Drug Development in Age-Related Medicines and Challenges in Low and Middle Income Countries (LMICs): An academic perspective

KING'S College LONDON

ADS

Age-Related Medicines Focus Group Webinar

Dr Bahijja Raimi-Abraham

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King's College London Fight the Fakes Founder and Academic Lead

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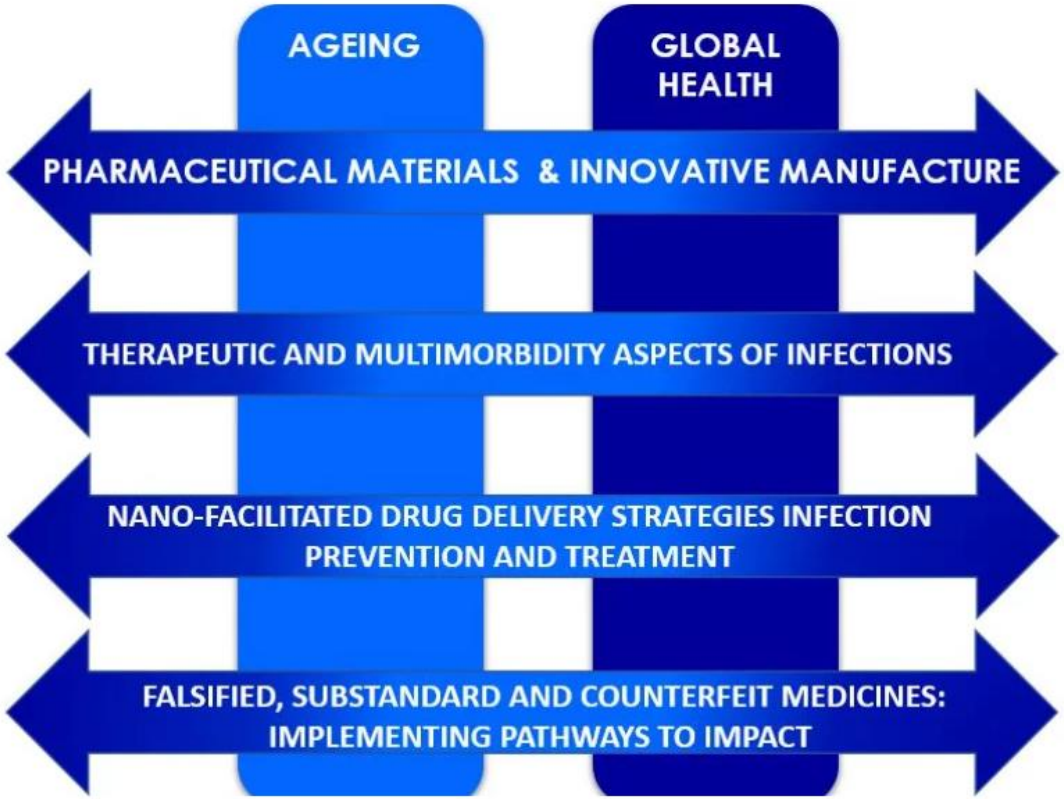
KING'S College LONDON

FIGHT THE FAKES

SPEAK UP ABOUT FAKE MEDICINES

Raimi-Abraham Group

The Raimi-Abraham Group @ King's College London
Our Research



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The Research Team

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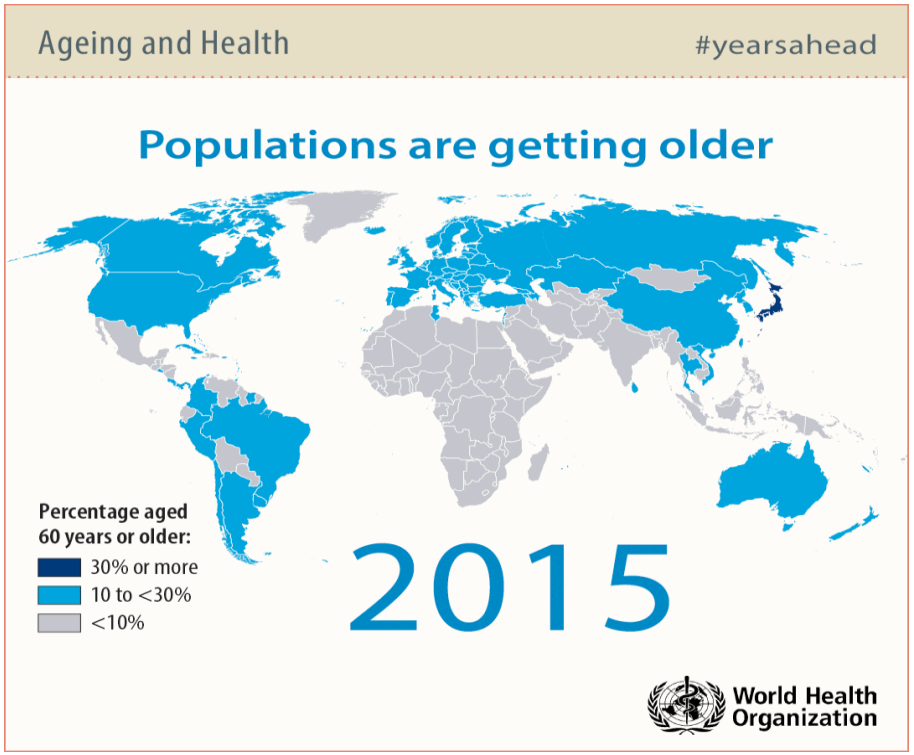
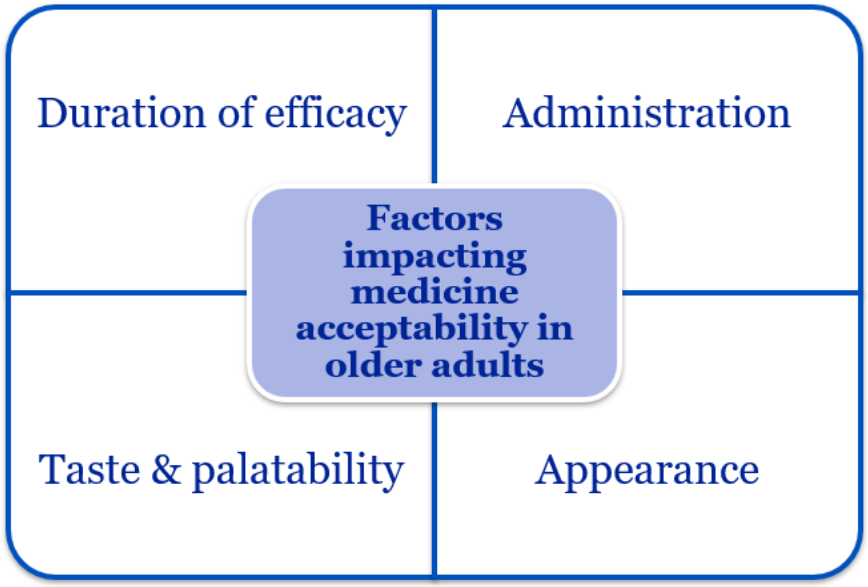
Why Ageing Related Medicines?



- WHO attributes the rapid size increase to a change in the leading cause of death—from infections to chronic non-communicable diseases—which increased life expectancy.
- Chronic conditions such as hypertension, high cholesterol, arthritis, diabetes, heart disease, cancer, dementia, and congestive heart failure.

Why Ageing Related Medicines?

Key Pharmaceutical Issues - *Obstacles for older people to accept their medication*



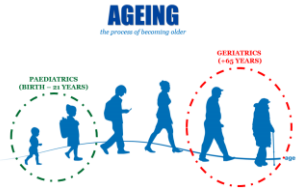
ISSUE	STRATEGIES IN PRACTICE
POLYPHARMACY	MEDICINE OPTIMISATION
PATIENT COMPLIANCE (IMMEDIATE RELEASE FORMULATIONS)	CHANGE TO MODIFIED RELEASE FORMULATIONS
DYSPHAGIA/NIL BY MOUTH	CRUSHING/SPLITTING OF SOLID ORAL DOSAGE FORM
↓ ABILITY TO REMEMBER TO TAKE MEDICATION (IMPAIRED)	REPACKAGING INTO MEDICINE COMPLIANCE AIDS (MCA)
INCLUSION OF OLDER PEOPLE IN CLINICAL TRIALS AND RESEARCH	PPI INITIATIVES

Wahlich J, Orlu M, Mair A, Stegemann S, van Riet-Nales D. Age-Related Medicine. *Pharmaceutics*. [2019]

Sara M. Hanning, Felipe L. Lopez, Ian C.K. Wong, Terry B. Ernest, Catherine Tuleu, Mine Orlu Gul, Patient centric formulations for paediatrics and geriatrics: Similarities and differences, International Journal of Pharmaceutics [2016]

My Age-Related Medicines Journey

Investigating the problem: What are their needs?



International Journal of Pharmaceutics 459 (2014) 65–69

Contents lists available at ScienceDirect

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journal homepage: www.elsevier.com/locate/ijpharm

Commentary

Public engagement workshop: How to improve medicines for older people?

Mine Orlu-Gul[a,*], Bahijja Raimi-Abraham[a], Elizabeth Jamieson[a], Li Wei[a], Macey Murray[a], Katarzyna Stawarz[b], Sven Stegemann[c], Catherine Tuleu[a], Felicity J. Smith[a]

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[c] Capsugel, Bornem, Belgium

- Attended by **78 older people** and professionals from academic research, industry and regulatory agencies (i.e. EMA, MHRA)
- **Aim: "*...to identify ways of improving current and future geriatric drug therapy.*"**

- **Medicines related challenges reported by older people and carers:**
  - Physical difficulties
  - Cognitive difficulties
  - Living difficulties
  - **Medicine related difficulties**
    - **Usually polypharmacy related**
    - **Co-morbidities**
    - **Medication reviews**
    - **Lack of advice from pharmacist**
    - **Query re: appropriate doses for patient**
    - **Confusion over names of medicines & generics**
    - **Admission to hospital**
  - Other shared difficulties

My Age-Related Medicines Journey

Investigating the problem : My skills & knowledge gap

- **Successful UCL Public Policy Funding**
  - EPSRC Knowledge Transfer Partnership

- **The European Medicines Agency (EMA)**
  - Evaluations of marketing-authorisation applications → centralised procedure (similar to FDA medicines in Europe)

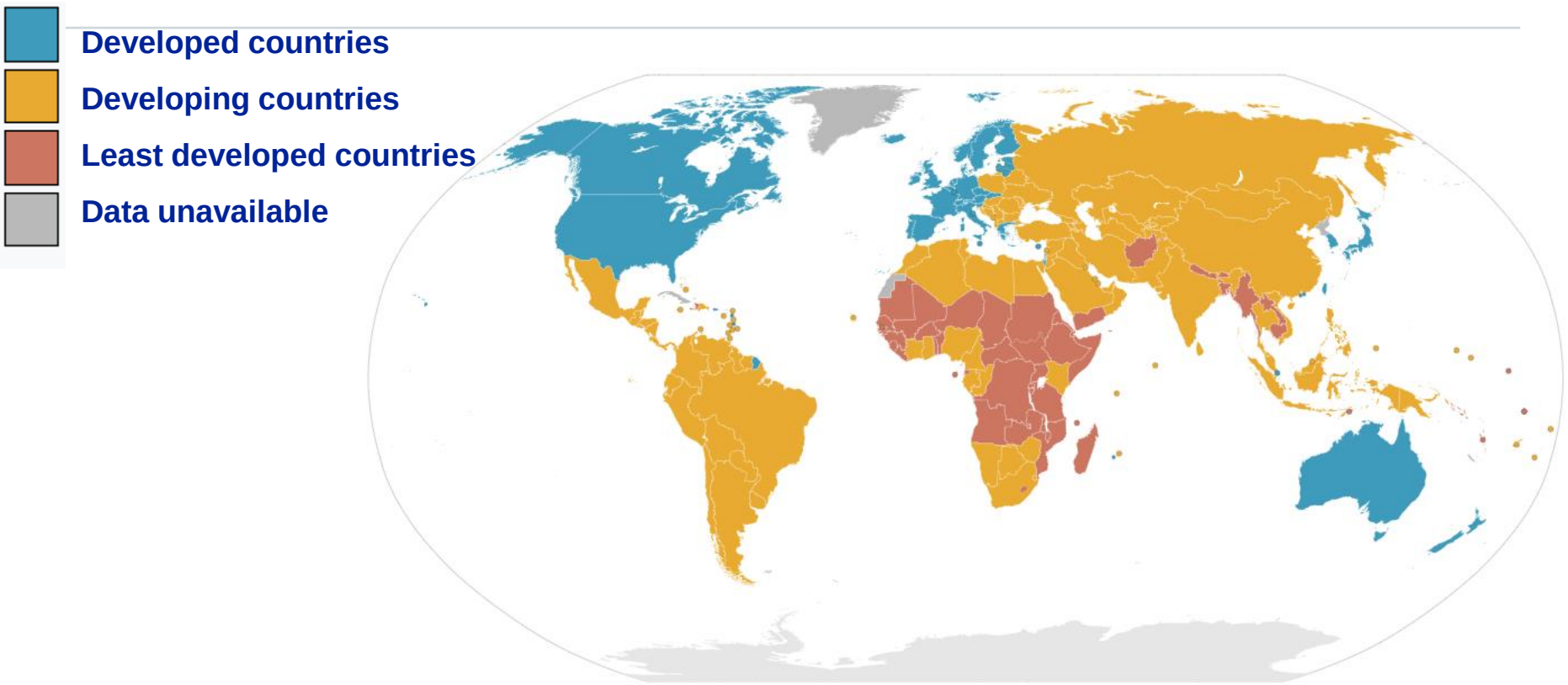
- **Scientific Advice department at the EMA**
  - A department which offers scientific advice and protocol assistance (a type of scientific advice for companies developing orphan medicines) to companies involved in developing medicines.
  - **Developed the EMA Geriatric Medicines Strategy in 2011**

Regional Focus (UK – LMIC)

Regions are classified as "developing" regions and "developed" regions.

4 income groups (low, lower-middle, upper-middle, and high)

"Developing country" vs "Low-income or middle-income economies (LMIC)"

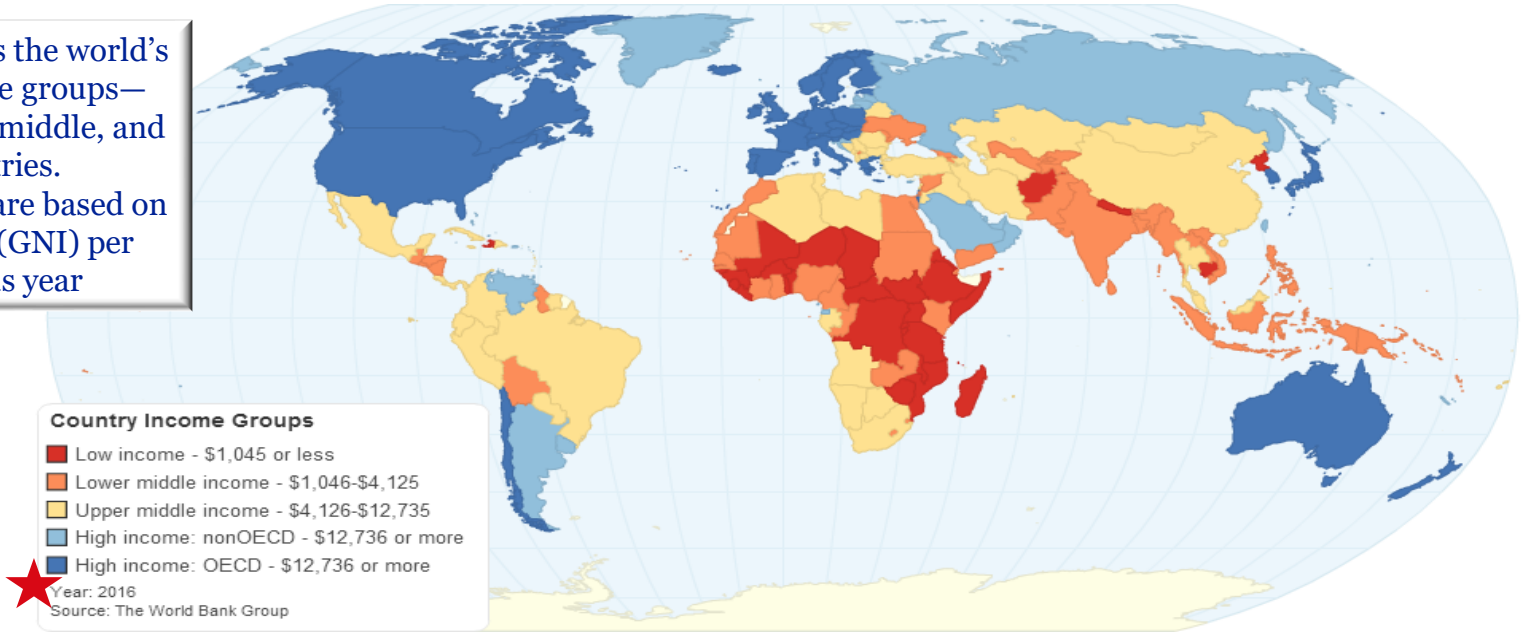


Developed nations - countries that are more industrialized and have higher per capita income levels.

Developing nations - countries that are less industrialized and have lower per capita income levels. Can be divided further into moderately developed or less developed countries.

"Developing country" vs "Low-income or middle-income economies (LMIC)"

The World Bank assigns the world's economies to four income groups—low, lower-middle, upper-middle, and high-income countries.
Updated every July 1 and are based on Gross National Income (GNI) per capita of the previous year



Countries can move to a lower or higher category each year

Economics moving to a higher category (1st Jul. 2020)

Economy	New group	Old group
Benin	Lower-middle income	Low income
Indonesia	Upper-middle income	Lower-middle income

Economics moving to a lower category (1st Jul. 2020)

Economy	New group	Old group
Algeria	Lower-middle income	Upper-middle income
Sri Lanka	Lower-middle income	Upper-middle income

Pharmaceuticals and LMICs/Developing Countries – An age-old problem

Pharmaceuticals and developing countries: problems and prospects*

D.C. Jayasuriya

*This review is based on a special seminar conducted at the WHO/Harvard University Collaborating Center on Health Legislation, Boston, USA, 1990.

Introduction

The WHO Conference of Experts on the Rational Use of Drugs held in Nairobi in 1985 is a watershed in the evolution of the policies of the World Health Organization (WHO) on pharmaceuticals [1]. Immediately after the conference, there were frequent references to the 'Spirit of Nairobi.' This did not relate to witchcraft, ubiquitous though it is in that part of the world, but to the consensus that emerged from the Conference. The deliberations were conducted in a spirit of co-operation and not confrontation, thus dismissing fears that were entertained in some quarters before – and, in fact, during – the Conference that regulators, consumerists, prescribers, and manufacturers will never be able to reach unanimity on a concerted course of action.

In the aftermath of the Conference, WHO convened small working groups to formulate three sets of guidelines:

- Guidelines for Developing National Drug Policies;
- Guidelines on Ethical Criteria for Medicinal Drug Promotion;
- Guidelines for Small Drug Regulatory Authorities.

The Conference was organized, and the guidelines subsequently formulated, in a scenario characterized by many disquieting features [2]. In order to appreciate the significance of the turn of events, it is useful to provide a brief perspective of some of these features.

Some problems in the pharmaceutical section

Global imbalance in drug supplies

globally [3]. With almost 75% of the population having access to only 20% of the drugs, it is not surprising that WHO has estimated that between 1.3 to 2.5 billion people around the world have little or no access to drugs [3].

As long as such large numbers are deprived of, or denied access to, drugs, "Health for All by the Year 2000" will remain only a laudable but unrealistic goal. This inequity in access brings into sharp focus a range of socio-economic issues, which have much wider ramifications [4] than the mere inability to provide everyone with the drugs they need. While lack of infrastructure development and logistical problems loom large, there are fundamental underlying political and economic issues, which tend to be relegated to the background. In the absence of political will, the formulation and implementation of drug policies often do not get the necessary patronage. Without such patronage, adequate resources are usually not available to improve the drug procurement and supply system. Without exception, the men, women and children who are denied access to drugs are those who have much less than the others in every respect, whether it be food, clothing or any other basic amenity of life. Ill health aggravated by lack of access to effective medicines exacerbates further existing inequities and disabilities.

Too many drugs on the market

Superficially, at least, it is paradoxical that, while large numbers are deprived of drugs in many parts of the world, some markets are flooded with them. Brazil, for instance, is estimated to have over 50,000 products on the market [3]. Similarly, countries like Mexico and

Challenges identified in 1991

- ❑ Global imbalance in drug supplies
- ❑ Too many drugs on the market
- ❑ Irrational use of drugs
- ❑ Availability of drugs of doubtful quality, safety and efficacy

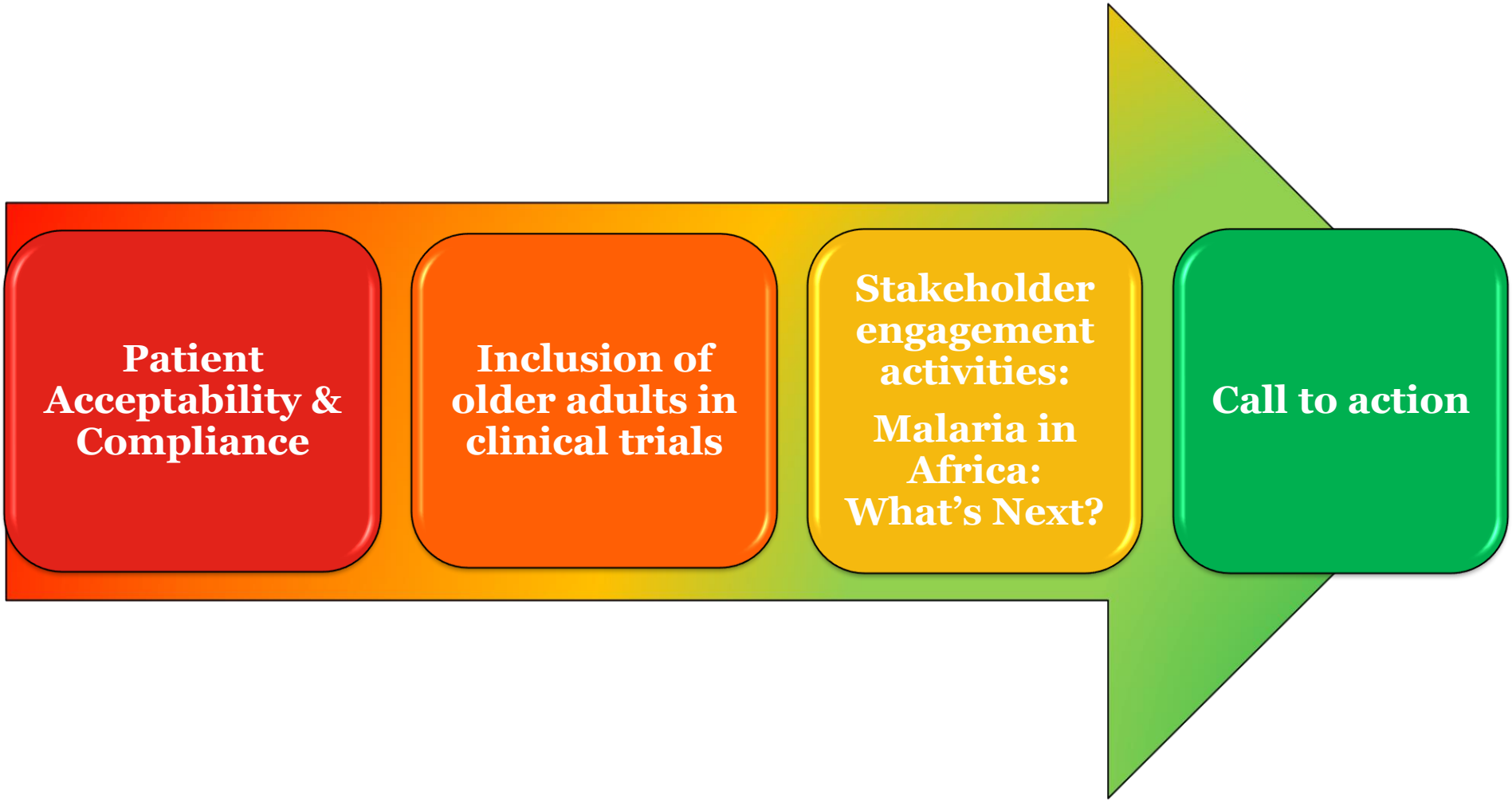
What about age-related medicines?

Jayasuriya DC. Pharmaceuticals and developing countries: problems and prospects. Pharm Weekbl [Sci] **1991**;13(6):244-7

Published in 1991 – issues still relevant today…

Drug Development and Age-Related Medicines

UK, LMIC/Developing countries



Polypharmacy – A Global Issue for Older Adults

Obstacles for older adults to accept their medication

What is Polypharmacy?

Obstacles for older adults to accept their medication

Masnoon et al. BMC Geriatrics (2017) 17:230
DOI 10.1186/s12877-017-0621-2

BMC Geriatrics

RESEARCH ARTICLE Open Access

What is polypharmacy? A systematic review of definitions

Nashwa Masnoon[1,2*], Sepehr Shakib[3,4], Lisa Kalisch-Ellett[1] and Gillian E. Caughey[1,3,4]

Abstract

Background: Multimorbidity and the associated use of multiple medicines (polypharmacy), is common in the older population. Despite this, there is no consensus definition for polypharmacy. A systematic review was conducted to identify and summarise polypharmacy definitions in existing literature.

Methods: The reporting of this systematic review conforms to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) checklist. MEDLINE (Ovid), EMBASE and Cochrane were systematically searched, as well as grey literature, to identify articles which defined the term polypharmacy (without any limits on the types of definitions) and were in English, published between 1st January 2000 and 30th May 2016. Definitions were categorised as i. numerical only (using the number of medications to define polypharmacy), ii. numerical with an associated duration of therapy or healthcare setting (such as during hospital stay) or iii. Descriptive (using a brief description to define polypharmacy).

Results: A total of 1156 articles were identified and 110 articles met the inclusion criteria. Articles not only defined polypharmacy but associated terms such as minor and major polypharmacy. As a result, a total of 138 definitions of polypharmacy and associated terms were obtained. There were 111 numerical only definitions (80.4% of all definitions), 15 numerical definitions which incorporated a duration of therapy or healthcare setting (10.9%) and 12 descriptive definitions (8.7%). The most commonly reported definition of polypharmacy was the numerical definition of five or more medications daily ($n = 51$, 46.4% of articles), with definitions ranging from two or more to 11 or more medicines. Only 6.4% of articles classified the distinction between appropriate and inappropriate polypharmacy, using descriptive definitions to make this distinction.

Conclusions: Polypharmacy definitions were variable. Numerical definitions of polypharmacy did not account for specific comorbidities present and make it difficult to assess safety and appropriateness of therapy in the clinical setting.

Keywords: Polypharmacy, Multimorbidity, Comorbidity, Inappropriate prescribing, Aged, Systematic review

Background

Multimorbidity, commonly defined as the co-existence of two or more chronic health conditions, is common in the older population [1]. The presence of multiple chronic conditions increases the complexity of therapeutic management for both health professionals and patients, and impacts negatively on health outcomes. Multimorbidity is associated with decreased quality of life, self-rated health, mobility and functional ability as well as increases in hospitalisations, physiological distress, use of health care resources, mortality and costs [2–4]. Globally, the health burden of multimorbidity is expected to rise significantly as a result of the growing number of older people and increasing numbers of people living with multimorbidity [5].

The use of multiple medicines, commonly referred to as polypharmacy is common in the older population with multimorbidity, as one or more medicines may be used to treat each condition. Polypharmacy is associated with adverse outcomes including mortality, falls, adverse drug reactions, increased length of stay in hospital and readmission to hospital soon after discharge [6–8]. The

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Table 1 Breakdown of polypharmacy definitions according to the category of definition

Term	Numerical only	Numerical in a given duration of time or setting	Descriptive	Total number of definitions
Polypharmacy	81	9	9	99
Minor Polypharmacy	8	0	0	8
Moderate polypharmacy	1	0	0	1
Major polypharmacy	11	1	0	12
Hyperpolypharmacy	1	1	0	2
Excessive polypharmacy	8	2	0	10
Severe polypharmacy	1	0	0	1
Persistent polypharmacy	0	1	0	1
Chronic polypharmacy	0	1	0	1
Appropriate polypharmacy	0	0	1	1
Rational polypharmacy and indiscriminate prescribing	0	0	1	1
Pseudopolypharmacy	0	0	1	1
Total number of definitions according to category of definition	111	15	12	138

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[2]Department of Pharmacy, Royal Adelaide Hospital, North Terrace, Adelaide, South Australia, Australia
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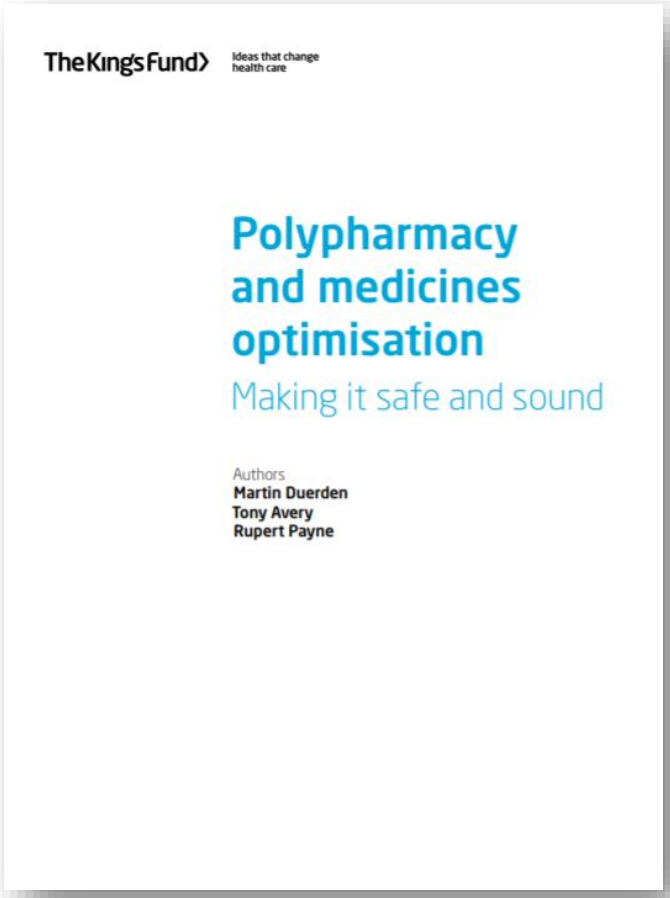
Table 2 Various numerical only definitions of polypharmacy and associated terms in existing literature

Term	Number of medications	Number of studies	References
Polypharmacy	≥ 2	1	[13]
	2 to 9	1	[14]
	≥ 3	1	[15]
	3 to 6	1	[16]
	≥ 4	6	[17–22]
	≥ 4 or ≥ 5	1	[23]
	≥ 5	51	[11, 24–73]
	≥ 6	10	[10, 74–82]
	≥ 7	2	[83, 84]
	5 to 9	3	[85–87]
	≥ 9	1	[88]
	≥ 10	1	[89]
	≥ 11	1	[90]
	number of drug classes	1	[91]
Minor Polypharmacy	2 to 4	6	[92–97]
	2 to 3	1	[98]
	0 to 4	1	[99]
Moderate polypharmacy	4 to 5	1	[98]
Major polypharmacy	≥ 5	6	[92–95, 97, 100]
	≥ 6	3	[96, 98, 101]
	5 to 9	1	[99]
	≥ 11	1	[74]
Hyperpolypharmacy	≥ 10	1	[102]
Excessive polypharmacy	≥ 10	7	[30, 58, 65, 70, 85–87]
	≥ 21	1	[74]
Severe polypharmacy	≥ 10	1	[99]

What is Polypharmacy?

Obstacles for older adults to accept their medication

POLYPHARMACY



Appropriate polypharmacy

-prescribing for an individual for complex conditions or for multiple conditions in circumstances where medicines use has been optimised and the medicines are prescribed according to best evidence.

Problematic/inappropriate polypharmacy

-multiple medications are prescribed inappropriately, or where the intended benefit of the medication is not realised.

Polypharmacy – A global issue for older adults

Obstacles for older adults to accept their medication

Age UK calls for a more considered approach to prescribing medicines for older people

Published on 20 August 2019 11:35 AM

The report, 'More Harm than Good', provides evidence showing that prescribing more drugs isn't always the best option, particularly when it comes to older people. It also demonstrates that at the moment medicines are sometimes being prescribed:

- in excessive numbers
- in unsafe combinations
- without the consent or involvement of the older people concerned
- and without the support and help older people need to take them.

Polypharmacy – A global issue for older adults

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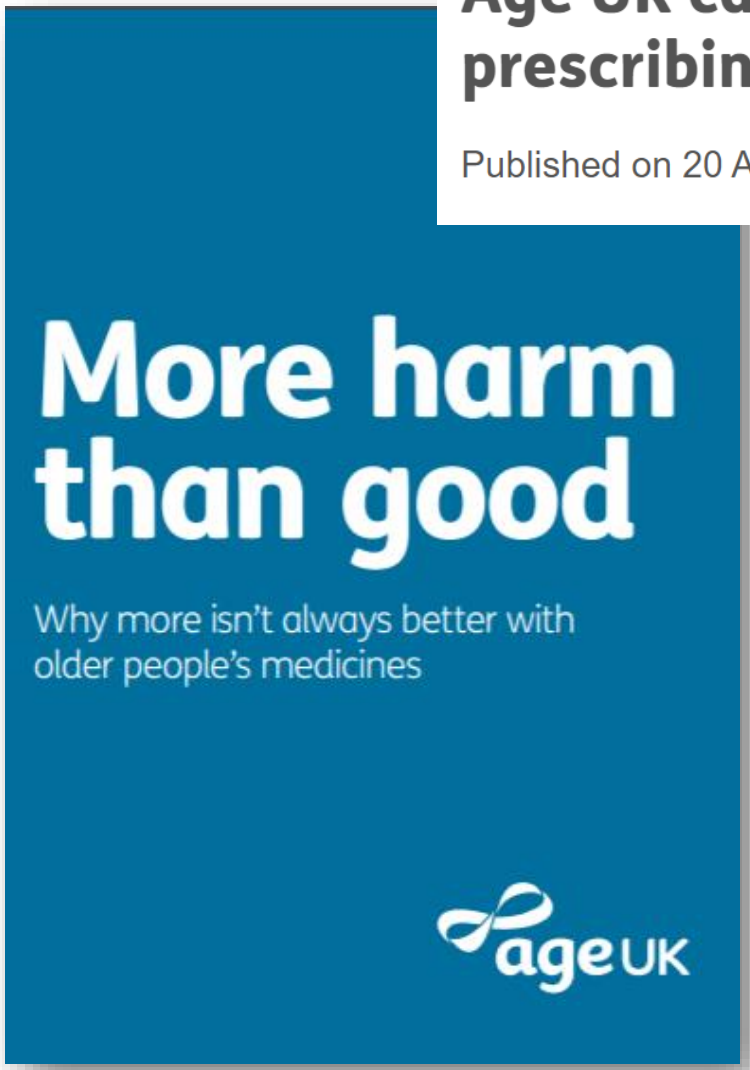


Age UK calls for a more considered approach to prescribing medicines for older people

Published on 20 August 2019 11:35 AM

Age UK is calling on the NHS to ensure that:

1. There is zero tolerance of inappropriate polypharmacy.
2. Older people are fully supported and involved in decisions about their medicines.
3. High quality medicine reviews are routine for all older people taking medicines on a long-term basis.
4. Care planning and new prescribing decisions take full account of existing medicines.
5. Care homes maintain an appropriate clinical pharmacy lead and an accurate record of medicines.
6. Polypharmacy (taking prescribed medicines to treat one or more health conditions) is a core competency of clinicians working with older people.
7. Older people, especially those living with dementia, have access to the support they need to manage their medicines.

Polypharmacy – A global issue for older adults

Obstacles for older adults to accept their medication

UNIVERSITY COLLEGE HOSPITAL UCH IBADAN

ISSN 1118-9096
West African Journal of Pharmacy

"Polypharmacy especially in older people with multiple diseases often results in poor health status and outcomes."

- Cross sectional study - 400 elderly patients aged 60 years+
- Polypharmacy was taken as concurrent consumption of =5 medications.
- Socio- demographic characteristics, lifestyle habits, attitudinal factors on medication understanding, medication pattern and intake were assessed through a questionnaire.

Polypharmacy and factors associated with their prevalence among older patients attending a geriatric centre in South-West Nigeria

Wuraola Akande-Sholabi[1], Lawrence Adebusoye[2] and Olufemi Olowookere[2]
[1]Department of Clinical Pharmacy and Pharmacy Administration, Faculty of Pharmacy, University of Ibadan, Nigeria.
[2]Chief Tony Anenih Geriatric Centre, University College Hospital, Ibadan, Nigeria.

Key Findings

- ❑ 25% of respondents were on multiple-drug therapy
- ❑ Risk of polypharmacy was twice in respondent on multiple-drug therapy and 3.7 times in respondents who intentionally skipped their medications
- ❑ Those who received prescription from more than one physician on regular basis had 2.3 times risk of polypharmacy.
- ❑ Factors, which mostly led to patients skipping medications, include the cost and availability of the medications.

Polypharmacy – A global issue for older adults

Obstacles for older adults to accept their medication

SOLUTION: MEDICINE OPTIMISATION

"...a person-centred approach to safe and effective medicines use, to ensure people obtain the best possible outcomes from their medicines."

"Shared decision-making is an essential part of evidence-based medicine, seeking to use the best available evidence to guide decisions about the care of the individual patient, taking into account their needs, preferences and values'. *(Greenhalgh et al. 2014; Sackett et al. 1996)*

Clinical Practice

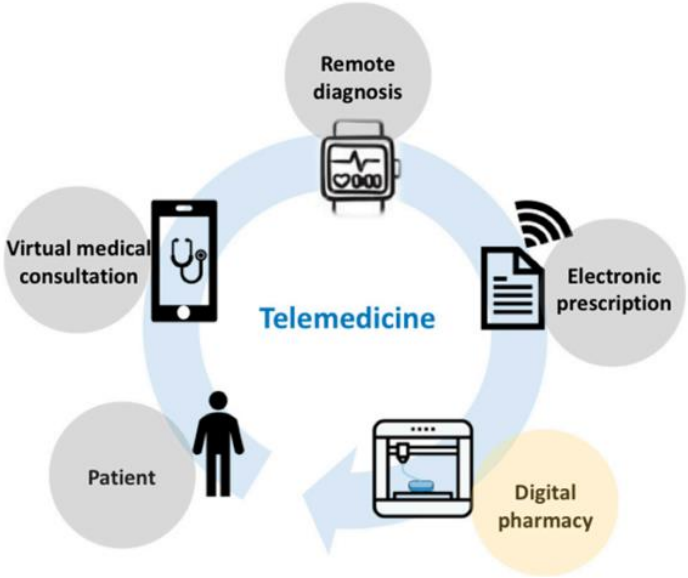
Pharmaceutical Science

- Modified release
- Personalized approach to drug development
  - Tailored dose
  - Flexible dosing
  - Individualised
  - Fixed dose combination drug products

Greenhalgh T et al.(2014) Evidence based medicine: a movement in crisis? BMJ 348:3725
Sackett D et al. (1996) Evidence based medicine: what it is and what it isn't. BMJ 312:71–72

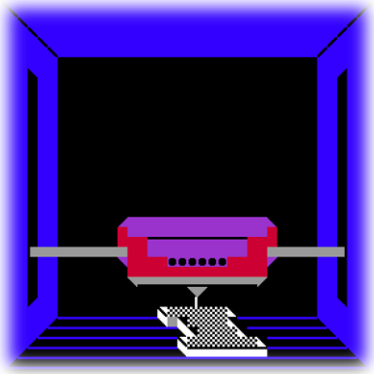
Why 3D Printing

- A.K.A Additive Manufacturing (developing since 1984)
- **"Personalized 3D printed medicines appear as the missing piece in the care cycle of telemedicine"**



Araújo MRP, Sa-Barreto LL, Gratieri T, Gelfuso GM, Cunha-Filho M. The Digital Pharmacies Era: How 3D Printing Technology Using Fused Deposition Modeling Can Become a Reality. Pharmaceutics. 2019

- **High degree of flexibility and control enables preparation of multi APIs with complex and tailored release profiles**
- Cost-effective customization and reduced assembly.



- Simple, reliable, and affordable.
- **First 3D printed pill (FDA approved)**
  - Modified Powder Bed Fusion

Modified Release

JOURNAL OF 3D PRINTING IN MEDICINE, VOL. 4, NO. 1 | RESEARCH ARTICLE

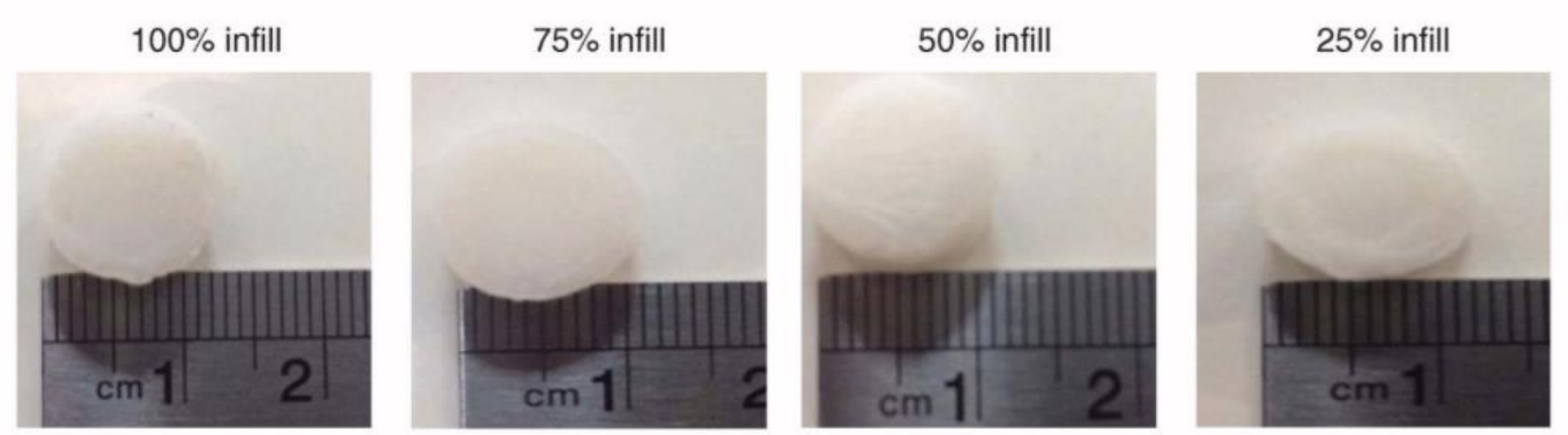
normal

Fabrication of modified-release custom-designed ciprofloxacin tablets via fused deposition modeling 3D printing

Nasir Abbas, Nadia Qamar, Amjad Hussain, Sumera Latif, Muhammad Sohail Arshad, Qazi Amir Ijaz, Faisal Mahmood & Nadeem Irfan Bukhari

Published Online: 1 Jun 2020 | https://doi.org/10.2217/3dp-2019-0024

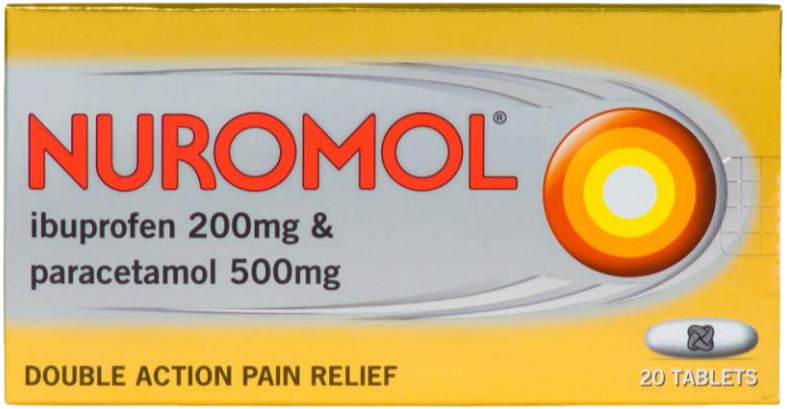
"…. identified a direct link between the release rate of the antibiotic, and the tablet's infill percentage, which enabled them to control its dosage by adjusting its printing parameters…."

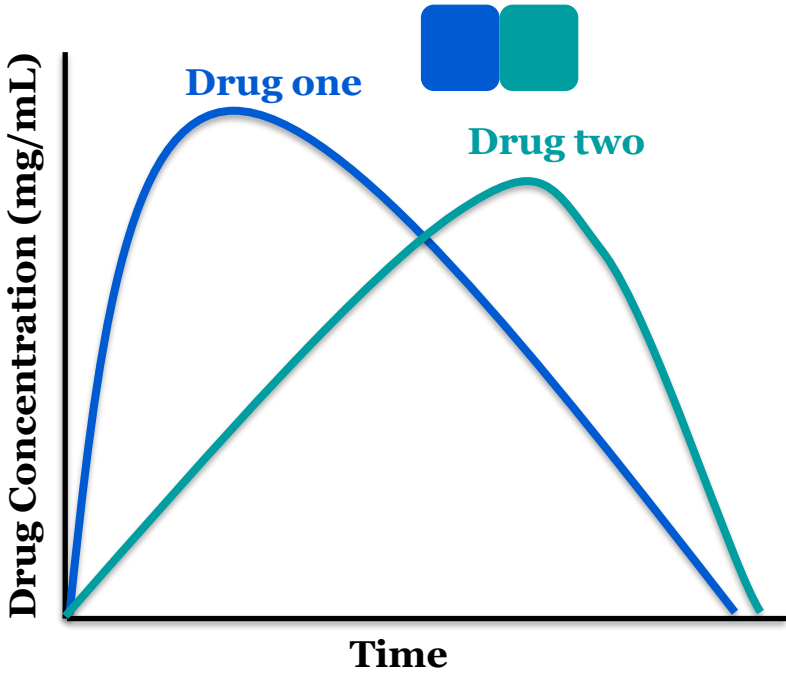


Personalized Approach to Drug Development

Fixed Dose Combination Products

- **Fixed Dose Combination:** Two or more drugs contained in a single dosage form, such as a capsule or tablet.
  - Advantage to patient – reduce number of tablets
  - Ability to compose different combined profiles of APIs that may be specific for the relative dosages in a given FDC product





pharmaceutics

MDPI

Article

3D-Printed Solid Dispersion Drug Products

Suet Li Chew [1], Laura Modica de Mohac [1,2] and Bahijja Tolulope Raimi-Abraham [1,*]

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2 Department of Sciences for Health Promotion and Mother-Child Care "G. D'Alessandro", University of Palermo, 90100 Palermo, Italy

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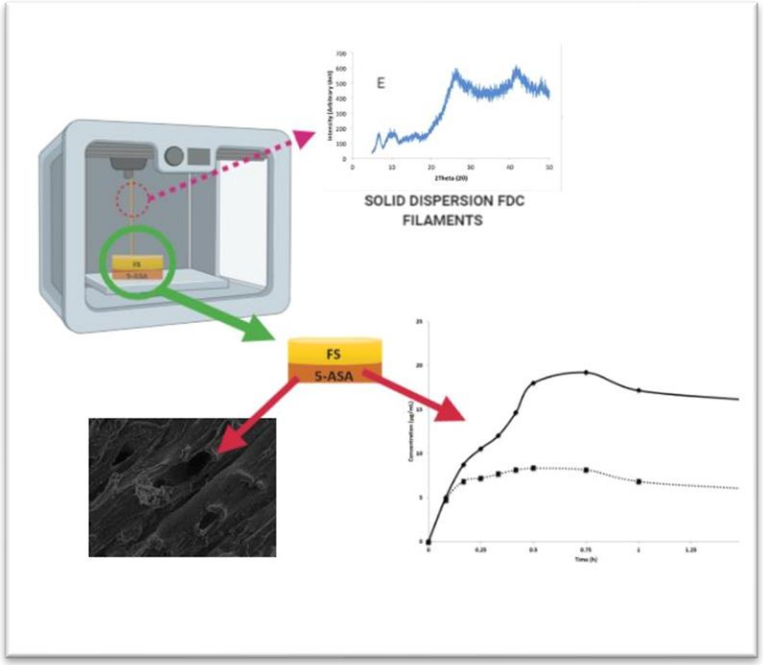
To explore the potential of increasing drug-loading efficiency by altering solvent choice, and to study the in vitro dissolution profiles of the FDM-printed monolithic FDC tablet developed.



Objectives

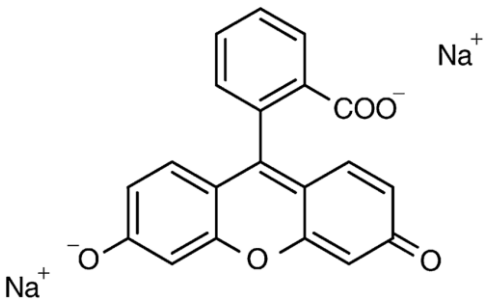
i. What is the influence of solvent type on drug loading efficiency?

ii. What is the effect on the drug impregnation method of filament hardness?

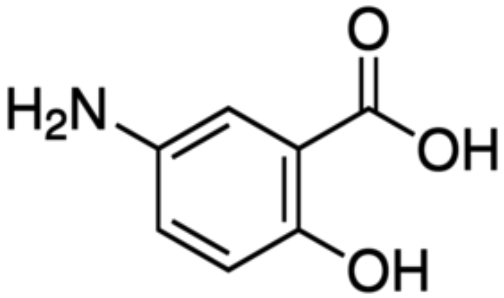
iii. What is the solid state of the drug loaded filaments?

iv. What is the *in vitro* dissolution profile of the FDC?

Materials

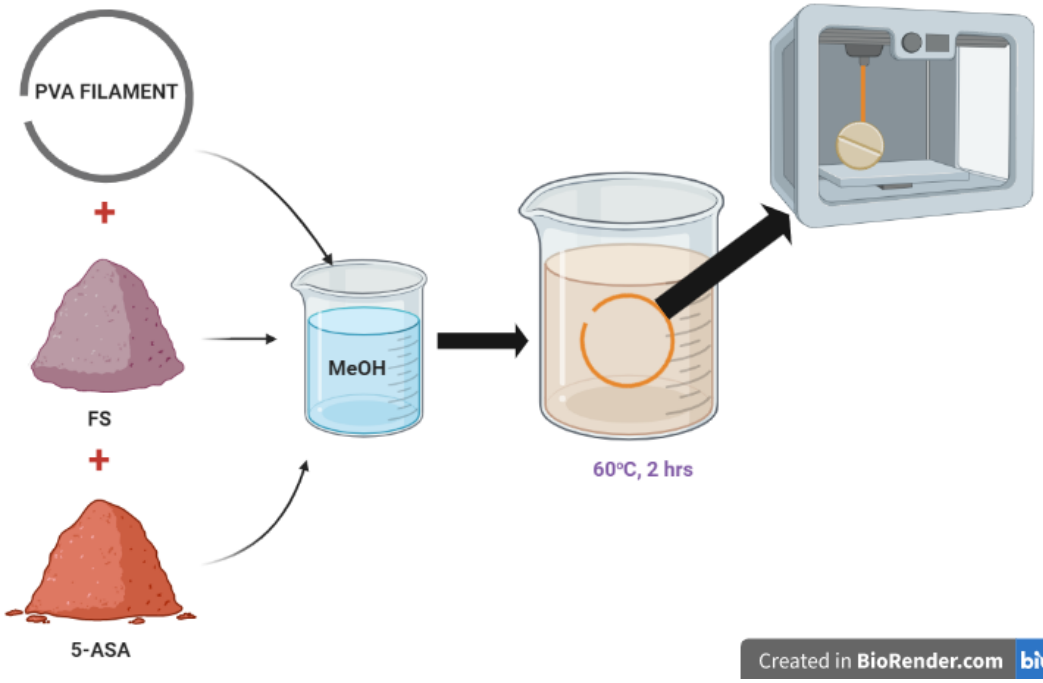


Fluorescein sodium (FS)



5-aminosalicyclic acid (5-ASA)

Polyvinyl alcohol (PVA) filament, 1.75 mm diameter

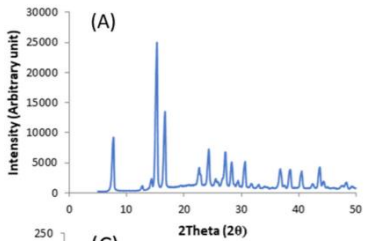


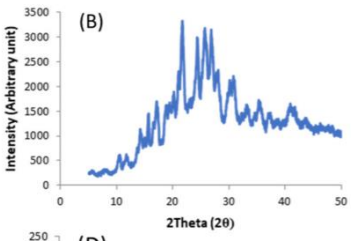
Chew, S.L.; Modica de Mohac, L.; Tolulope Raimi-Abraham, B. 3D-Printed Solid Dispersion Drug Products. (2019) Pharmaceutics

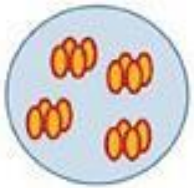
Results : Filament Characterisation

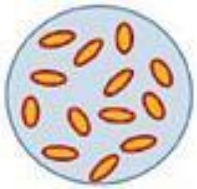
Solid State Characterization of Filaments

Generation of an amorphous solid dispersion

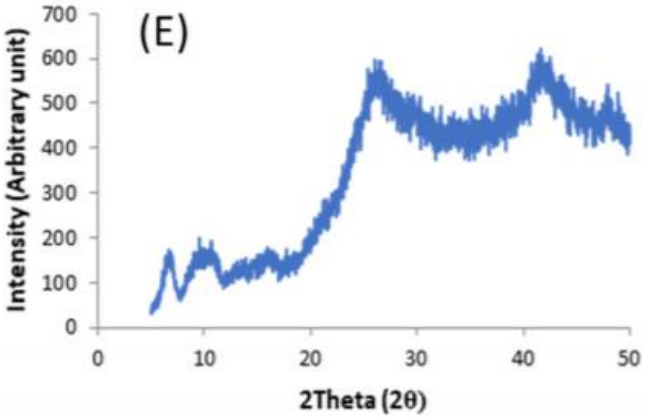








	Glass suspension		Glass solution
API	Crystalline	Amorphous	Molecularly dispersed
Matrix (polymer)	Amorphous	Amorphous	Amorphous
System stability	Very stable	Only kinetically stabilized (oversaturation)	Stable (drug below saturation solubility)

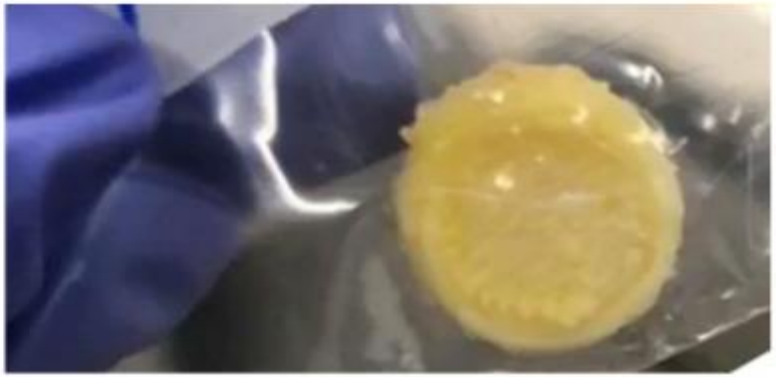


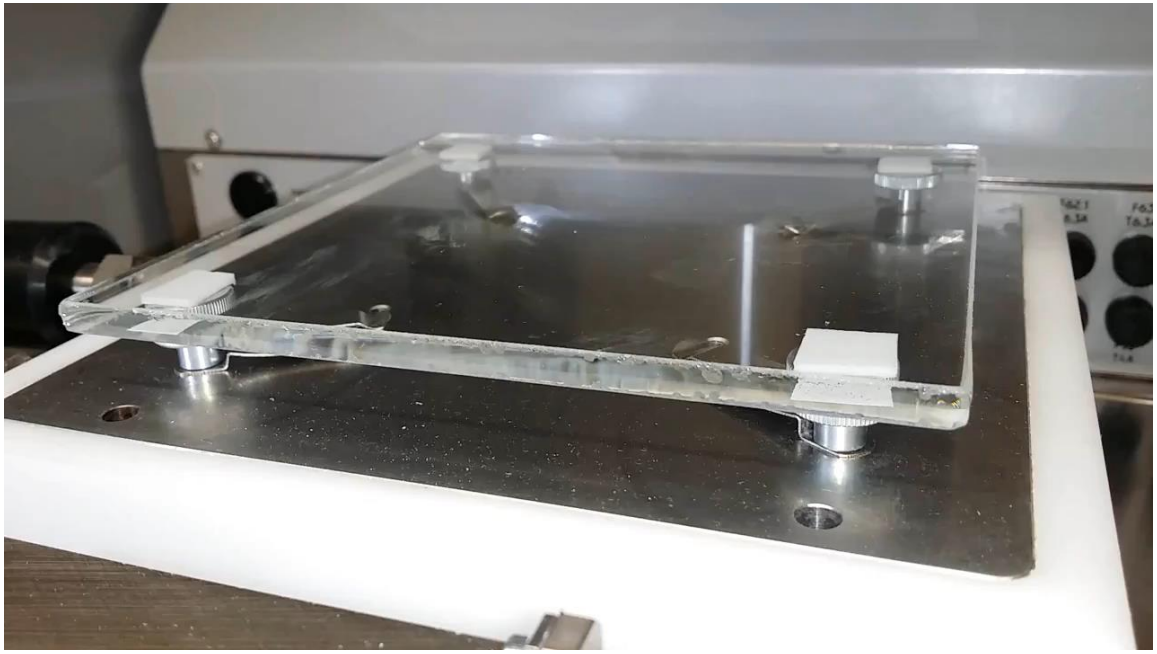
✓ **Enhanced drug dissolution = increase oral bioavailability**

Chew, S.L.; Modica de Mohac, L.; Tolulope Raimi-Abraham, B. 3D-Printed Solid Dispersion Drug Products. (2019) Pharmaceutics

Results : 3D Printed Dosage Form Characterisation

Morphology Studies

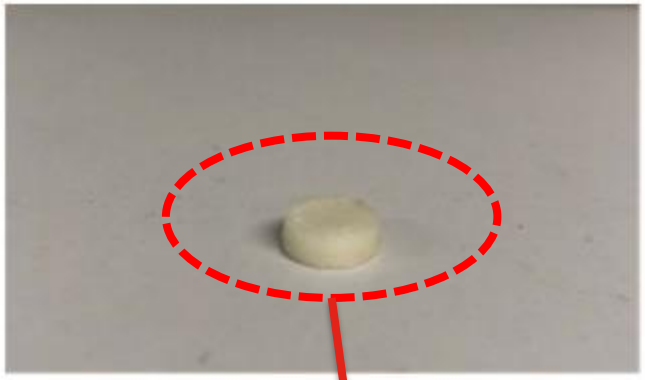


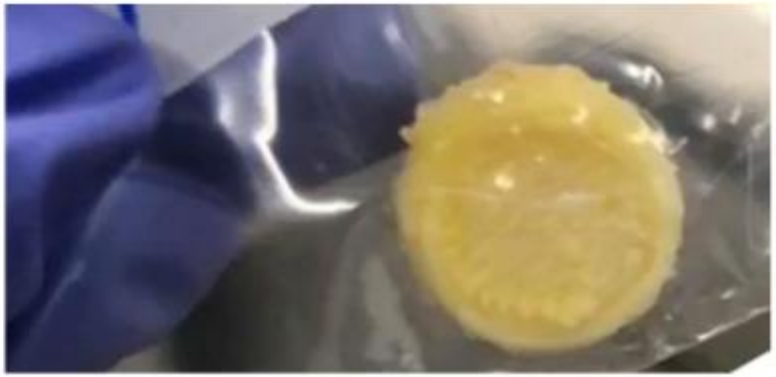


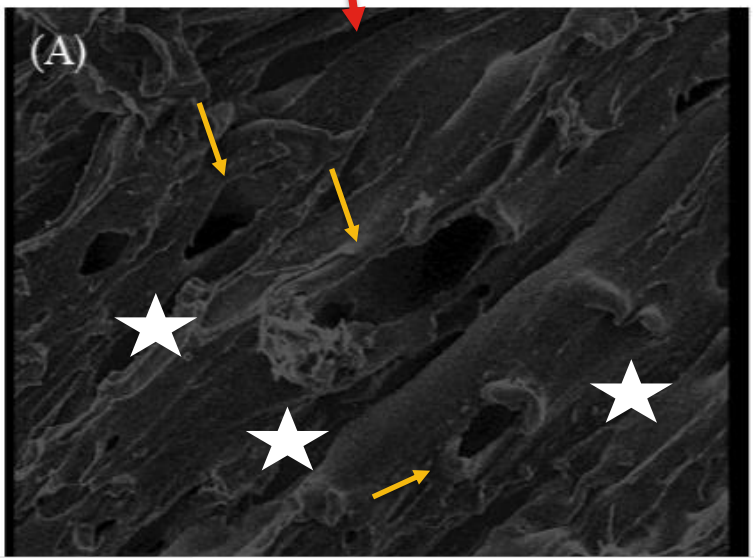
FDM 3D printing :
Layer-by-layer building of object via molten polymer fusion onto previously solidified extrudate layer during printing was expected to give extrudate-stacking appearance

Results : 3D Printed Dosage Form Characterisation

Morphology Studies







- Multiple voids on the dosage form surface.
- Dosage form shows extrudate-stacking as expected.

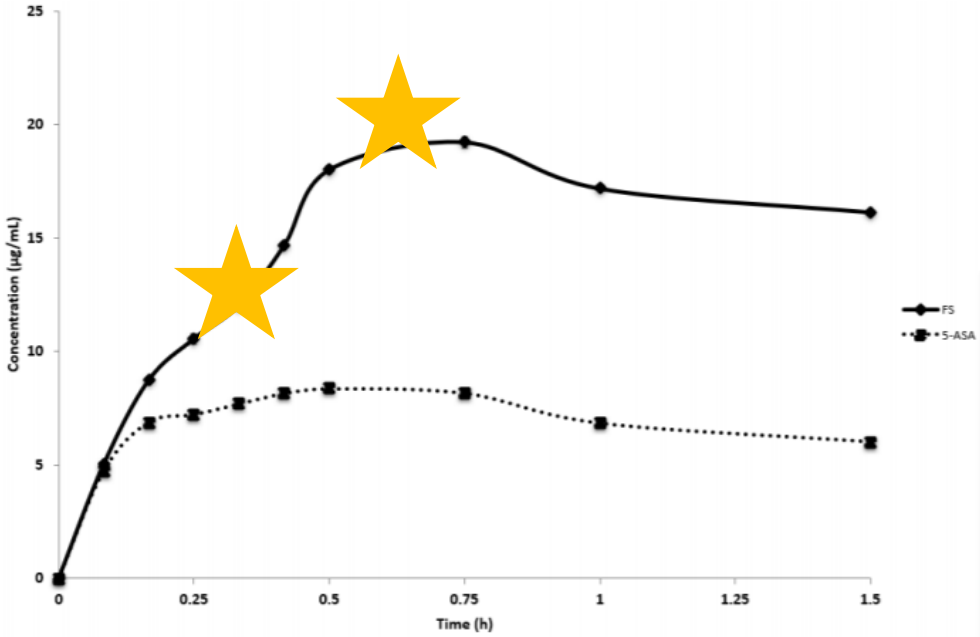
Chew, S.L.; Modica de Mohac, L.; Tolulope Raimi-Abraham, B. 3D-Printed Solid Dispersion Drug Products. (2019) Pharmaceutics

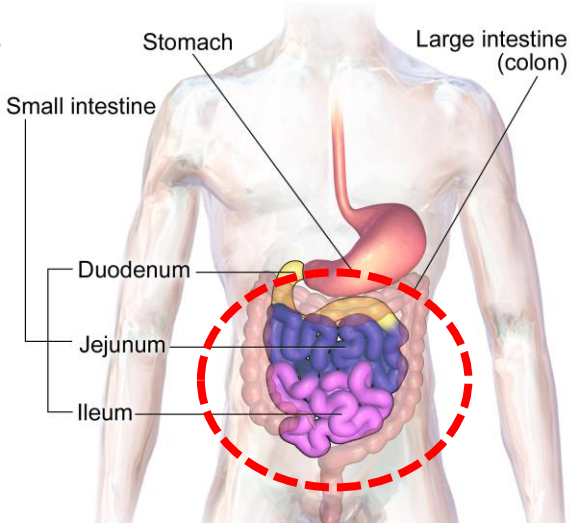
❑ Further work = Porosity Studies

Results : 3D Printed FDC Dosage Form Characterisation

In Vitro Dissolution, pH 6.8 phosphate buffer

- Two different dissolution profiles
- Spring-and-parachute dissolution profile of both FS and 5-ASA.





majority of drug absorption occurs at the small intestine = large surface area

Amorphous SDs: Spring-and-parachute dissolution

- Drug should first dissolve along with the soluble polymer matrix to create a supersaturated solution ("the spring")
- After which supersaturation is maintained long enough for drug absorption ("the parachute") to take place.

Chew, S.L.; Modica de Mohac, L.; Tolulope Raimi-Abraham, B. 3D-Printed Solid Dispersion Drug Products. (2019) Pharmaceutics

Personalized Approach to Drug Development

Fixed Dose Combination Products

Journal of Controlled Release 217 (2015) 308–314

Contents lists available at ScienceDirect

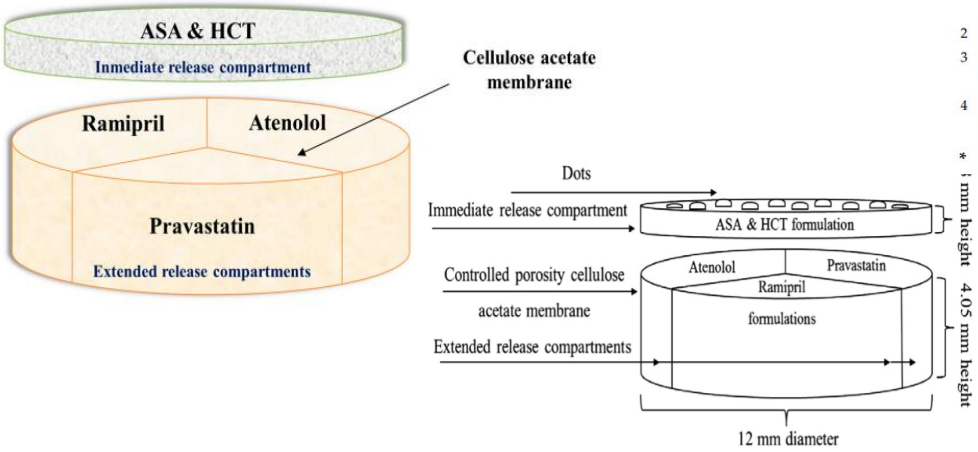
Journal of Controlled Release

journal homepage: www.elsevier.com/locate/jconrel

3D printing of five-in-one dose combination polypill with defined immediate and sustained release profiles

Shaban A. Khaled [a], Jonathan C. Burley [a], Morgan R. Alexander [a], Jing Yang [b], Clive J. Roberts [a,*]

[a] Laboratory of Biophysics and Surface Analysis, School of Pharmacy, The University of Nottingham, Nottingham NG7 2RD, UK
[b] Division of Drug Delivery and Tissue Engineering, School of Pharmacy, The University of Nottingham, Nottingham NG7 2RD, UK



pharmaceutics

MDPI

Article

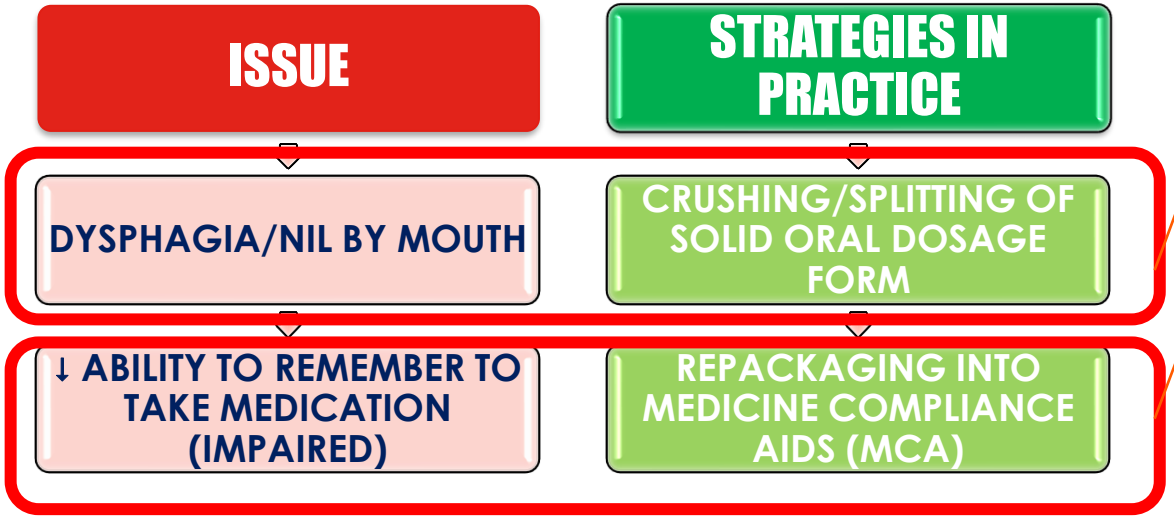
3D Printing of a Multi-Layered Polypill Containing Six Drugs Using a Novel Stereolithographic Method

Pamela Robles-Martinez [1], Xiaoyan Xu [1], Sarah J. Trenfield [1], Atheer Awad [1], Alvaro Goyanes [2,3], Richard Telford [4], Abdul W. Basit [1,2,*] and Simon Gaisford [1,2,*]

1 Department of Pharmaceutics, UCL School of Pharmacy, University College London, 29–39 Brunswick Square, London WC1N 1AX, UK; pamela.martinez.13@ucl.ac.uk (P.R.-M.); xiaoyan.xu.13@ucl.ac.uk (X.X.); sarah.trenfield.16@ucl.ac.uk (S.J.T.); atheer.awad.15@ucl.ac.uk (A.A.)
2 FabRx Ltd., 3 Romney Road, Ashford TN24 0RW, UK; a.goyanes@fabrx.co.uk
3 Departamento de Farmacología, Farmacia y Tecnología Farmacéutica, R + D Pharma Group (GI-1645), Universidade de Santiago de Compostela, 15782 Santiago de Compostela, Spain
4 School of Chemistry and Forensic Sciences, University of Bradford, Richmond Road, Bradford BD7 1DP, UK; R.Telford@bradford.ac.uk
* Correspondence: a.basit@ucl.ac.uk (A.W.B.); s.gaisford@ucl.ac.uk (S.G.)

What are the key pharmaceutical issues?

Obstacles for older people to accept their medication



ALTERED DOSAGE FORM
(e.g. use of thickening agents/drug administration via enteral feeding tubes)

- **UNLICENSED USE OF MEDS**
- **↓ STABILITY OF MEDS**
- **POTENTIAL BIOAVAILABILITY CHANGES**
- **TOXICITY**

Multicompartment Compliance Aids (MCAs)

Obstacles for older people to accept their medication

- **Also known as Multi-compartment Compliance Aids (MCAs), Monitored Dosage Systems (MDS), Dosette boxes or Nomads®**
- **Patient (commonly older adults)**
  - Manage their own drug regimen
  - Reminder to take medication
- **Career/healthcare professional**
  - Monitor

7-DAY REGIMEN

SINGLE ADMINISTRATION TIME-POINT

DAY OF THE WEEK

EXAMPLE 1: PILLMATE

- Can be bought from your local pharmacy

PILLMATE DAY OUT ~£0.80

PILLMATE WEEKLY~£0.99

PILLMATE WEEKLY ~£2

EXAMPLE 2: DISPENSED FROM THE LOCAL PHARMACY

- Dispensed, clinically and accuracy checked by pharmacy dispenser and pharmacist

EXAMPLE 3: DISPENSED FROM YOUR LOCAL PHARMACY – ALARM SYSTEM

- Dispensed, clinically and accuracy checked by pharmacy dispenser and pharmacist
- Movable carousel with divisions
- Audible reminder

Multicompartment Compliance Aids (MCAs)

Obstacles for older people to accept their medication

Challenges

- Main roles of manufacturers packaging = protect the product from exposure to conditions where phenomenon can occur that can alter its performance
- Manufacturers discourage the repackaging of medications = little data available to support this process.

- The use of MCAs involves the transfer of medicines from the manufacturer's original packaging into the MCA
- **How do we develop medicines for this use? Or *should we* start developing medicines for this use?**

JPHSR Journal of Pharmaceutical Health Services Research

ROYAL PHARMACEUTICAL SOCIETY

JPHS 2017, 8; 81–89

Received June 27, 2016
Accepted March 22, 2017
DOI 10.1111/jphs.12176
ISSN 1759-8885

Research Paper

Investigating the physical stability of repackaged medicines stored into commercially available multicompartment compliance aids (MCAs)

Bahijja Tolulope Raimi-Abraham[c], Alba Garcia del Valle[b], Carlota Varon Galcera[b], Susan Anne Barker[a] and Mine Orlu[a]

[a]Department of Pharmaceutics, School of Pharmacy, University College London, London, UK , [b]University of Barcelona, Barcelona, Spain and [c]King's College London, Institute of Pharmaceutical Science, London, UK

Raimi-Abraham B.T*, Garcia del Valle A, Galcera GV, Barker S.A, Orlu-Gul M. A Pilot Study Investigating the Stability of Repackaged Medicine Stored into Commercially Available Multi-Compartment Compliance Aids (MCAs).
Journal of Pharmaceutical Health Services Researc

Multicompartment Compliance Aids (MCAs)

Obstacles for older people to accept their medication

- **Aim: to investigate the stability profile of atenolol, aspirin and lansoprazole dosage forms repackaged together in two different commercially available MCAs**

- Compared with drug powders alone
  - Influence of excipients

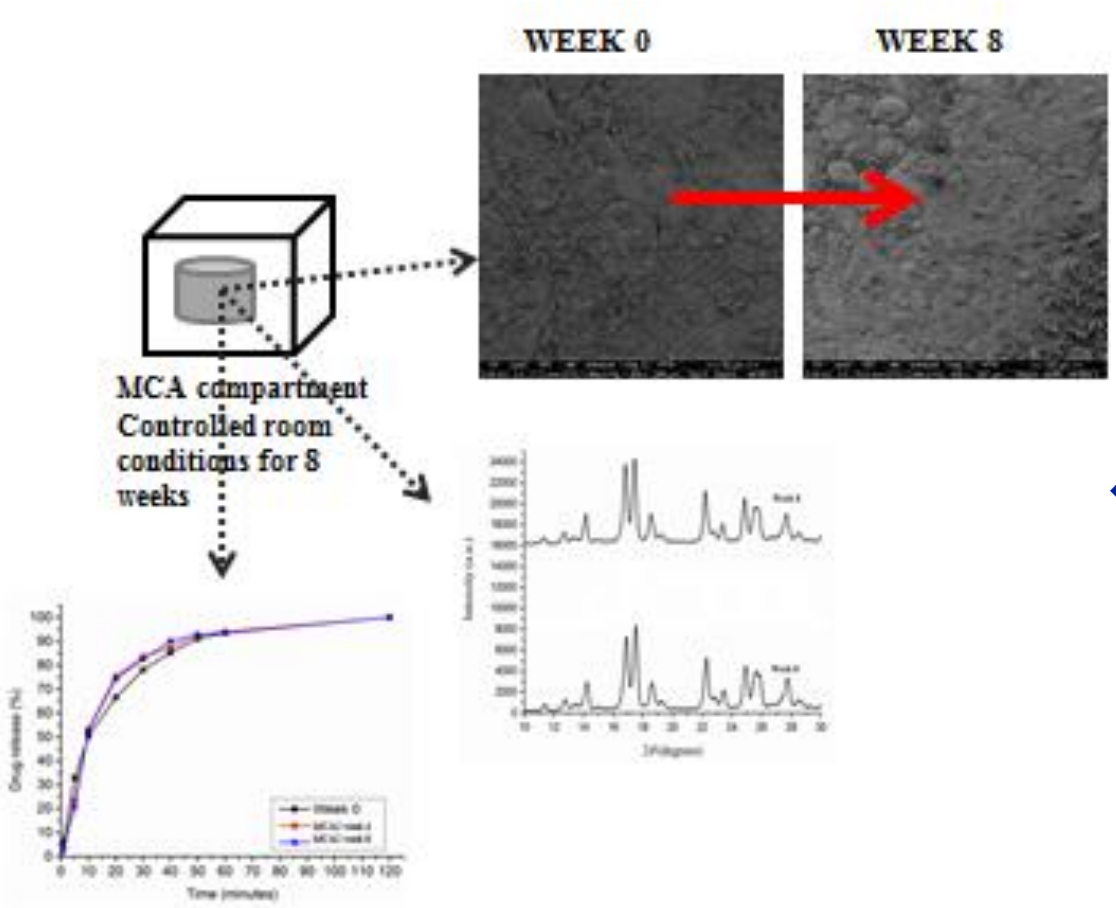
- Physical stability of the repackaged formulations was evaluated.
  - After 8 weeks of storage (under controlled ambient conditions), changes in the disintegration (tablets only) and dissolution properties (all formulations) were examined in accordance with British Pharmacopoeia (BP) specifications.

Raimi-Abraham B.T*, Garcia del Valle A, Galcera GV, Barker S.A, Orlu-Gul M. A Pilot Study Investigating the Stability of Repackaged Medicine Stored into Commercially Available Multi-Compartment Compliance Aids (MCAs). **Journal of Pharmaceutical Health Services Research**

Multicompartment Compliance Aids (MCAs)

Obstacles for older people to accept their medication

Key Findings



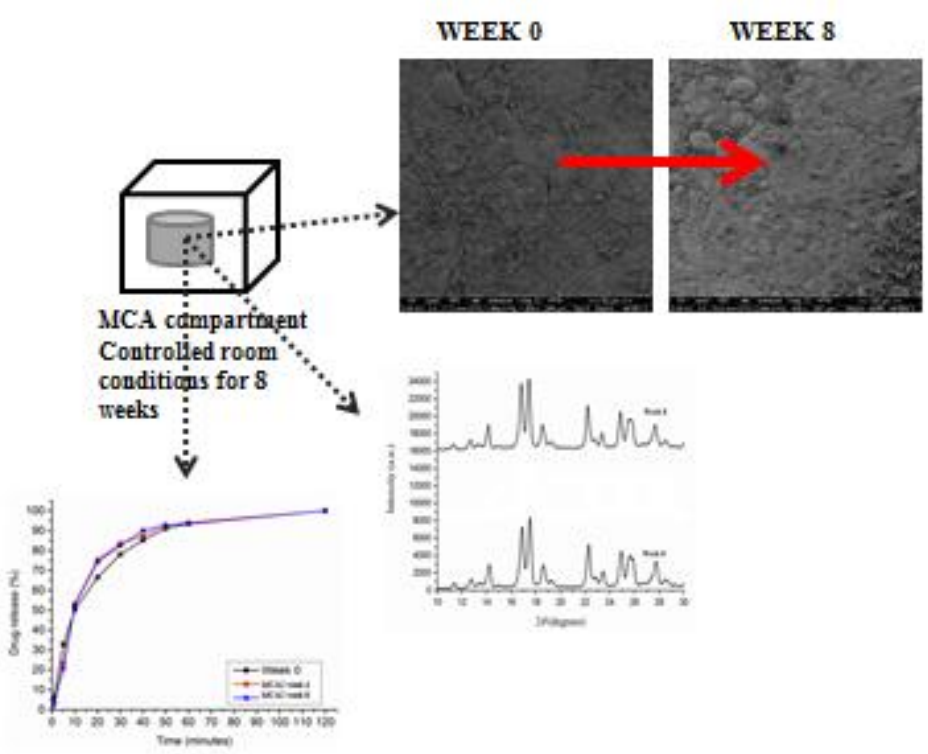
- **Aspirin DT and lansoprazole GR-C <u>statistically significant differences</u>** were observed in **<u>water content</u>**
  - Increase - aspirin DT
  - Decrease for lansoprazole GC

- Presence of excipients (including film coat and capsule shell) may influence the water uptake mechanisms within a formulation
  - Impact on the dosage form properties and performance

Multicompartment Compliance Aids (MCAs)

Obstacles for older people to accept their medication

Key Findings



- The ***in vitro*** **disintegration** and **dissolution** properties of **repackaged formulations were <u>faster</u> compared to week 0.**
- **The rate of lansoprazole release** from GR-C showed a **<u>different profile in the acid stage</u>**
  - More of the drug was released in weeks 4 and 8 compared to week 0.

Inclusion of Older Adults in Clinical Trials

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Journal of Geriatric Oncology 8 (2017) 151–153

Contents lists available at ScienceDirect

Journal of Geriatric Oncology

Perspectives

Regulatory considerations on the enrollment of older adults in oncology clinical trials

Bahijja Tolulope Raimi-Abraham [a,d,1], Maria Silvia de Orbe Izquierdo [b,d], Olivier Collignon [c,d], Francesca Cerreta [d,*]

[a] University College London School of Pharmacy, 29-39 Brunswick Square, London WC1N 1AX, United Kingdom
[b] Fundación para la Investigación Biomédica del Hospital Universitario Ramón y Cajal, Instituto Ramón y Cajal de Investigación Sanitaria (IRYCIS), Ctra. de Colmenar Viejo, Km. 9,100, 28034 Madrid, Spain
[c] Luxembourg Institute of Health, Competence Center for Methodology and Statistics, 1A rue Thomas Edison, L1445 Strassen, Luxembourg
[d] European Medicines Agency, 30 Churchill Place, London E14 5E, United Kingdom

Key questions & focus:

1. How does the geriatric population in oncology clinical trials compare to epidemiology data?*
2. Inclusion/Exclusion criteria? Any biases?
3. Any trends observed with ADRs?

Ochsner Journal 19:294–295, 2019

DOI: 10.31486/toj.19.0068

Barriers to Conducting Clinical Trials in Developing Countries

Adeel Khoja, MSc, MBBS,[1] Fizzah Kazim, MBBS,[2] Naureen Akber Ali, MSc, BScN[3]

[1]Department of Medicine, Aga Khan University, Karachi, Pakistan [2]Dow Medical College, Dow University of Health Sciences, Karachi, Pakistan [3]School of Nursing and Midwifery, Aga Khan University, Karachi, Pakistan

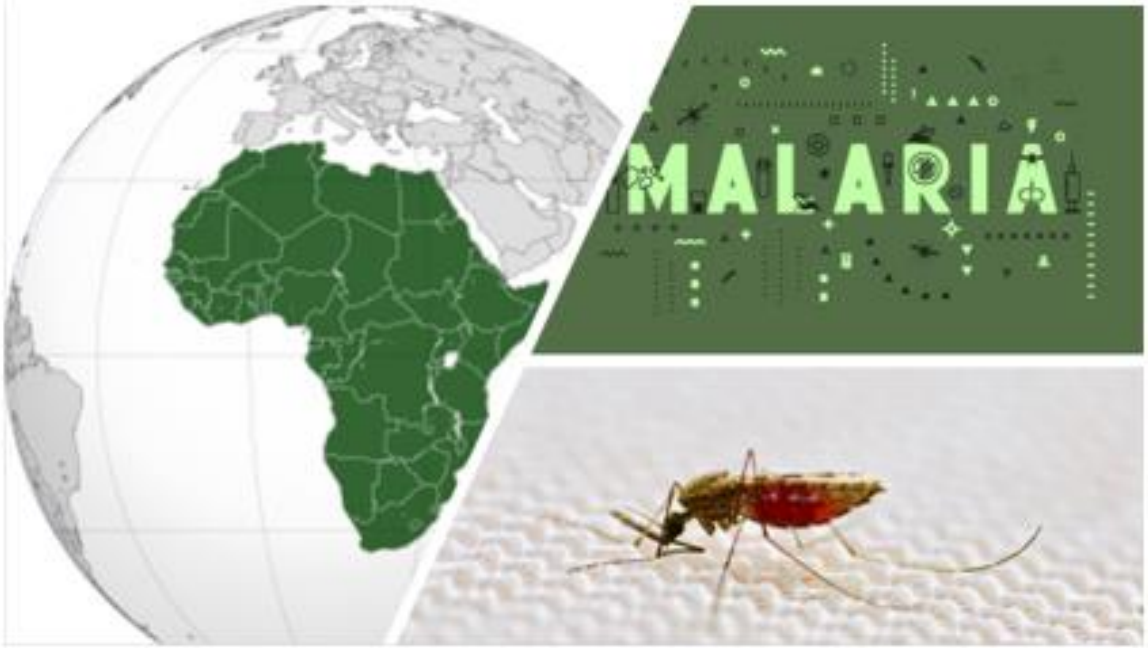
Key Challenges

- Lack of focus on clinical trials research in the curricula in medical schools and teaching hospitals
- Lack of research-based higher educational institutions have led to a death of skilled personnel
- Lack of financial resources
- Lack of skilled personnel
- Cultural and religious beliefs that create fear of exploitation in the general population
- Regulatory administrative issues

Example of UK – LMIC stakeholder engagement

Malaria in Africa: What's next?

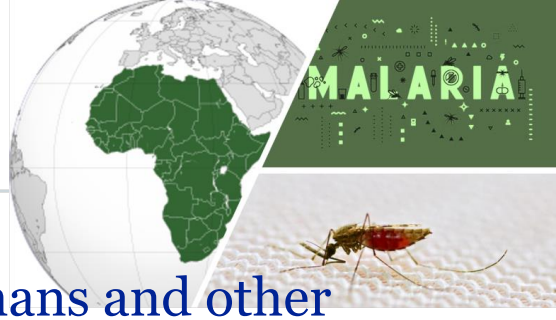
Understanding Malaria and its Potential for Resistance in Nigeria and Ghana



Hosted by Dr Bahijja Raimi-Abraham (King's College London)

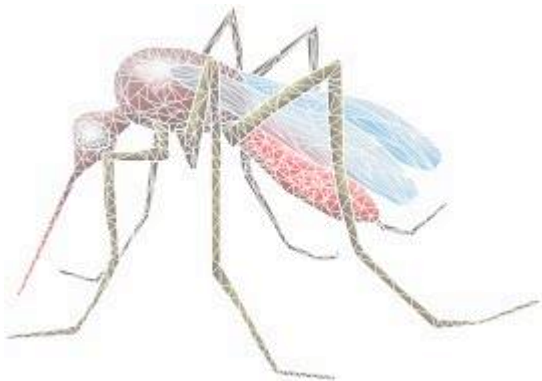
Funded by King's ODA Research Partnership Seed Fund 2019 Call

Malaria



- A mosquito-borne infectious disease that affects humans and other animals.
- Life-threatening disease caused by parasites that are transmitted to people through the bites of infected female Anopheles mosquitoes.
- In 2018, there were an estimated 228 million cases of malaria worldwide.
- Malaria is caused by single-celled microorganisms of the *Plasmodium* group.
- Five species of *Plasmodium* can infect and be spread by humans.
  - *P. falciparum (causes most deaths)*
  - *P. vivax*
  - *P. ovale*
  - *P. malariae*
  - *P. knowlesi*

Despite the relatively large number of antimalarial drugs available, malaria remains the most common and deadly parasitic disease in the world

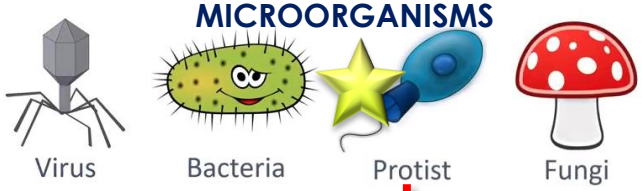


Malaria in Africa: What's next?

Understanding Malaria and its Potential for Resistance in Nigeria and Ghana

Raimi-Abraham Group

MICROORGANISMS



PROTISTAN PARASITES - SPOROZOAN
(PLASMODIUM PARASITE)

***PHARMACEUTICAL CHALLENGES**

Antimalarial drug resistance

Malaria

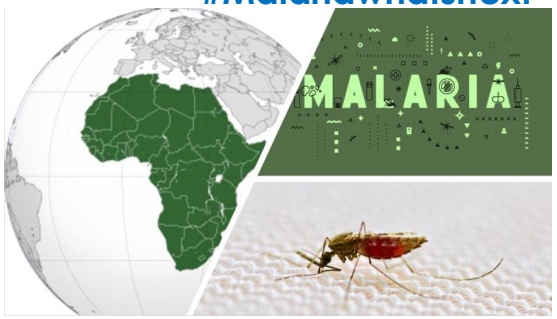
Antimalarial drug resistance in the Greater Mekong Subregion: How concerned should we be?

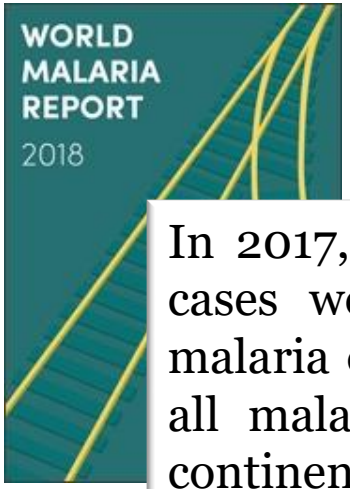
Q&A with Dr Pedro Alonso, Director of the Global Malaria Programme

29 September 2017

World Health Organization

#Malariawhatsnext





In 2017, there were ~219 million malaria cases worldwide. An estimated 450,000 malaria deaths with approximately 90% of all malaria deaths occur on the African continent.

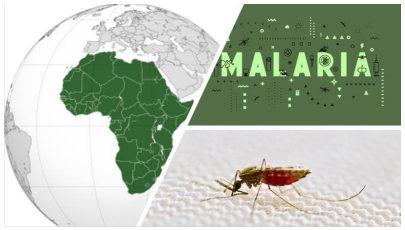
Malaria in Africa: What's next?

Understanding Malaria and its Potential for Resistance in Nigeria and Ghana

- ~70% of the world's malaria burden is concentrated in 11 countries
  - 10 in sub-Saharan Africa namely Burkina Faso, Cameroon, Democratic Republic of the Congo, **Ghana,** Mali, Mozambique, Niger, **Nigeria,** Uganda and United Republic of Tanzania
  - 11th - India.

NB

- Malaria does not currently occur naturally in the United Kingdom (UK)
- Travel-associated cases reported in 2017
  - 10.8% higher than those reported in 2016
  - 15.0% above the mean number of cases reported between 2008 and 2017.

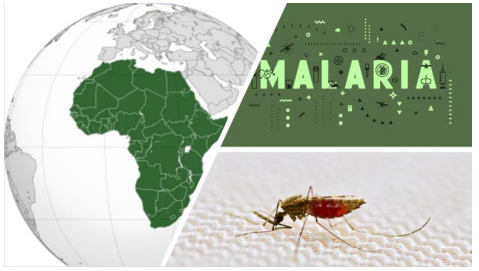


Malaria in Africa: What's next?

Understanding Malaria and its Potential for Resistance in Nigeria and Ghana

#Malariawhatsnext **29th and 30th of October 2019**

"Using a **multidisciplinary and cross sector strategy towards tackling Malaria** (and its resistance) in Nigeria and Ghana by hosting a **two-day networking workshop event at King's College London focused on developing a research strategy and action plan."**



Official Development Assistance (ODA) funding

Global Challenges Research Fund

Malaria in Africa: What's next?

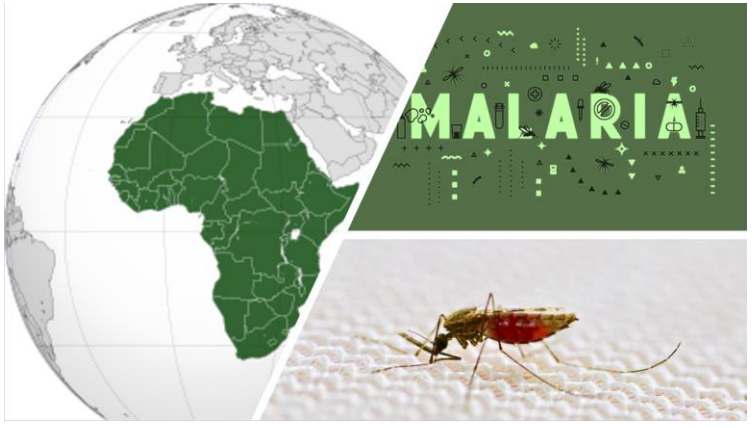
Understanding Malaria and its Potential for Resistance in Nigeria and Ghana

#Malariawhatsnext **29th and 30th of October 2019**

Raimi-Abraham Group

"The **objective** of this people-centered networking workshop event will be to focus on **interventions** directed **towards the groups of people in Nigeria and Ghana who have a role in tackling antimicrobial resistance and are part of the solution including healthcare professionals, academics, industry professionals, policy makers and regulators."**

To foster meaningful discussion and interactions for impact.



Malaria in Africa: What's next?

Understanding Malaria and its Potential for Resistance in Nigeria and Ghana

Raimi-Abraham Group

Speakers & Participants

UK Parliament

Public Health England

UCL

UKRI Medical Research Council

medway school of pharmacy

MOTT MACDONALD

wellcome

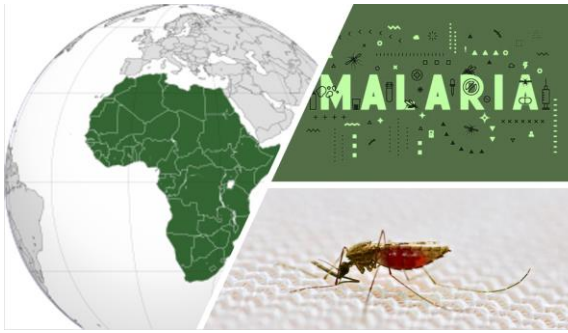
NCDC
NIGERIA CENTRE FOR DISEASE CONTROL

The Commonwealth

KING'S College LONDON

malaria consortium
disease control, better health

Imperial College London



Malaria in Africa: What's next?

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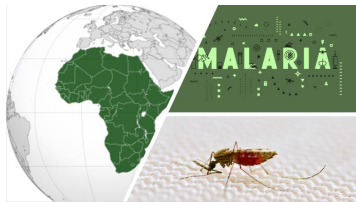
Raimi-Abraham Group

#Malariawhatsnext

- **Day One: IDENTIFYING THE PROBLEM**

29TH OF OCTOBER 2019: IDENTIFYING THE PROBLEM				
	START TIME	END TIME	ACTIVITY	SPEAKER
1	09:30	10:15	REGISTRATION & NETWORKING	
2	10:15	10:20	GENERAL WELCOME & HOUSEKEEPING	BAHIJJA RAIMI-ABRAHAM (KING'S COLLEGE LONDON)
3	10:20	10:30	SCHOOL WELCOME	BEN FORBES (SCHOOL OF CANCER AND PHARMACEUTICAL SCIENCES)
4	10:30	10:45	SETTING THE SCENE: IDENTIFYING THE PROBLEM (DAY ONE)	BAHIJJA RAIMI-ABRAHAM (LECTURER IN PHARMACEUTICS)
5	10:45	11:15	MALARIA CONSORTIUM ACTIVITIES	HELEN COUNIHAN (MALARIA CONSORTIUM)
6	11:15	11:45	DRUG RESISTANCE MALARIA AND CO-INFECTIONS	DIANE ASHIRU-OREDOPE (PUBLIC HEALTH ENGLAND/COMMONWEALTH PHARMACIST ASSOCIATION)
7	11:45	12:00	NETWORKING BREAK	
8	12:00	12:30	AMR & MALARIA IN GHANA	CYNTHIA AMANING DANQUAH (KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY)
9	12:30	13:00	AMR & MALARIA IN NIGERIA	JOSHUA OBASANYA (DIRECTOR NIGERIA CENTRE FOR DISEASE AND CONTROL)
10	13:00	14:30	LUNCH	
12	14:30	17:00	PROBLEM IDENTIFICATION WORKSHOP	ALL
13	17:30	18:00	DAY ONE SUMMARY & CLOSING DISCUSSIONS	ALL
14	18:00	20:00	NETWORKING EVENT & PRESENTATION OF CERTIFICATES	ALL



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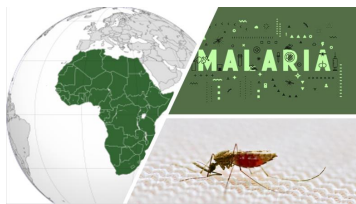
Raimi-Abraham Group

#Malariawhatsnext

30TH OF OCTOBER 2019: PATHWAYS TO IMPACT				
	START TIME	END TIME	ACTIVITY	SPEAKER
1	08:30	09:00	REGISTRATION & NETWORKING	
2	09:00	09:30	DAY ONE SUMMARY & SETTING THE SCENE: PATHWAYS TO IMPACT (DAY TWO)	BAHIJJA RAIMI-ABRAHAM (KING'S COLLEGE LONDON)
3	09:30	10:00	MALARIA: THE JOURNEY, THEN TO NOW	TREVOR JONES (KING'S COLLEGE LONDON)
4	10:00	10:30	GLOBAL PERSPECTIVE	OBINNA NNEWUIHE (COMMONWEALTH SECRETARIAT)
5	10:30	11:00	GLOBAL PERSPECTIVE: FUNDING	DAVID PAN (MEDICAL RESEARCH COUNCIL)
6	11:00	11:15	NETWORKING BREAK	
7	11:15	11:45	GLOBAL PERSPECTIVE: FUNDING	TOBY LESLIE (MOTT MACDONALD)
8	11:45	12:15	DIAGNOSIS IN MALARIA	DELMIRO FERNANDEZ-REYES (UNIVERSITY COLLEGE LONDON)
9	12:15	13:15	LUNCH	
10	13:15	13:45	MANAGING IMPORTED MALARIA IN THE UK	JOHN KLEIN (ST THOMAS' HOSPITAL)
11	13:45	15:45	PATHWAYS TO IMPACT WORKSHOP	ALL
12	15:45	16:15	WHERE DO WE GO FROM HERE: NEXT STEPS & ACTION PLAN	ALL
13	16:15	17:00	MALARIA CONSORTIUM	MAXWELL KOLAWOLE
14	17:00		CLOSE	

- Day Two: PATHWAYS TO IMPACT



Malaria in Africa: What's next?

#Malariawhatsnext

A two day international multidisciplinary meeting focused on Malaria in Nigeria & Ghana, November 2019

Malaria in Africa: What's next?

Understanding Malaria and its Potential for Resistance in Nigeria and Ghana

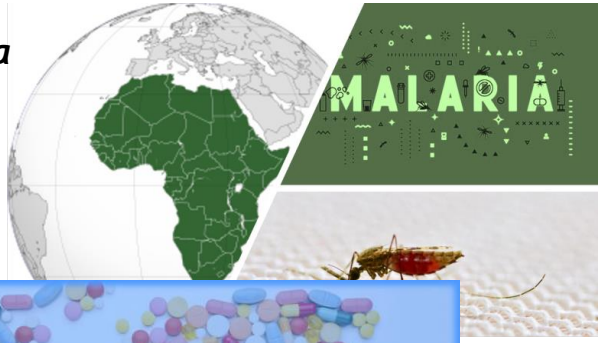
#Malariawhatsnext

DOWNLOAD THE BROCHURE

https://theraimiabrahamgroup.wixsite.com/globalhealth

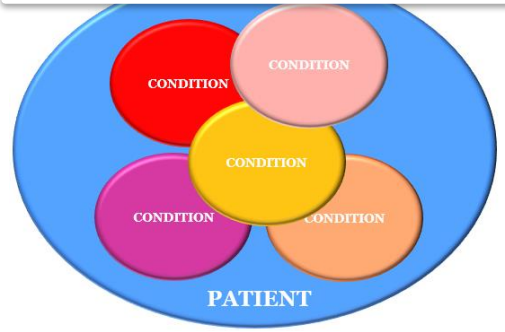
Malaria in Africa: What's next?

Understanding Malaria and its Potential for Resistance in Nigeria and Ghana



PROBLEMS IDENTIFIED – Relevant to Drug Development of Age Related Medicines

MULTIMORBIDITY



Multimorbidity defined as the coexistence of two or more chronic diseases in one individual, can include

- ✓ Physical/Mental Health Condition
- ✓ Complex Symptom such as Chronic Pain
- ✓ Sensory Impairment
- ✓ Alcohol or Substance Misuse
- ✓ Learning Disability

FAKE MEDICINES

FALSIFIED, SUBSTANDARD AND COUNTERFEIT MEDICINES: IMPLEMENTING PATHWAYS TO IMPACT

Who are Fight the Fakes?

- A campaign that aims to raise awareness about the dangers of fake medicines.

- Gives a voice to those who have been personally impacted and shares the stories of those working to put a stop to this threat to public health.

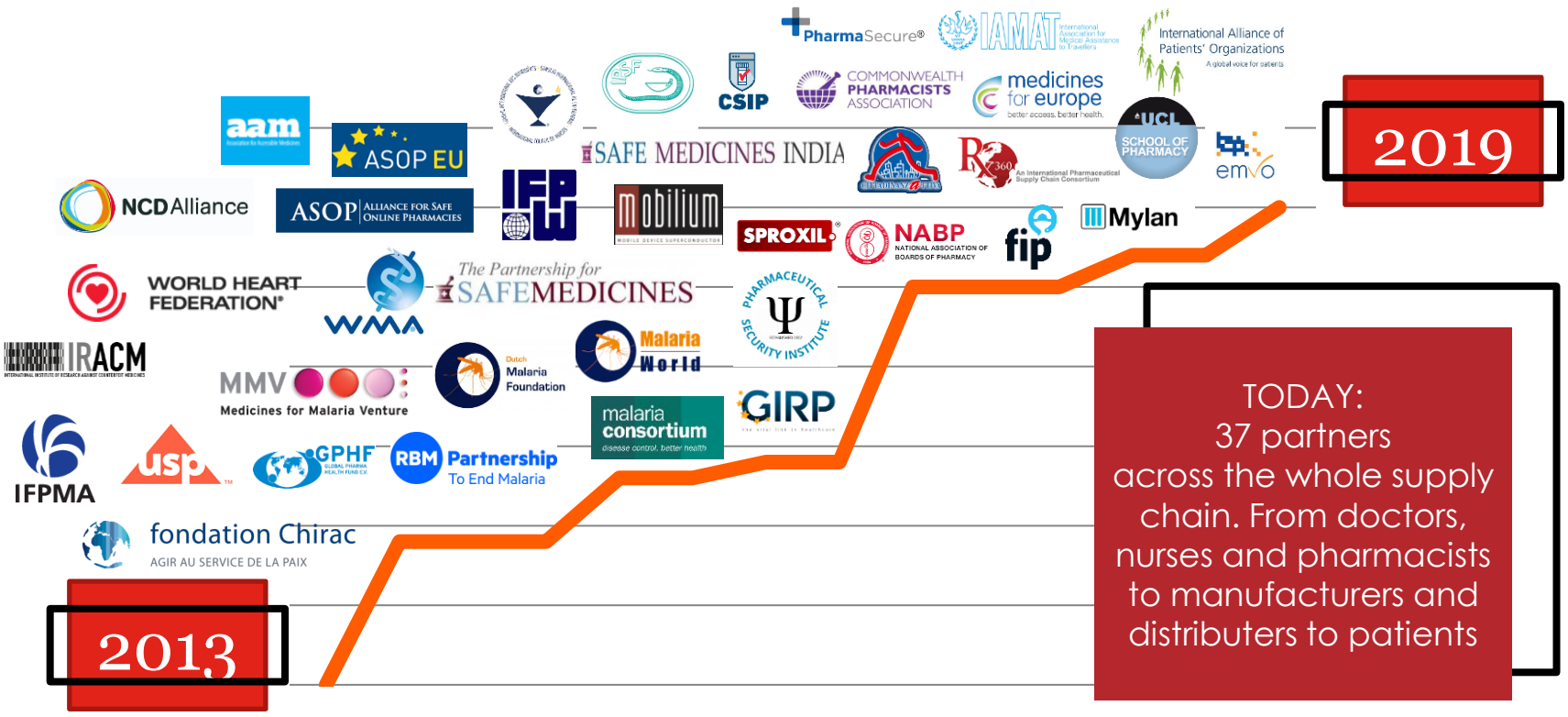
- Build a global movement of organizations and individuals who will shine light on the negative impact that fake medicines have on people globally.

- Reduce the negative consequences on individuals worldwide.

10 founding partners in 2013

Originally set up in 2013 by 10 organizations

Who and when?


2019
2013
TODAY:
37 partners
across the whole supply chain. From doctors, nurses and pharmacists to manufacturers and distributers to patients
PharmaSecure
IAMAT
International Alliance of Patients' Organizations
CSIP
COMMONWEALTH PHARMACISTS ASSOCIATION
medicines for europe
aam
ASOP EU
SAFE MEDICINES INDIA
UCL SCHOOL OF PHARMACY
emvo
NCD Alliance
ASOP ALLIANCE FOR SAFE ONLINE PHARMACIES
IFPW
mobilium
SPROXIL
NABP
fip
Mylan
WORLD HEART FEDERATION
WMA
The Partnership for SAFEMEDICINES
PHARMACEUTICAL SECURITY INSTITUTE
IRACM
MMV
Medicines for Malaria Venture
Dutch Malaria Foundation
Malaria World
malaria consortium
GIRP
IFPMA
usp
GPHF
RBM Partnership To End Malaria
fondation Chirac
AGIR AU SERVICE DE LA PAIX

King's College London Fight the Fakes

KING'S College LONDON

FIGHT THE FAKES

SPEAK UP ABOUT FAKE MEDICINES

Founded - March 2020

We are a **multidisciplinary undergraduate** and **postgraduate student-led** campaign with a focus on **falsified antimalarials** and **antibiotics**, two of the most reported counterfeit drugs.

In addition, our campaign also includes raising awareness of the **rising** use of falsified, counterfeit and substandard medicines in the United Kingdom.

The Team

Dr. Bahijja Raimi-Abraham
Founder and Academic Lead

Tamara Akpobolokemi
Founding Committee Member and Global Liaison Lead

Michelle Herrera Corvalan
Founding Committee Member and Events Lead

Jeeves Dhadwar
Committee Member and Social Media Officer

Jamee Ahmed
Founding Committee Member and Social Media Lead

Riddhi Mistry
Committee Member and Partnership Officer

KING'S College LONDON

FIGHT THE FAKES
SPEAK UP ABOUT FAKE MEDICINES

Our Strategy

KING'S College LONDON

FIGHT THE FAKES
SPEAK UP ABOUT FAKE MEDICINES

Founded - March 2020

- **Establish partnership with other FTF global partners and non-FTF global partners.**
- **Research**
  - Quality assessment
  - Solution focused multidisciplinary projects
- **Analysis of available literature**
  - Critical reviews
  - Systematic reviews & meta-analysis

KING'S College LONDON

FIGHT THE FAKES

SPEAK UP ABOUT FAKE MEDICINES

Save the date !

Fight the Fakes Week 2020

- 3rd, 7th -11th of December 2020
- Virtual events (talks/panel sessions/podcast)
  - 2021 Strategy
  - Board of Advisors Announcement

FOLLOW US ON SOCIAL MEDIA

@KingsFtF

@KingsFighttheFakes

King's College London
Fight the Fakes

King's College London Inaugural Fight the Fakes Week

Let's Fight the Fakes - Through the Pandemic & Beyond

All events are virtual.

- 3rd Dec [6 - 7pm] - Welcome Event
- 7th Dec [1-2pm] - Partners & Our Shared Agenda
- 8th Dec [6 - 7pm] - Dangers of Fake Medicines Online
- 9th Dec [6 - 7pm]- How to Identify Fake Medicines
- 10th Dec [5:30 - 7pm] - Fake Medicines in Africa: Its impact on people and health systems
- 11th Dec [2-3pm] - How do we solve the issue of fake antimalarials?

BOOK NOW

Eventbrite

King's College London Fight the Fakes

Scan me

Save the date !

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@KingsFighttheFakes

@KingsFtF

https://kclfightthefakes.wixsite.com/kingsfti

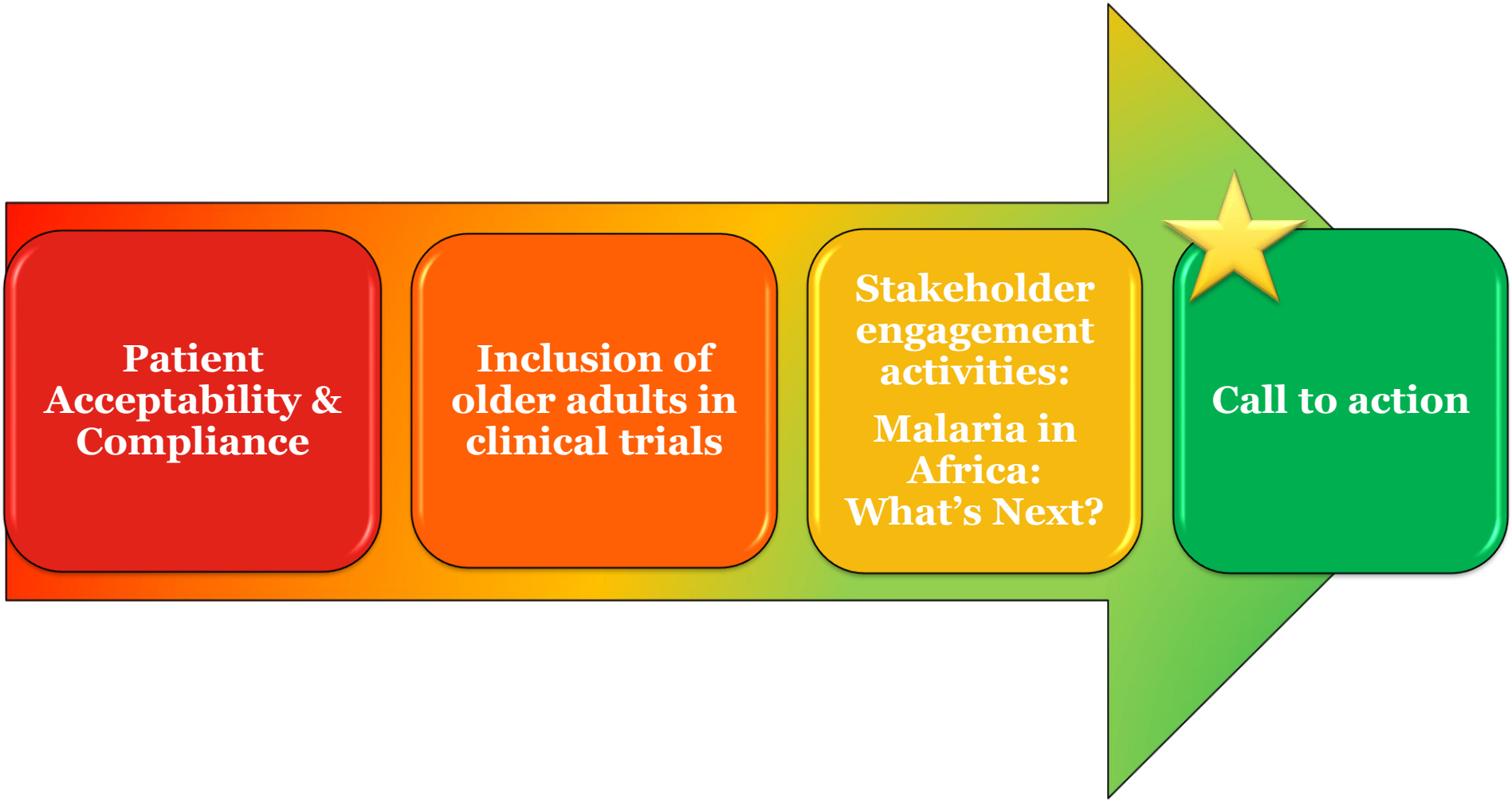
KING'S College LONDON

FIGHT THE FAKES

SPEAK UP ABOUT FAKE MEDICINES

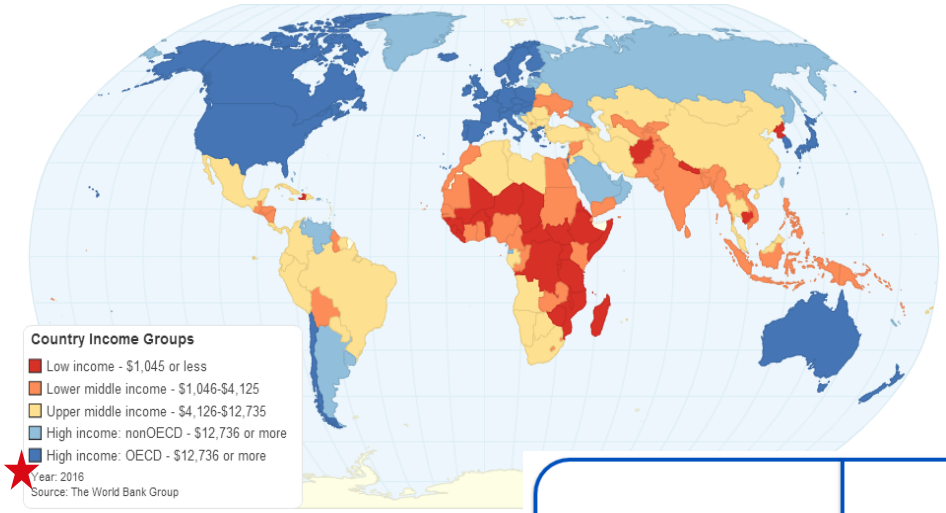
Drug Development and Age-Related Medicines

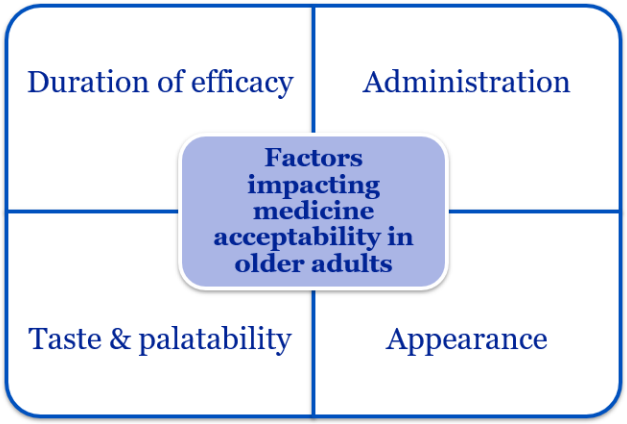
UK, LMIC/Developing countries

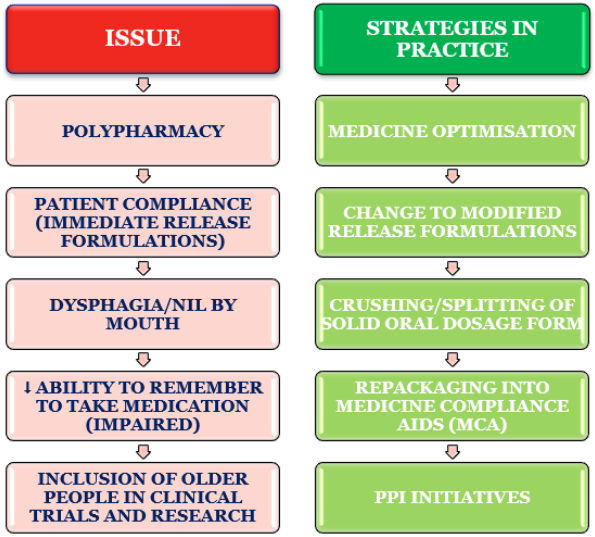


Call Action

- **Global collaboration**
  - Individual
  - APS Age Related Medicines Focus Group







ADDRESSING THE GLOBAL ISSUE - DRUG DEVELOPMENT OF AGE-RELATED MEDICINES

SYNERGISTIC PARTNERSHIPS

(syn·er·gy)

the interaction or cooperation of two or more *organizations*, *substances*, or *other agents* to produce a combined effect *greater than the sum* of their separate effects.

The term synergy comes from the Greek word synergia συνέργια *from synergos*, συνεργός, *meaning* ***"working together"***

ADDRESSING THE GLOBAL ISSUE - DRUG DEVELOPMENT OF AGE-RELATED MEDICINES

SYNERGISTIC PARTNERSHIPS: CATALYST FOR IMPACT & INNOVATION

"When people work together toward a joint goal, they can accomplish something larger, greater, and with more impact than something done in isolation."

COLLABORATION + SYNERGY = IMPACT & INNOVATION

ADDRESSING THE GLOBAL ISSUE - DRUG DEVELOPMENT OF AGE-RELATED MEDICINES

UNRELATED EXAMPLE

Support The Guardian

The Guardian

News | Opinion | Sport | Culture | Lifestyle

There are many more examples of innovations like this. One of the commonest operations in the UK is hernia repair, in which a piece of surgical mesh is stitched into the abdominal wall to strengthen it. The commercial mesh used in the operation costs from £30 to £700 a piece, depending on the type and size of the order.

Yet surgeons working in the developing world have found that mesh – mosquito netting that has been sterilised – works just as well. It costs less than £1 a piece and is prepared and used globally by the charity, Hernia International, which arranges for the netting to be cut, sterilised, sealed and packaged through recognised European sterilisation processes. More than 100,000 hernias are performed each year in the UK, at a cost of more than £3m for the supply of mesh. This could be cut to around £100,000 if we were to move to low cost mesh, a saving of 97%.

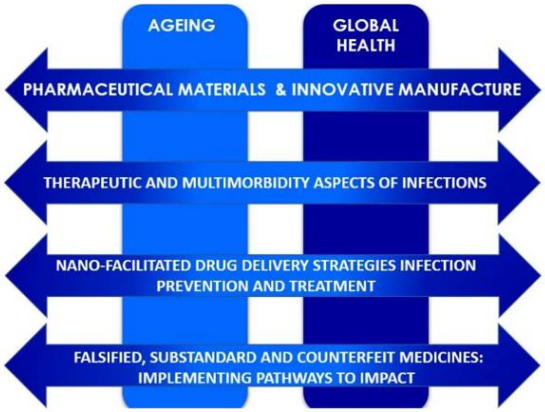
The cheap innovations the NHS could take from sub-Saharan Africa

Ara Darzi

Surgeons have found that sterilised mosquito netting can be used for hernia repair - one of several options that could save the NHS £100m in five years

Fri 27 Oct 2017 10.47 BST

The Raimi-Abraham Group @ King's College London
Our Research



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@TheRaimiAbrahamGroup
@TheRaimiAbrahamGroup

thanks for listening!

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