Access to medications and conducting clinical trials in LMICs

KDIGO

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CLINICAL STUDIES WORLDWIDE

13911
85545
2364
2207
6539
53529
7994
4553
3558
18476
3675
3162
3928
5053

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Colors indicate the number of studies with locations in that region

Labels give the exact number of studies

www.clinicaltrials.gov

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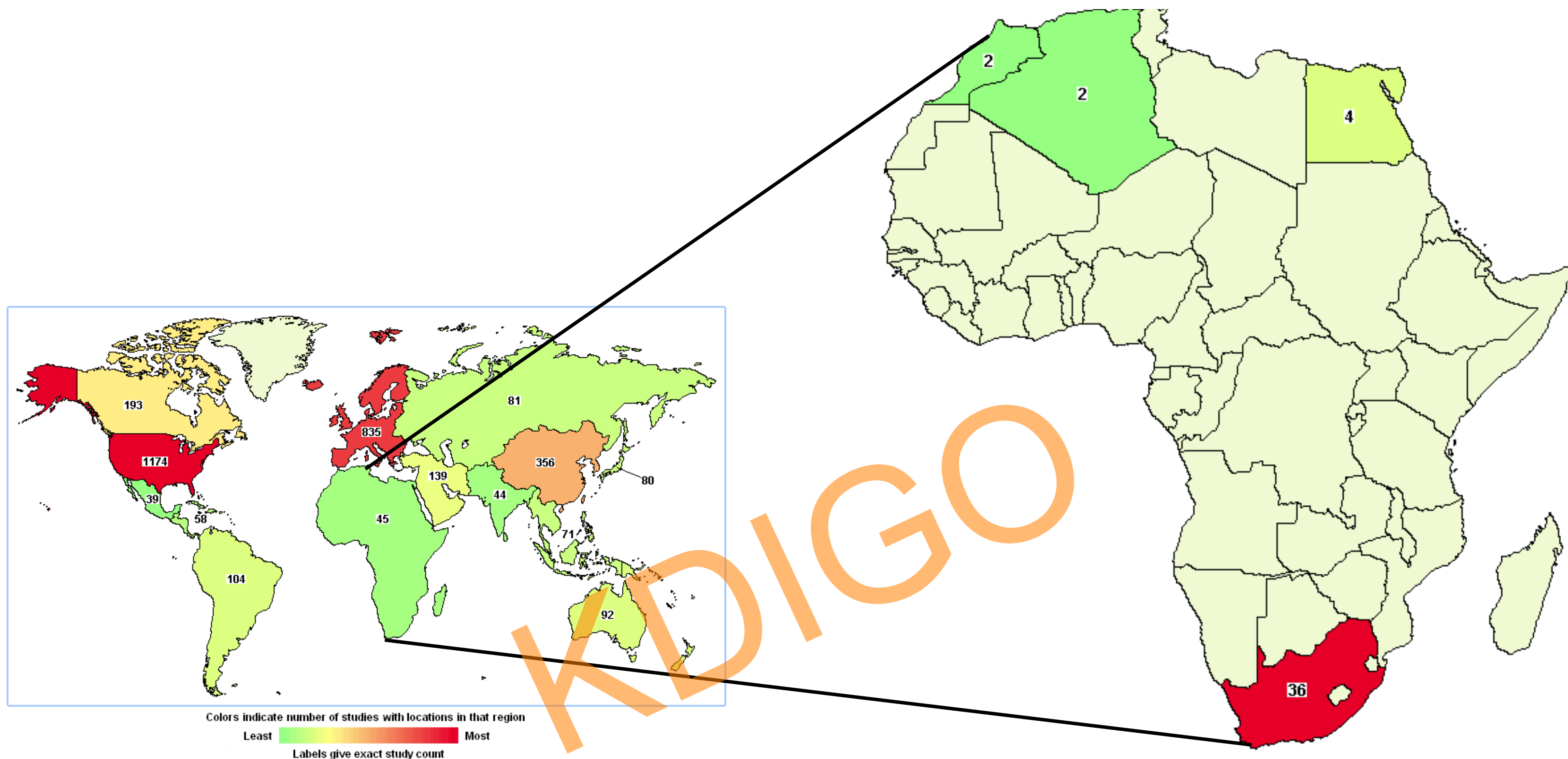

Figure 1: Studies on "Chronic kidney disease" worldwide.
The search yielded 2851 studies worldwide; the number of studies in South America, Africa, India and China together is less than number of studies in Europe alone.

Okpechi, I. G. et al. Nat. Rev. Nephrol. 11, 189–194 (2015)

www.clinicaltrials.gov

The number of clinical trials in a country is

The Barometer of GCP

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Why are so few Pharma sponsored studies in CKD done in Africa?

Too few Nephrologists.

Burden of clinical work.

Lack of local Government funding.

Resource limitation.

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Table 3 Workforce and numbers of haemodialysis and PD patients in Africa versus some non-African countries

Table 3 | Workforce and numbers of haemodialysis and PD patients in Africa versus some non-African countries

Country	Year	Population[115]	GNI per capita*	Physicians (per 10,000 population)[116–121]	Nephrologists (pmp)[122–124]	Prevalence of HD (pmp)[11,122,124–127]	Prevalence of CAPD (pmp)[11,122,124–127]	Renal transplants per year[11,122,124–127]
North Africa								
Egypt	2008	81,121,000	6,060	179,900 (24)	500 (6.5)	421.0	45.0	500
Morocco	2008	31,951,000	4,600	1,303 (11)	135 (4.5)	162.0	30.0	13
Tunisia	2008	10,549,000	9,060	2,245 (<1)	70 (7)	650.0	20.0	70
West Africa								
Cote d'Ivoire	2008	19,737,000	1,810	2,746 (1.4)	ND	6.0	ND	ND
Ghana	2009	24,391,000	1,620	2,033 (0.8)	2 (0.1)	6.4	0	0
Mali	2008	15,369,000	1,030	729 (0.5)	ND	1.3	ND	ND
Nigeria	2008	158,423,000	2,240	55,376 (3.5)	70 (0.3)	6.3	0	70
Senegal	2008	12,433,000	1,910	741 (0.6)	2 (0.2)	4.0	2.0	0
East and Central Africa								
Cameroon	2004	19,598,000	2,270	3,124 (1.6)	6 (0.3)	3.6	ND	ND
DRC	2004	65,965,000	320	5,827 (0.9)	7 (0.1)	ND	0.2	ND
Ethiopia	2007	82,949,000	1,040	1,806 (0.2)	2 (<0.1)	ND	ND	ND
Kenya	2002	40,512,000	1,640	4,506 (1.1)	15 (0.5)	6.4	0.7	10
Southern Africa								
Mauritius	2004	1,280,000	13,980	1,303 (10.2)	10 (8.3)	ND	ND	ND
South Africa‡	2011	50,586,000	10,360	38,236 (7.6)	108 (2.1)	41.4	21.2	250
Non-African countries								
SLANH region	2006	544,233,000	4,756	ND	ND	280.6	96.7	8,224
UK	2008	63,047,000	35,840	ND	ND	342.0	69.0	22,300§
USA	2010	313,847,000	47,310	ND	ND	1,132.5	89.6	179,361§

Data obtained from references 115–117. *GNI per capita for 2010: data obtained from http://www.globalhealthfacts.org/data/topic/map.aspx?ind=118&by=Location&order=d&fmt=120. ‡Health Professions Council of South Africa (HPCSA) 2012 Statistics. http://www.hpcsa.co.za/statistics.php. §These data are the total number of prevalent renal transplant recipients in the indicated year. Abbreviations: CAPD, continuous ambulatory peritoneal dialysis; DRC, Democratic Republic of the Congo; GNI, Gross National Income; HD, haemodialysis; ND, no data; PD, peritoneal dialysis; pmp, per million population; SLANH, Latin American Society of Nephrology and Hypertension.

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Swanepoel, C. R. *et al*. (2013) Nephrology in Africa—not yet *uhuru*
Nat. Rev. Nephrol. doi:10.1038/nrneph.2013.168

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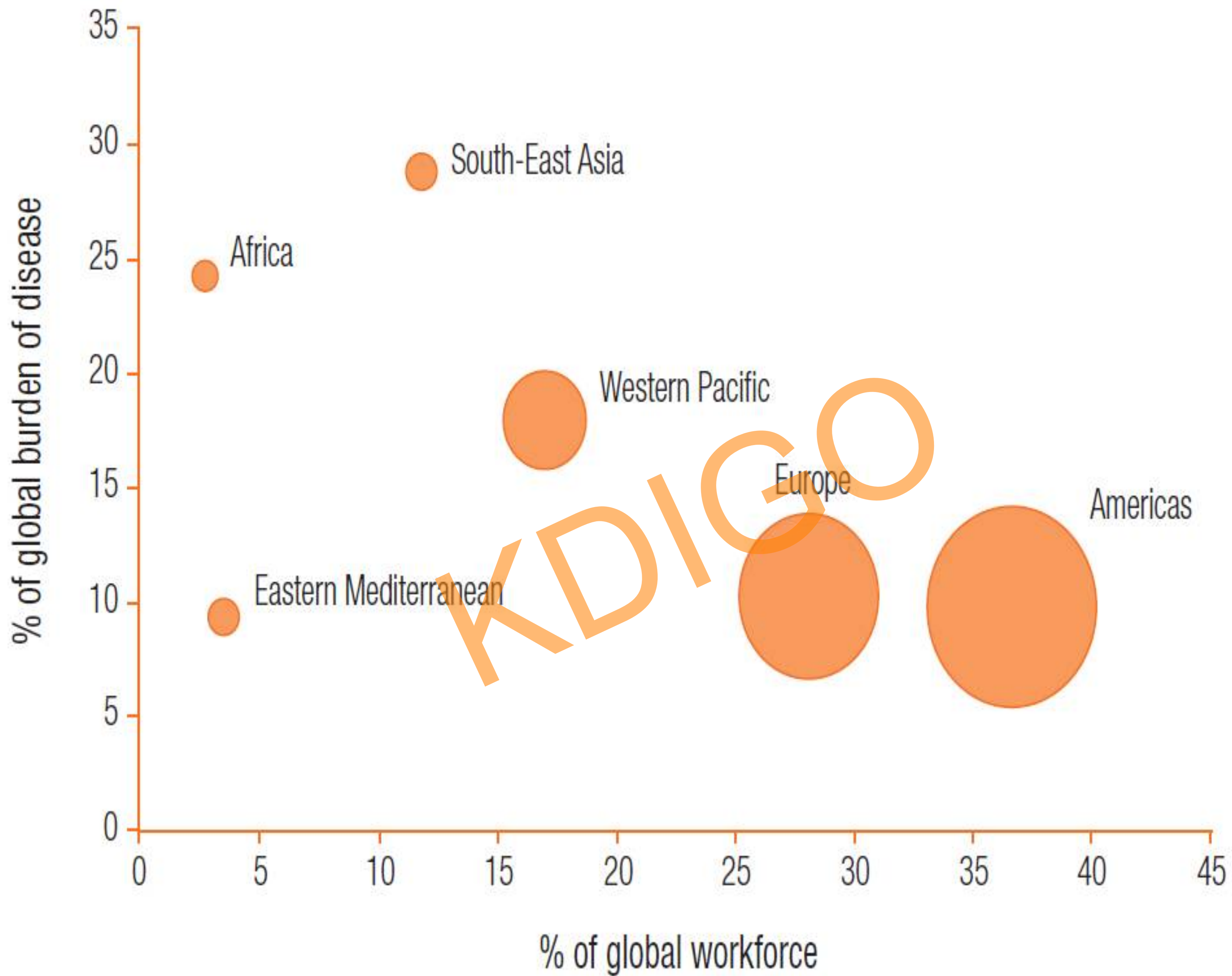

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PREFACE TO THE FIRST EDITION

This book concerns the aboriginal of Africa, now generally referred to as "the African," or colloquially "the Native."

Africa is being opened up rapidly and medical service for the Native is being extended every day; but few books concerning the sick African are available, so I am not going to make the customary apology for "putting yet another book on the market." Indeed, I have long felt that such a book, designed for clinical work, would be of service particularly to Europeans coming into contact with the Native for the first time.

This book does not pretend to be a text-book, but rather a guide to those working amongst the Natives. It is intended primarily for the use of members of the medical profession, but will, I hope, be of assistance to missionaries and Native medical orderlies. In my description of diseases I have not gone into great detail, but have endeavoured so to stress their salient features that the clinician will be able to recognise them without difficulty.

Many of the clinical manifestations of disease in the Native differ. often markedly, from those of the same diseases in the European. These differences I have described in the light not only of my own experience, but whenever possible of that of other medical men who have seen Native clinical practice.

The civilisation and the outlook of the Native in no way resemble those of the white man. In Native practice this fact must be taken into account, for it involves an entirely different angle of approach in investigation and treatment. Moreover, many practical difficulties such as the long distances to be covered, the lack of facilities and the insufficiency of the funds available for medical purposes, must be taken into consideration.

This book has been written purely from the clinical aspect. I have purposely omitted most of the details of helminthology, protozoology and parasitology. I have endeavoured to show how best to treat the patient in the most practical and simple way, without losing sight of the difficulties of Native practice. Inadequate as such treatment must often be, it is the only possible because of the obstacles presented by economy and the Native's standard of civilisation.

My classification is not based on the aetiology of disease (e.g. protozoal or bacterial). Wherever possible, each condition is discussed in a separate chapter.

I had better confess that this book has been written with no pretensions to style; but I have tried to make myself clear, and it is my great hope that those who turn to this book will find what they are seeking unmistakably and helpfully presented.

I desire to express my gratitude to Dr. A. P. Martin, O.B.E.,

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The Sick African. Michael Gelfand.
Salisbury October 2, 1943

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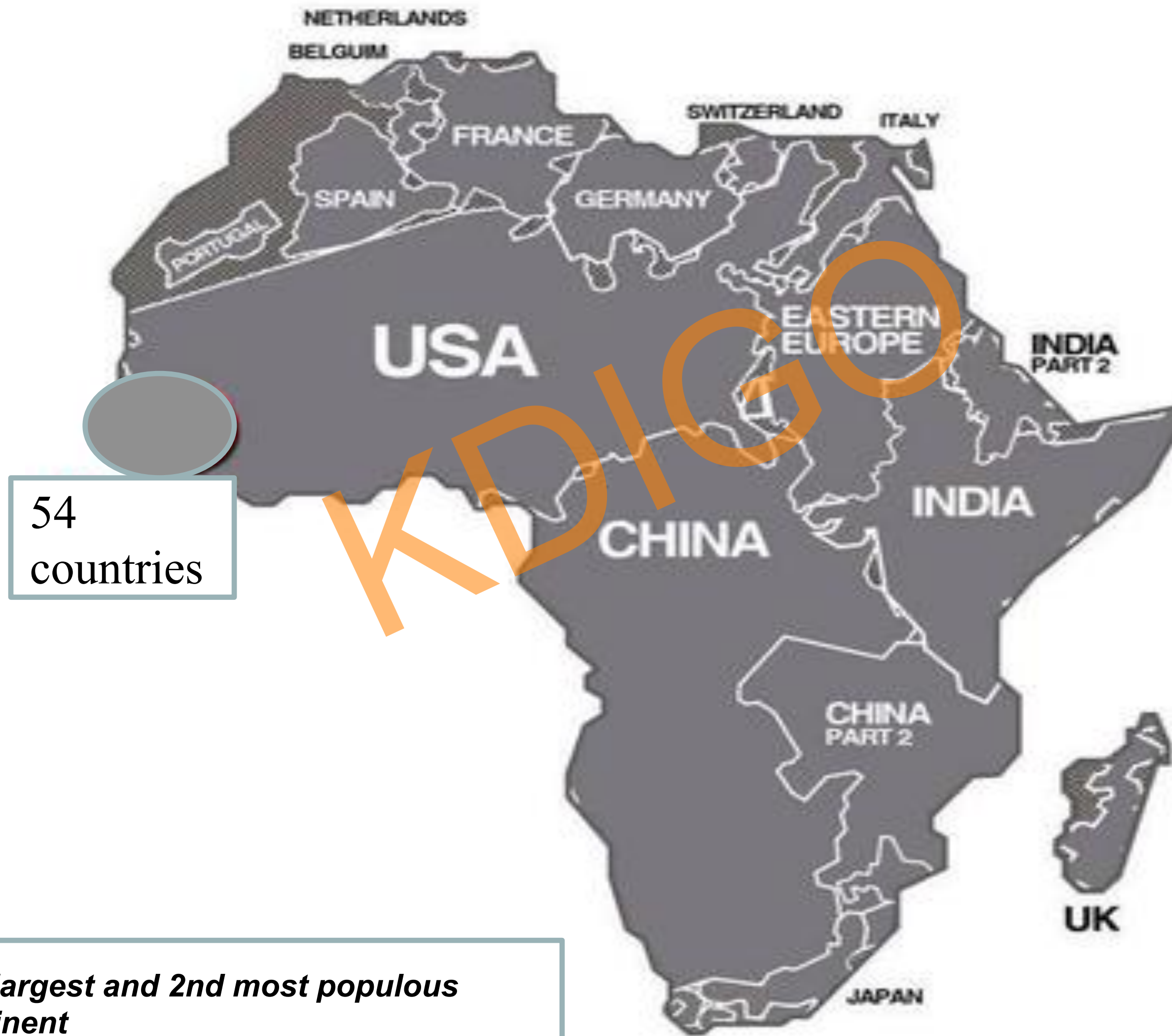
THE TRUE SIZE OF AFRICA



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54 countries

2nd largest and 2nd most populous continent

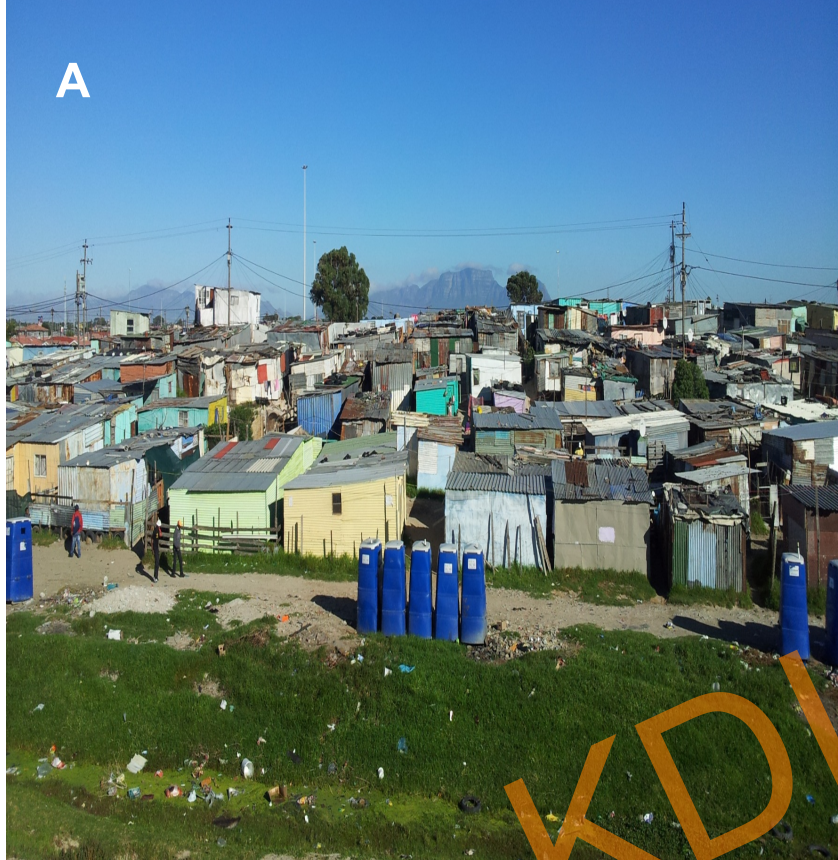

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Figure 7: (A) An informal township (Khayelitsha) in Cape Town with shacks and outdoor toilet systems (foreground) where some of our dialysis patients come from. The majestic Table Mountain can be seen at the background (A); (B)&(C) shows the living conditions of Sudanese PD patients as well as difficulties encountered by health care workers trying to access these patients on a home visit day (Images C & D courtesy of Dr Abu-Aisha Hassan)

Swanepoel, C. R. *et al*. (2013) Nephrology in Africa—not yet *uhuru*
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Resource limitation !

Dr X

- .... nephrologist and I'm very interest by nephropathology.
- During my specialization, my interest to this subject grew, and I wish to start training nephropathology and implement it in my country.
- I spent 3 month training in nephropathology in Tunisia, were I got some basics.
- I tried to implement nephropathology in my hospital, helped by general pathology. It is very difficult, because the pathologist is not interested and is busy with non nephrology biopsies. Microscope not easy to access

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Resource limitation !

Dr X

- Another problem is the cost of the biopsy which is very expensive and the lack of many coloration: only trichrome, hematoxyline eosine and PAS colorations are available; others such as silver or red congo are not as well as material for immunofluorescence or polarizing microscope.
- So what we are doing it is just try to read the biopsy according to the time the pathologist give us (because of microscope) and coloration available.
- I really want to ameliorate my knowledge and try to implement a nephropathology laboratory in ………...

I hope you can help us.

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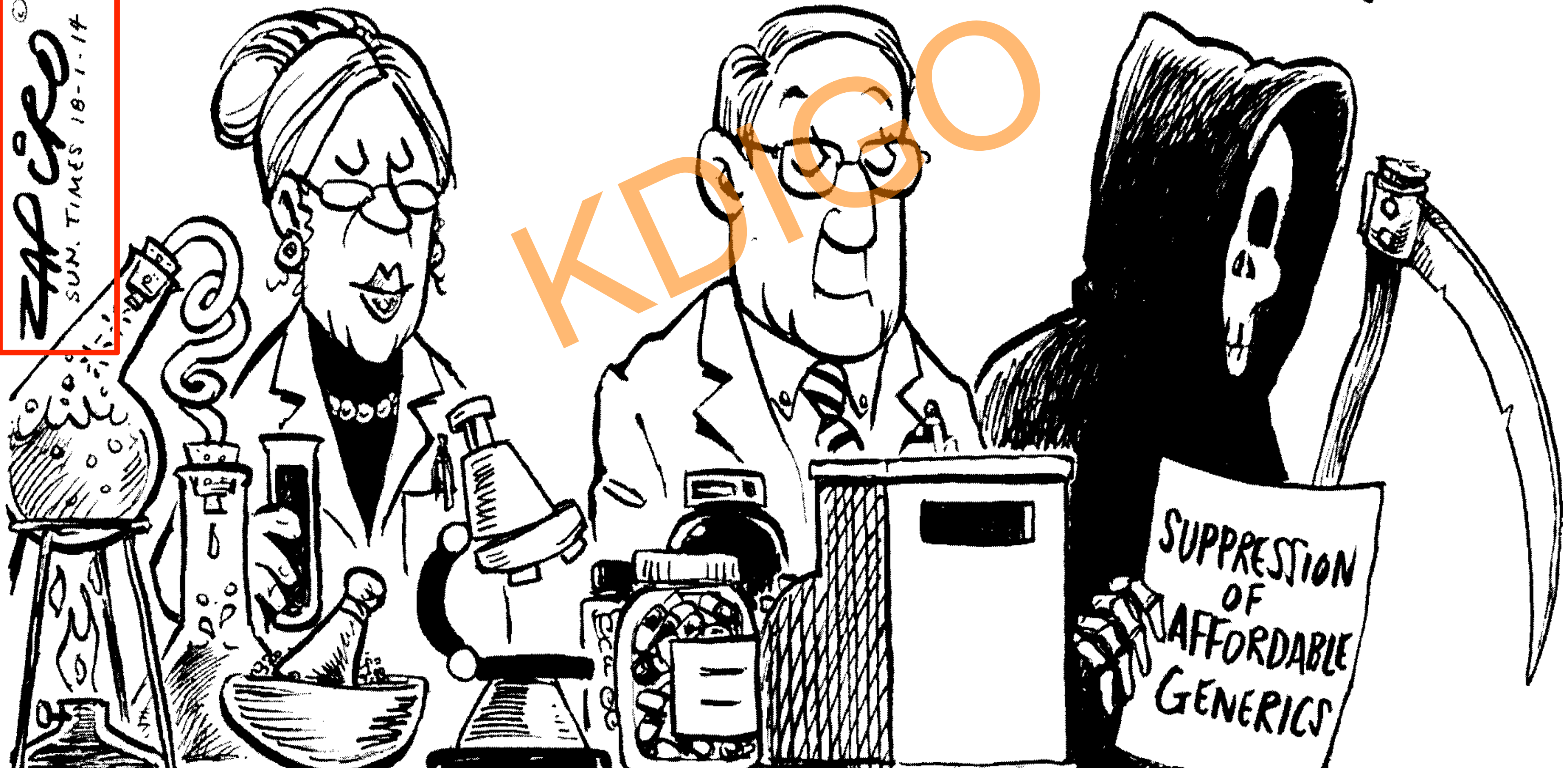
BIG PHARMA

RESEARCH DIVISION

PROFIT DIVISION

3RD WORLD GENOCIDE DIVISION



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Health Minister in South Africa -Aaron Motsoaledi - has labelled a campaign by these companies as genocide and a conspiracy of "satanic magnitude".(SABC)

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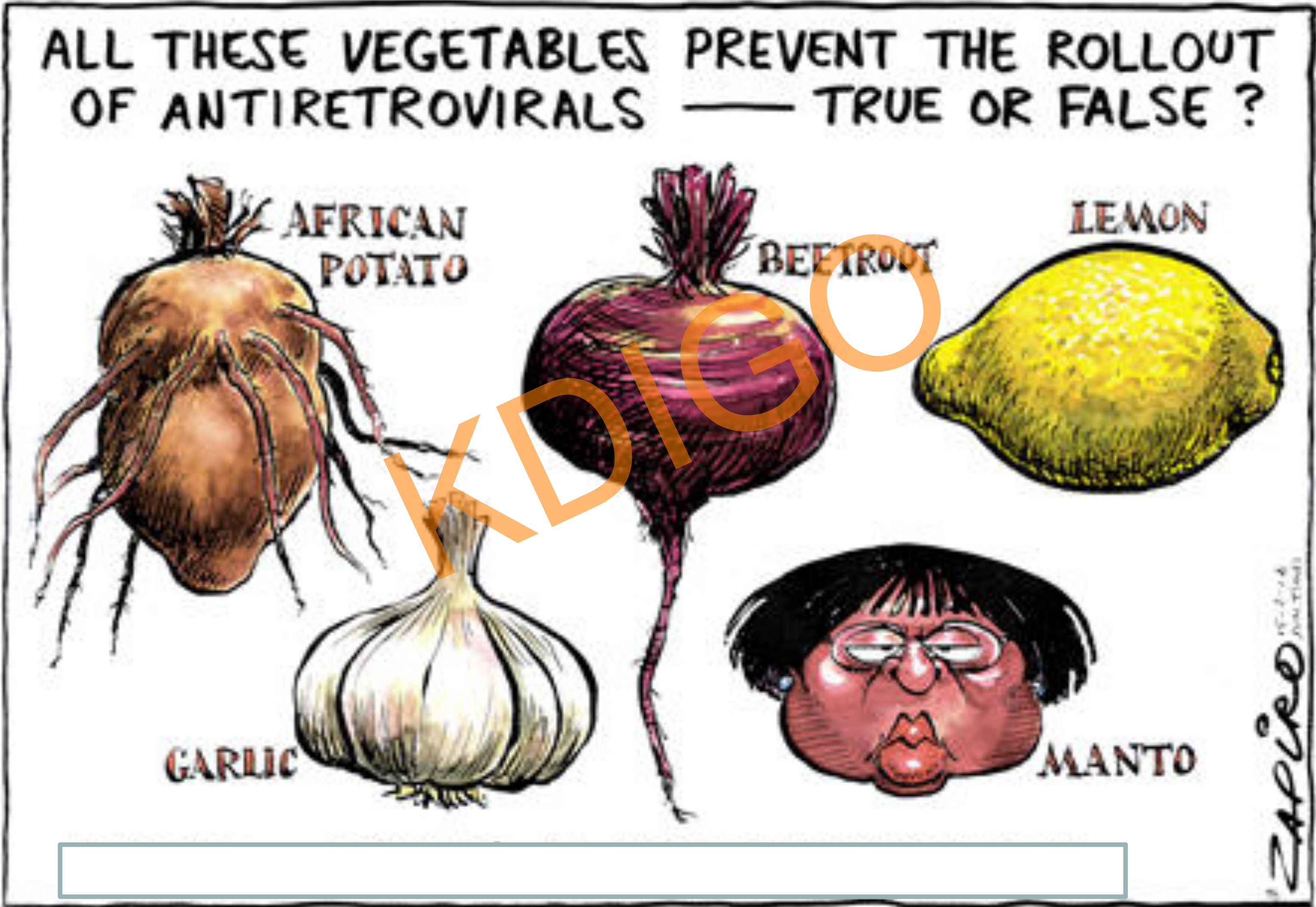
The conflict arises from a department of trade and industry document in which the government proposes measures on intellectual property, including patents over life-saving drugs. (SABC)

Incompetent politicians…



15th Feb 2004 in Sunday Times

Access to medications and conducting clinical trials in LMICs

“ Trials may be the only means by which sick individuals are afforded the opportunity for treatment...”

“ ...an urgent need exists to establish infrastructure that supports research endeavours”

“ The largest hurdle in access to medications is the chaotic nature of the DRAs of many countries...”

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Okpechi, I. G. et al. Nat. Rev. Nephrol. 11, 189–194 (2015); published online 10 February 2015; doi:10.1038/nrneph.2015.6

Africa is a violent continent.

Civil strife and war mongering add to the burden of disease and hinder Medical progress.

Charles Villa-Vicencio, Emeritus Professor at University of Cape Town.

SA 's   Truth and Reconciliation Commission

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What can KDIGO do?

Use collaboration between private and public enterprises.

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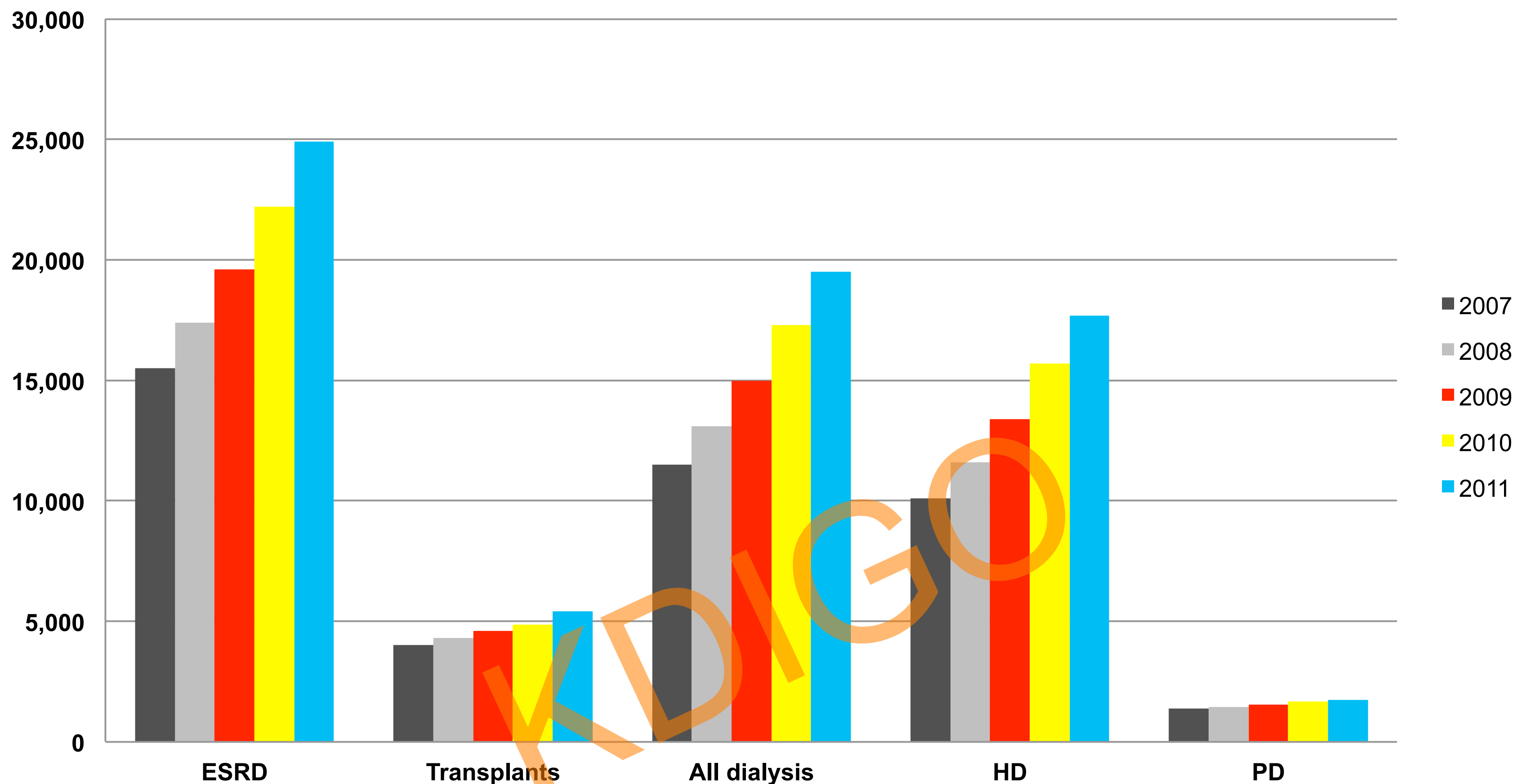

Figure 3: Renal replacement therapy in Sub-Saharan Africa 2007 – 2011*

*Countries included: Angola, Benin, Botswana, Burkina Faso, Cameroon, Democratic Repbulic of Congo, Cote d'Ivoire, Ethiopia, Gabon, Kenya, Madagscar, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, South Africa, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia and Zimbabwe.

Source: Fresenius Medical Care – Market Survey (2007 – 2011)

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African economies are booming.

According to the latest figures from the World Bank.

Kenya, Nigeria and Ethiopia are among the fastest growing economies in the world – but many have questioned if this growth is sustainable.

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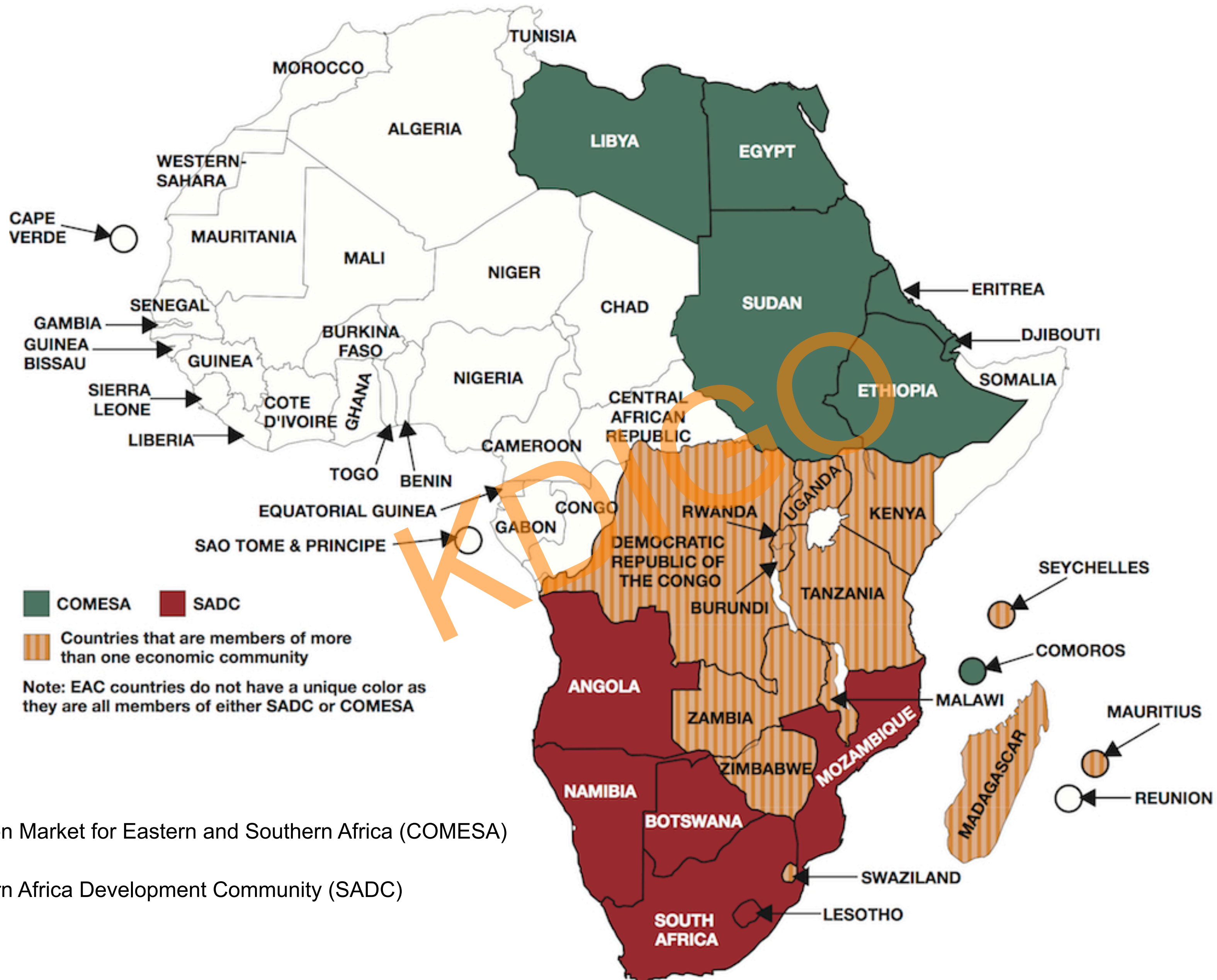
Three Regional Economic Communities (RECs)



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Common Market for Eastern and Southern Africa (COMESA)

Southern Africa Development Community (SADC)

What can KDIGO do?

Invest in opinion leaders.

* Have KDIGO guideline sessions at local congresses in LMICs.

* In Africa join with NEPAD and/or the WHO

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New Partnership for Africa's Development.

In May 2014 NEPAD designated

10 Centres

named

Regional Centres of Regulatory Excellence

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Okpechi, I. G. et al. Nat. Rev. Nephrol. 11, 189–194 (2015)

The hope exists that

“ Regulatory capacity in Africa will develop through these centres in partnership with national governments across the continent.

As the centres are not-for-profit organizations

They may become loud and powerful voices in the ears of governments—via their regulatory bodies—and strong advocates for patient rights”.

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Okpechi, I. G. et al. Nat. Rev. Nephrol. 11, 189–194 (2015)

Box 1 | NEPAD designated RCOREs[32]

- WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance, University of Ghana Medical School, Ghana (RCORE in pharmacovigilance)
- Kilimanjaro School of Pharmacy and St. Luke's Foundation, Tanzania (RCORE in training in core regulatory functions)
- WHO Collaborating Centre for the Quality Assurance of Medicines, North-West University, Potchefstroom Campus, South Africa (RCORE in quality assurance and quality control of medicines)
- Centre for Drug Discovery, Development & Production, University of Ibadan, Nigeria (RCORE in training in core regulatory functions)
- Medicines Control Authority of Zimbabwe (RCORE in medicine registration and evaluation, quality assurance/quality control and clinical trials oversight)
- National Drug Authority, Uganda (RCORE in licensing of the manufacture, import, export and distribution of medicines, and inspection and surveillance of manufacturers, importers, wholesalers and dispensers of medicines)
- Direction General de la Pharmacie du Medicament et des Laboratoires, University of Ouagadougou, Burkina Faso (RCORE in clinical trials oversight)
- Food & Drugs Authority, Ghana (RCORE in medicine evaluation, registration and clinical trials oversight)
- Pharmacy & Poisons Board, Kenya (RCORE in pharmacovigilance)
- Tanzania Food & Drugs Authority and School of Pharmacy, Muhimbili University of Health and Allied Sciences, Tanzania (RCORE in medicine evaluation and registration)

Abbreviations: NEPAD, New Partnership for Africa's Development; RCORE, Regional Centre of Regulatory Excellence.

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Okpechi, I. G. et al. Nat. Rev. Nephrol. 11, 189–194 (2015); published online 10 February 2015; doi:10.1038/nrneph.2015.6

IT ALWAYS SEEMS IMPOSSIBLE UNTIL ITS DONE

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Nelson Mandela
Former President of South Africa
(Born 1918)

QuoteHD.com

KDIGO

- **Developing and Implementing Resource Sensitive Guidelines**

Co-Chairs: Brenda Hemmelgarn & Charles Swanepoel

- What are some effective strategies to facilitate implementation of KDIGO recommendations in countries having limited resources, high demand, and overextended medical caregivers?

- How do (can) KDIGO recommendations provide guidance when the "next best" treatment course is necessary, rather than following recommendations literally?

- How can KDIGO facilitate adaptation of its recommendations by local experts?

- Can we establish uniform methods to adapt recommendations to facilitate better acceptance and utilization in LMICs?

- Are changes needed in the format, style, dissemination tactics or wording to make recommendations more usable in LMICs?

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A current study into business environments across Africa has revealed several insights into what needs to change to ensure that the economic boom continues long into the future, while also creating jobs, building infrastructure and lowering poverty. In-depth interviews with 40 CEOs, business leaders, entrepreneurs and government officials for the Africa Capitalism Research Project are revealing how business can play a bigger role in contributing to strengthening enterprise in Africa

End corruption

Overcoming the skills shortage

Shape a culture of hard work

This leads onto another important problem identified by African leaders – the need for more trust between government and the private sector.

Foster collaboration between private and public enterprises

Invest in mentorship and apprenticeship to build capacity

Invest in leadership

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