the Internet use

Unfortunately, not a so clear frontier!

A dream: all healthcare workers coordinated for secured and efficient e-health

At the end, an integration of more promising DTCT into healthcare system?



Conclusions and Perspectives
Contexts

- **Rapid screening tests in primary care for low-risk situations with possible lab confirmation**
  - ✓Management under healthcare professional responsibility
  - ✓Europe: CE-mark and IVD-Regulation to increase analytical quality
  - ✓Simplified quality assurance and traceability
  - ✓Potential contribution of clinical laboratories as experts
- **Self-testing/Regulated DTCT**
  - ✓Need for a periodic result verification compared to lab for quantitative self-monitoring
  - ✓And for a multilateral cooperation between healthcare professionals including labs, pharmacists, nurses and IVD companies

Conclusions and Perspectives

Issues and success keys

- **To be addressed**
  - ✓Distinguish hospital setting, primary care and self testing for adapted guidelines
  - ✓At international level for primary care: IFCC C-POCT published a position paper on the question of POCT outside hospital (2023)
  - ✓Case of self testing/DTCT ?
- **Heterogeneous approach in European countries**
  - ✓Lack of national/international regulations on Home tests/DTCT
  - ✓For a better and adequate risk management for patient care and safety
- **Role of European LM specialists**
  - ✓**Either** rules are defined and healthcare workers including clinical labs may be rapidly implicated into an efficient patient care chain including home tests
  - ✓**Or** “e-health” and “m-health” will be developed worldwide inside “Internet of Things” without LM and without any healthcare management on a commercial basis

Thanks for your attention

Session internationale – 17/11/2023

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