Global medical Device access

Challenges and Opportunities

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ESC European Society of Cardiology

Importance of Access to Medical Devices

Benefits to patients and healthcare providers !

- to patients

✓ Reliability
✓ reduced need for assistance
✓ increased comfort/security
✓ a sense of control

- to healthcare providers!

✓ Efficiency
✓ Reliability
✓ Automation
✓ human error reduction
✓ ease of use

+ Economic Benefits!

➔ Reducing Hospital Stay, Treatment Costs,,,

Access to medical devices is crucial for delivering effective healthcare services, ensuring timely diagnosis and treatment, and improving patient outcomes

Current Situation in Africa

frontiers | Frontiers in Medical Technology

TYPE Original Research
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Experiences of medical device innovators as they navigate the regulatory system in Uganda

Brenda T. Nakandi[1†], Owen Muhimbise[1†], Ashley Djuhadi[2†], Martha Mulerwa[3], Janet McGrath[4], Philippa Ngaju Makobore[3], Andrew M. Rollins[5] and Robert T. Ssekitolek

good health and well-being (SDG3) (3). However, healthcare facilities in low- and middle-income countries (LMICs) have limited access to functional essential medical devices (4, 5). A study assessing access to essential technologies for safe childbirth in LMICs showed that 40% of medical equipment were non-functional compared to high-income countries (HICs), with less than 1% non-functional medical equipment (6). This disparity stems from a reliance on imported equipment in LMICs hospitals—80% of which is donated (7)—and insufficient training for proper use and maintenance (8–10). In turn, this renders equipment unreliable to provide timely diagnosis, prevention, monitoring, and treatment of disease, thus accentuating inequities in overall health outcomes (2), which contribute to the high mortality rates in LMICs (11, 12).

Pharm Med (2017) 31:383–397
DOI 10.1007/s40290-017-0210-x

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CURRENT OPINION

Medicines Regulation in Africa: Current State and Opportunities

Margareth Ndomondo-Sigonda[1,2] · Jacqueline Miot[1] · Shan Naidoo[3] · Alexander Dodoo[4] · Eliangiringa Kaale[5]

Limited access to Medical devices

Dependence on Imports: High Costs, Delays

DES cost: 300 to 800 €
Mitral clip: 360000 €
TAVI: Edwards: 24 000 € Medtronic
Evolued: pro+ 14000 €
Myval:18000 €

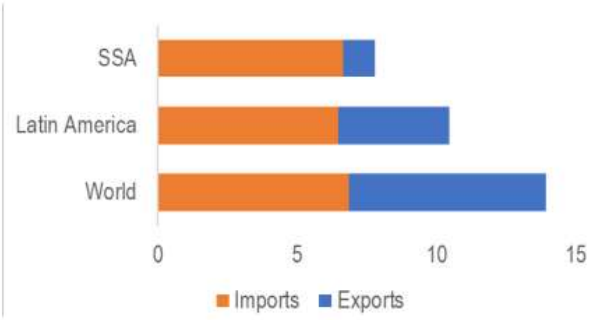
April 14, 2021

Trade in Medical Goods: Challenges and a Way Forward for Sub-Saharan Africa

Shushanik Hakobyan and Reda Cherif

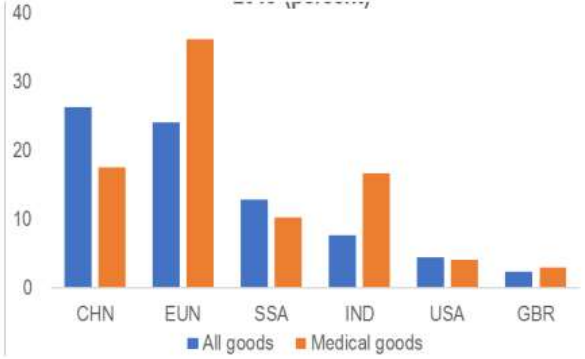
Sub-Saharan African countries rely heavily on imported medical products to meet their healthcare demands.

Figure 1. Share of Medical Goods in Total Exports and Imports, 2019 *(Percent)*



Sources: UN Comtrade; and IMF staff calculations.

Figure 3. Top Source Countries for SSA Imports, 2019 *(Percent)*




Inconsistent Regulatory
Frameworks but evolving!

Pharm Med (2017) 31:383–397
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Margareth Ndomondo-Sigonda[1,2] · Jacqueline Miot[1] · Shan Naidoo[3] · Alexander Dodoo[4] · Eliangiringa Kaale[5]

Published online: 3 November 2017

Abstract Sound regulatory systems are critical for protecting public health against use of medical products which do not meet international standards of quality, safety and efficacy. This review provides a summary of the current status of National Medicines Regulatory Authorities (NMRAs) in Africa, and various initiatives that have been established to improve their performance. All countries in Africa (except Sahrawi Republic), have NMRAs but their organizational set-up and functionality is variable. Some are located within Ministries of Health and others are semi-autonomous. There is progressive improvement in regulatory capacity, particularly in quality control and post-marketing surveillance, pharmacovigilance and clinical trials oversight. The African Vaccines Regulatory Forum, African Medicines Regulatory Harmonization Initiative, Network of Official Medicines Control Laboratories and WHO Prequalification Scheme have helped countries strengthen their regulatory capacities. The potential establishment of the African Medicines Agency (AMA) in 2018 is an opportunity to improve NMRAs' capacity in Africa.

Key Points

All African countries, except one, have National Medicines Regulatory Authorities

No national medicine regulatory authority in Africa can undertake the full range of regulatory functions

The proposed African Medicines Agency provides an opportunity for harmonizing and strengthening NMRAs in Africa

1 Introduction

Medical products, including medicines (drugs), vaccines, blood products, diagnostics and medical devices are critically important for healthcare delivery in all countries. Every country needs an assured supply of safe, efficacious, good quality and affordable medical products to promote public health and patient care [1]. Sound and effective

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their capacity is variable with most of them incapable of performing the core functions expected of NMRAs [1]. The WHO report shows that only 7% of African countries have moderately developed capacity with more than 90% having minimal or no capacity [4]. The absence of functional NMRAs in any country (i) exposes the population to potentially unsafe medical products of variable quality and effectiveness; (ii) facilitates the proliferation of substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products; and (iii) prevents rational use of medical products, all of which are detrimental to public health and patient safety [5, 6].

Historically, NMRAs were first established in Britain (1880s), Switzerland (1900), USA (1906), Norway (1928) and Sweden (1934) mainly for patent protection and trade promotion, though the laws in Norway and Sweden focused on product safety as well [7]. In the USA, the death of 100 people after intake of sulphanilamide elixir prompted legislation (Pure Food and Drugs Act, 1938) to be passed that required assessment of safety before any product is sold. In the early 1960s, the thousands of pregnancies affected by thalidomide-induced phocomelia and other defects served to transform

2 Current State of Medicines Regulatory Systems in Africa

Effective regulation of medical products requires a comprehensive legal basis with appropriate and adequate governance mechanisms; sound technical expertise and scientific tools; sustainable funding; coordination of regulatory activities; and monitoring and evaluation to assess performance [6, 12]. The legal basis gives the NMRA power to perform a function while the level of autonomy in executing its mandate, the appropriate structure that allows for proper coordination of various regulatory activities, availability of financial resources and adequate number of human resources with requisite competency to carry out their duties are prerequisites to its performance [13]. The core NMRA functions include: marketing authorization (MA); licensing of manufacturing establishments; imports and export control; inspection of manufacturing premises and distribution channels; market surveillance (product quality monitoring, pharmacovigilance, control of drug promotion and advertising); quality control; and oversight of clinical trials on drugs [12].

This paper focuses on policy and legal basis for regu-

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Organisational set-up and functions performed by NMRAs in Africa Source: Various Reports, Websites; including national government websites, WHO websites, African Union websites, and general web resources U information not available

Table 1 continued

Country	Organisational set up	Market surveillance	Safety surveillance	Control of drug promotion & advertisement	Control of clinical trials	International cooperation & harmonization	Quality management systems
Togo	Direction des Pharmacies, des Laboratoires et des Equipements Technique, MINISTRE DE LA SANTE ET DE LA PROTECTION SOCIALE; MoH	U	✔	✔	✔	✔	U
Tunisia	Direction de la Pharmacie et du Médicament; Semi-Autonomous	U	U	U	U	U	U
Uganda	National Drugs Authority; Semi-Autonomous	✔	✔	✔	✔	✔	✔
UR of Tanzania	1. Tanzania Food and Drugs Authority; Semi-Autonomous	✔	✔	✔	✔	✔	✔
	2. Zanzibar Food, Drugs and Cosmetics Board; Semi-Autonomous	✔	✔	U	U	✔	✔

DPM: checks each batch of stents each time…(AMC, technical important control unit**).**

⇩

National Medecine agency: centralised purchasing

4 Conclusion

The regulatory landscape in Africa has changed remarkably over the past few years. Apart from the Sahrawi Republic, every country in Africa currently has a NMRA; although, the functionalities are variable across countries and they are at different levels of growth, maturity and expertise. At least 35 African countries (64%) are members of PIDM with South Africa, Morocco, Nigeria, Egypt and Kenya classified as the main ICSR reporting countries. Thirty-four counties in SSA (72%) have quality-control laboratories with different levels of development, and 21 of these (63%) are engaged in market surveillance. However, there is a need to benchmark African NMRAs in a more transparent and objective manner, based on agreed criteria, to identify the different levels of capacities and performance. The outcome of the benchmarking process will be useful to support the ongoing harmonization efforts and facilitate capacity building among the agencies including twinning arrangements and sharing of best practices. The ongoing regulatory systems strengthening and harmonization efforts, such as AVAREF, AMRH and the planned establishment of the AMA, provide opportunities for improvement.

List of Countries that have ratified AMA treaty

ESC


Algeria


Benin


Botswana


Burkina Faso


Cameroon


Chad


Egypt


Ethiopia


Gabon


Ghana


Guinea


Lesotho


Mali


Mauritius


Nami[illegible]


Niger


Rwanda


Seychelles


Sierra Leone


Tunisia


Uganda


Zambia


Zimbabwe


Senegal


Cape Verde


Democratic Republic of Congo (DRC)


Kenya

Minister of Health attended the opening of the first meeting of the implementation of the initiative to harmonize legislation in the pharmaceutical sector in North African countries, which is organized within the framework of cooperation and joint action with the AMA, the African Union and the WHO

Ministère de la santé وزارة الصحة
35 min ·

🔴 وزير الصحة يؤكد أن تناغم التشريعات في قطاع الأدوية بدول شمال إفريقيا سيساهم في تسهيل وصول الأدوية الآمنة والنّاجعة للشّعوب الإفريقيّة ودعم رواجها في هذه السّوق الواعدة

📌 أشرف وزير الصحة علي المرابط اليوم الثلاثاء 16 أفريل 2024 بالعاصمة على افتتاح الاجتماع الأوّل لتنفيذ مبادرة تناغم التّشريعات في قطاع الأدوية بدول شمال إفريقيا الذّي ينتظم في إطار التّعاون والعمل المشترك مع الوكالة الإفريقية للأدوية والاتّحاد الإفريقي ومنظّمة الصحّة العالمية والذي تتواصل فعالياته إلى غاية يوم الخميس 18 أفريل الجاري.

ويمثّل هذا الحدث فرصة للدّول المشاركة وهي تونس، الجزائر، المغرب، ليبيا، مصر، وموريتانيا للارتقاء بقطاع الصنّاعات الدّوائيّة وتعزيز جودة المنتوجات الصحّية ومراقبتها ومزيد التّنسيق وتسهيل إجراءات التّبادل بين هذه الدّول في مجال الأدوية وذلك بمشاركة المشرفين على الهياكل ذات العلاقة ووكالات الأدوية بالبلدان المشاركة والخبراء والمختصّين من إفريقيا وممثّلي منظمّة الصحّة العالميّة.

وتمّ خلال الاجتماع الأوّل التّداول في أهمّية تسريع توحيد القوانين المتعلّقة بتصنيع الأدوية ومراقبة جودتها وتسهيل ترويجها لإتاحتها لكلّ الأفارقة، إضافة إلى فتح النّقاش بين الحضور والمشاركين عن بعد بشأن الصّعوبات التّي تعترض الأقاليم الإفريقيّة في مجال التّشريعات والقوانين المتّصلة بالدّواء وطرق تفعيل مشروع تناغم التّشريعات مع المواصفات الدّوليّة.

وأكّد وزير الصحّة في كلمته بالمناسبة على ضرورة تعزيز علاقات التّعاون بين الدّول الإفريقيّة والوكالات الإفريقيّة للأدوية لا سيّما على مستوى تناغم التّشريعات والقوانين المتعلّقة بإنتاج الأدوية وترويجها بما يساهم في وصول المواطن الإفريقي لحاجياته من هذه المادّة الحيويّة وتحقيق الأمن الدّوائي في

What about Tunisia?

La Tunisie leader de l'industrie des dispositifs médicaux en Afrique

Date de publication : 02/11/2023

Intitulé «Economic Development in Africa 2023», le dernier rapport de la Conférence des Nations Unies sur le Commerce et le Développement (CNUCED) indique que la Tunisie, l'Afrique du Sud, l'Égypte et Maurice détiennent la position de plus grands exportateurs de dispositifs médicaux en Afrique. Cette situation permettant à ces pays de devenir des plateformes dans ce domaine en Afrique. La valeur des exportations de dispositifs médicaux représente pour la Tunisie 193 millions de dollars en 2018-2020, 119 millions de dollars pour l'Afrique du Sud, 35,8 millions de dollars pour l'Égypte et 32,2 millions de dollars pour Maurice. Ce potentiel peut être exploité en introduisant des technologies et des solutions innovantes, en particulier dans les zones rurales. D'un autre côté, les entreprises doivent disposer de solides performances numériques pour obtenir un avantage concurrentiel dans un secteur axé sur la technologie et la numérisation.

Tunisia, leader in the medical devices industry in Africa

Entitled "Economic Development in Africa 2023", the latest report from the United Nations Conference on Trade and Development (UNCTAD) shows that Tunisia, South Africa, Egypt and Mauritius are the biggest exporters of medical devices in Africa. This situation enables these countries to become platforms in this field in Africa. The value of exports of medical devices represents $193 million for Tunisia in 2018-2020, $119 million for South Africa, $35.8 million for Egypt and $32.2 million for Mauritius. This potential can be exploited by introducing innovative technologies and solutions, particularly in rural areas. On the other hand, companies need strong digital performance to gain a competitive edge in a sector driven by technology and digitization.

Tunisia, leader in the medical devices industry in Africa

According to 2021 figures, only 20 African countries have pharmaceutical production capacity, including Tunisia, which is the leading producer and exporter in Africa, with production focused mainly on generic products, which account for around 70% of the total value of local production.Despite Tunisia's strong position on the African market, the country remains highly dependent on imports (mainly from France). In addition, shortages of medical equipment, including medical devices, linked to the COVID-19 pandemic, have made Tunisia vulnerable to external shocks

Impact de 2020 sur le commerce des Dispositifs Médicaux

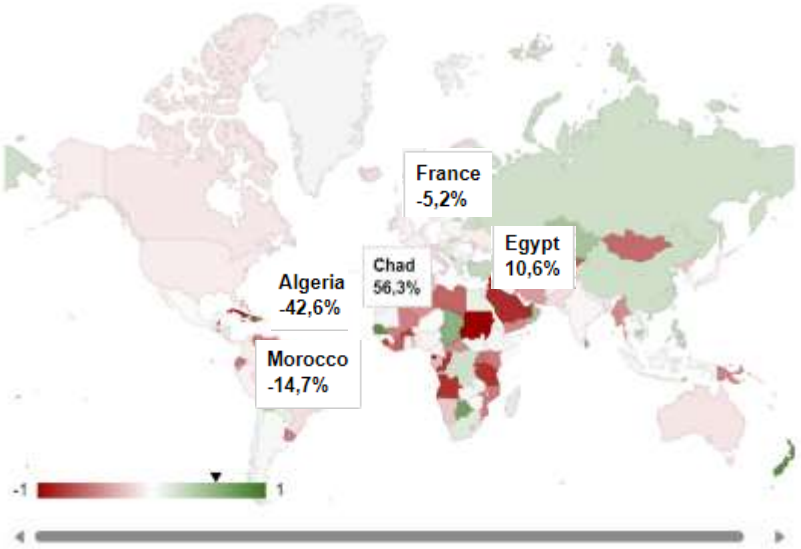
2020 impact on the medical devices business

Par Dieudonné Opota

le 27 Mai. 2021 · Généralités

Exportations

Taux de variation 2019-2020 des exportations de dispositifs médicaux, **tous codes**. Survolez avec la souris pour afficher les valeurs.



Classement général 2021

Selon les données de 2020, tient autant compte du **rapport exportations/importations** que de la **part dans les exportations mondiales**.
ΣE : total des exportations de DM dans le monde.
Var. : variation avec le classement 2020.

Rang	Var.	Pays	Exportations	Importations	E/I	E/ΣE
32	-8	Hungary	963,28M$	1 808,29M$	53%	0,39%
33	=	Lithuania	436,49M$	401,57M$	109%	0,17%
34	=	Spain	1 542,05M$	5 243,29M$	29%	0,62%
35	-3	Australia	1 454,78M$	4 894,99M$	30%	0,58%
36	+7	Philippines	376,81M$	408,93M$	92%	0,15%
37	-2	Pakistan	366,24M$	387,00M$	95%	0,15%
38	+1	Slovenia	383,36M$	439,95M$	87%	0,15%
39	+3	Turkey	740,99M$	1 834,76M$	40%	0,30%
40	+1	Estonia	245,21M$	209,95M$	117%	0,10%
41	-3	Bulgaria	252,51M$	253,01M$	100%	0,10%
42	+179	Tuvalu	1,67M$	0,02M$	11127%	0,00%
43	-6	Tunisia	193,56M$	214,25M$	90%	0,08%
44	+1	Slovakia	272,80M$	457,07M$	60%	0,11%
45	-1	Iceland	92,46M$	67,64M$	137%	0,04%

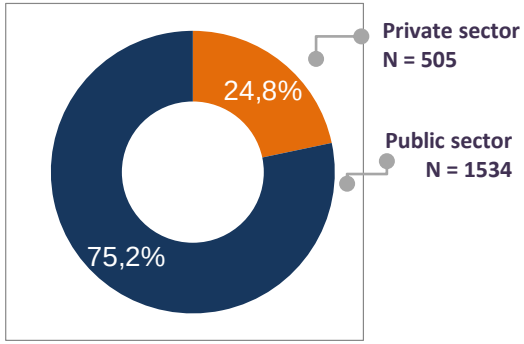

STCCCV
Société Tunisienne de Cardiologie
& de Chirurgie Cardio-Vasculaire
NATURE-PCI
Début d'inclusion le 30 janvier 2020

2 039
patients

113
investigators

29
centers

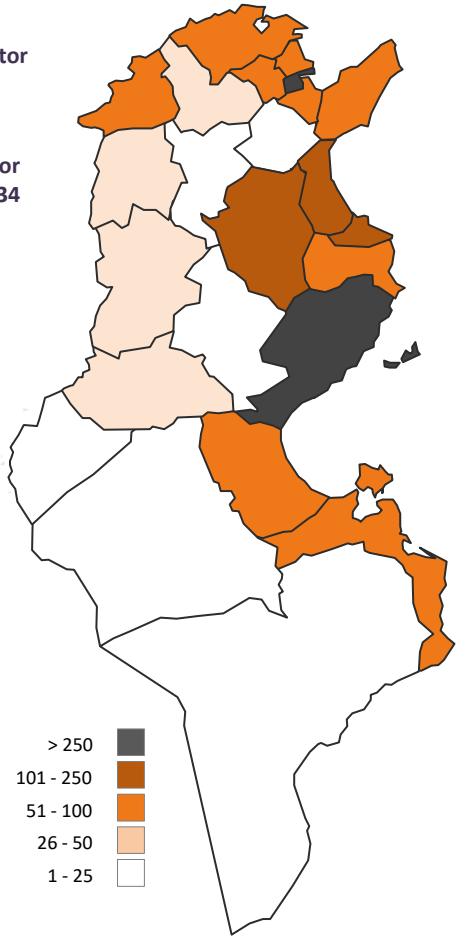
09 months
Inclusion period



2962 lesions

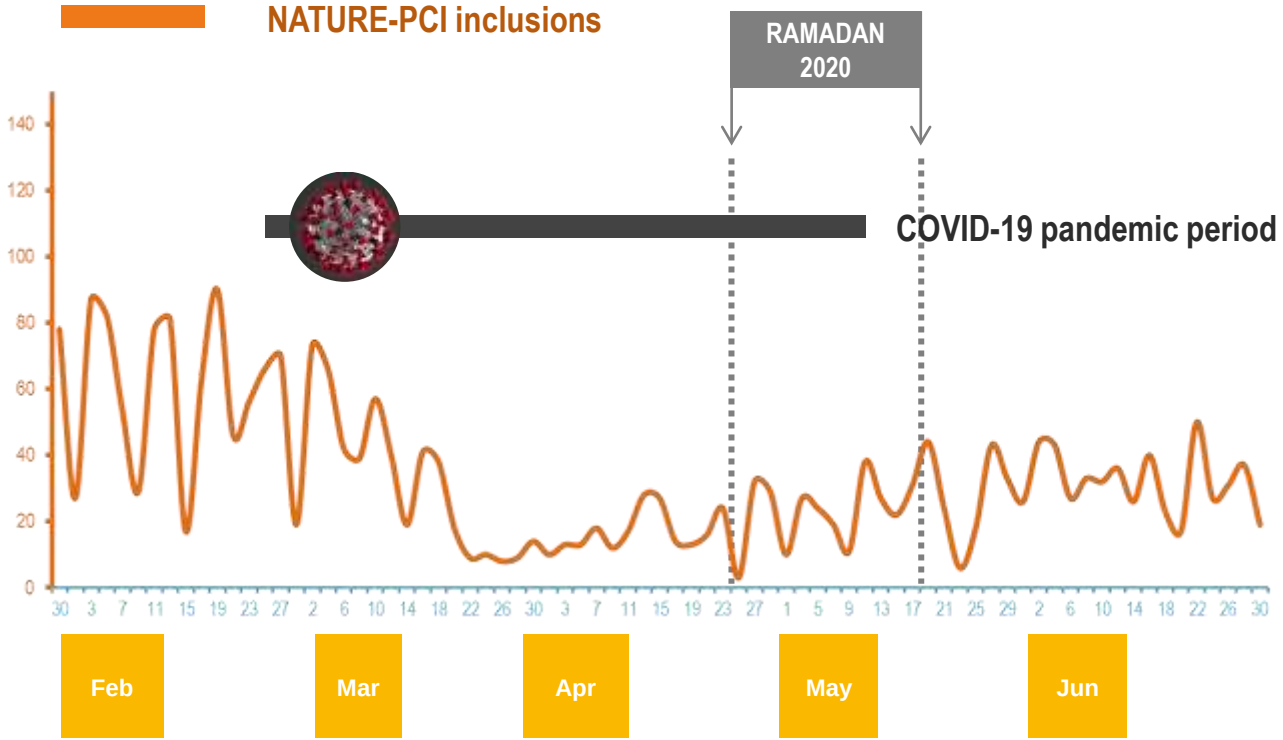
2925 PCI

Inclusions rate according to governorate



ESC

Daily PCI interventions during the enrollment period



Comparison between North Africa countries

1000 dilatation/10000 inhabitants in Tunisia

500 Dilatation/10000 inhabitants in Morocco

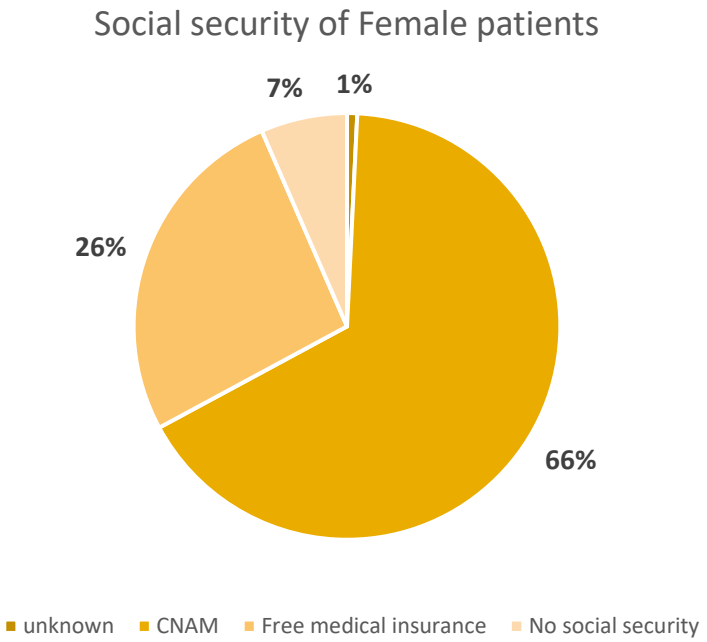
1200-1300 Dilatation/10000 inhabitants in France

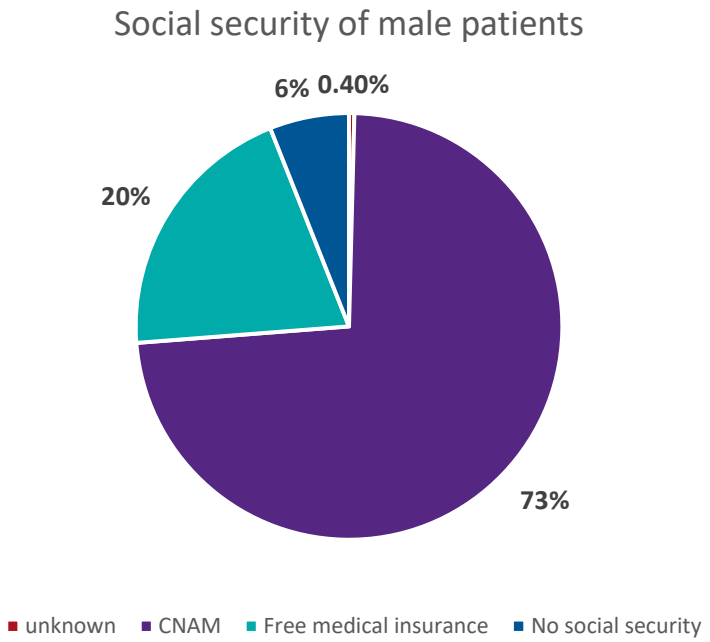
250 Dilatation/10000 inhabitants in Algeria

Cefficient of stenting =1.3

Reimbursement: 3 stents

Sex-based Social Security difference





Résultats préliminaires

Les Hôpitaux Publics

Centre d'investigation	Nombre total des TAVI implantées	Bras Rétrospectif	Bras Prospectif
Hôpital Militaire Principal d'Instruction de Tunis	149	128	21
Hôpital Aberrahmen Mami, Tunis	23	19	04
Hôpital La Rabta, Tunis	32	30	02

Centre d'investigation	Nombre total des TAVI implantées	Bras Rétrospectif	Bras Prospectif
Hôpital Hedi Chaker, Sfax	08	07	01

Résultats préliminaires

Les cliniques privées

Investigateurs	Nombre total des TAVI implantées	Bras Rétrospectif	Bras Prospectif
Région du grand Tunis (Dr Hajlaoui, Dr Lahidheb)	29	25	04
Région de Sousse (Dr Kacem, Cliniques Zayatine& Essalem)	03	-	03
Région de Sfax (Dr Kharrat, Dr Morched)	36	33	03

STCCCV
Société Tunisienne de Cardiologie & de Chirurgie Cardio-Vasculaire

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NATURE-CIED reveals cardiac pacing secrets in Tunisia

NATURE CIED: STUDY DESIGN

Nationwide Multicenter Prospective Observational Registry with 1 year follow-up period

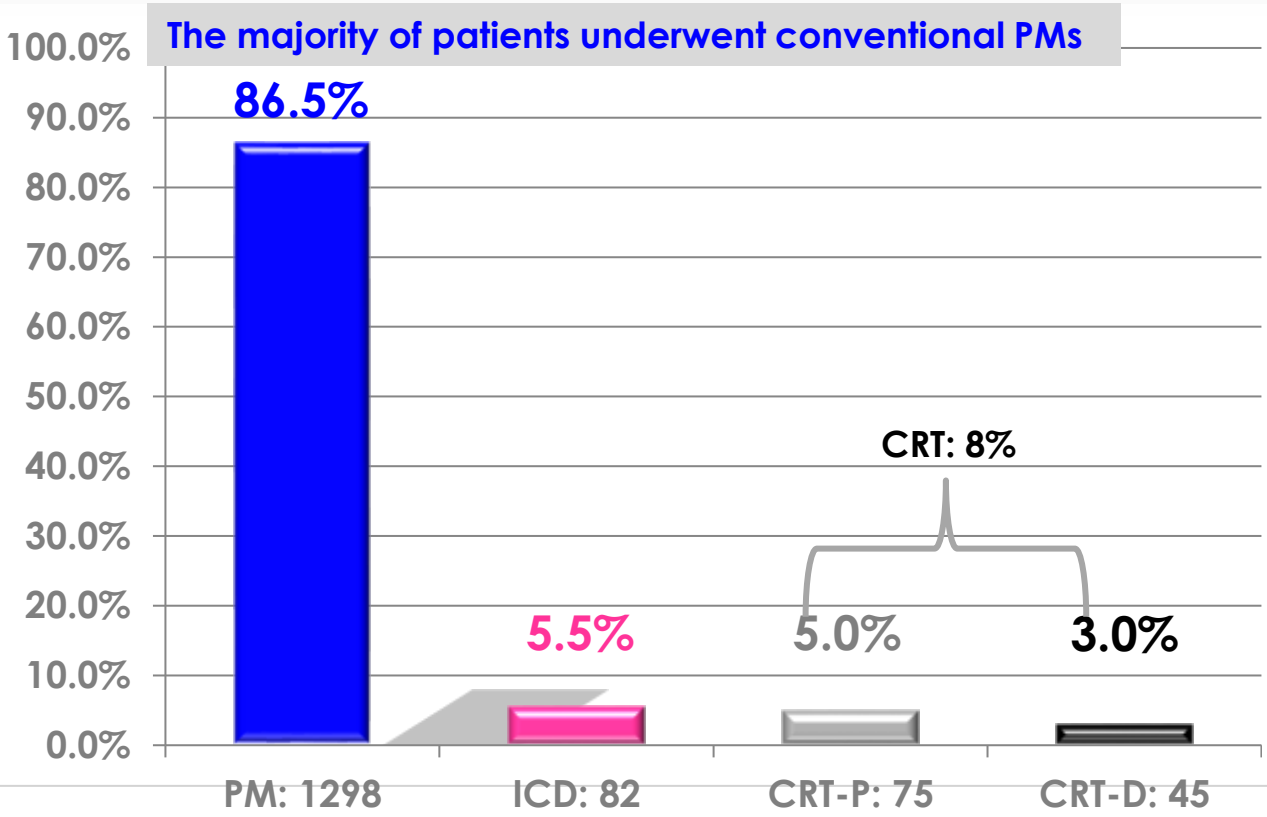
Patient enrollment: January 2021 - January 2022, at all public and private CIED implanting Centers that agreed to participate in the registry.

Inclusion criteria: all consenting patients who underwent CIED including primary implantation, generator replacement and upgrade system.

Exclusion criteria: non-consenting patients, those operated exclusively for lead dysfunction

INCLUSIONS DEPENDING ON TYPE OF CIED

1500 patients



3% in NATURE HF 2018

Opportunities and Solutions

Promoting Local Production and Innovation

Strengthening Healthcare Infrastructure and Training

invest in upgrading healthcare infrastructure to ensure adequate maintenance and utilization of medical devices.

Provide specialized training programs for healthcare professionals on the use, maintenance, and repair of medical devices.

Integrate medical device management and maintenance training into existing healthcare education to build a sustainable healthcare system.

Developing Robust Regulatory and Policy Frameworks

Harmonize regulatory standards and procedures across African countries to facilitate the timely and efficient approval of medical devices while ensuring safety and quality.

Implement risk-based regulatory approaches that prioritize the review and approval of essential medical devices, reducing barriers to market entry for life-saving technologies.

Recycle and Re-Use of Medical Devices

Conclusion

Access to medical devices is not just a matter of convenience!
➔it directly impacts patient outcomes and public health

Tunisia and other African countries face significant challenges in accessing medical devices
➔ high costs, reliance on imports and regulatory hurdles

However, encouraging local expertise, fostering innovation, and strengthening regulatory frameworks, Tunisia and Africa can overcome these challenges and build sustainable healthcare systems that prioritize accessibility, affordability, and quality

Thank you for your attention