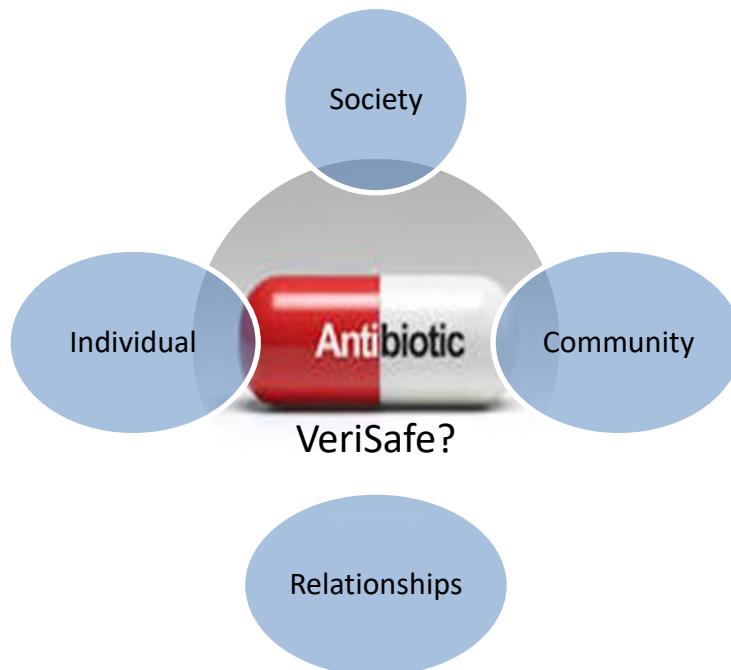


19-30 March 2018 17 June 2018



Challenge (topic): Innovation for the development of a novel diagnostic system or technology to collect data on/for antibiotic dispersion and repurposing of old drugs to address antimicrobial resistance

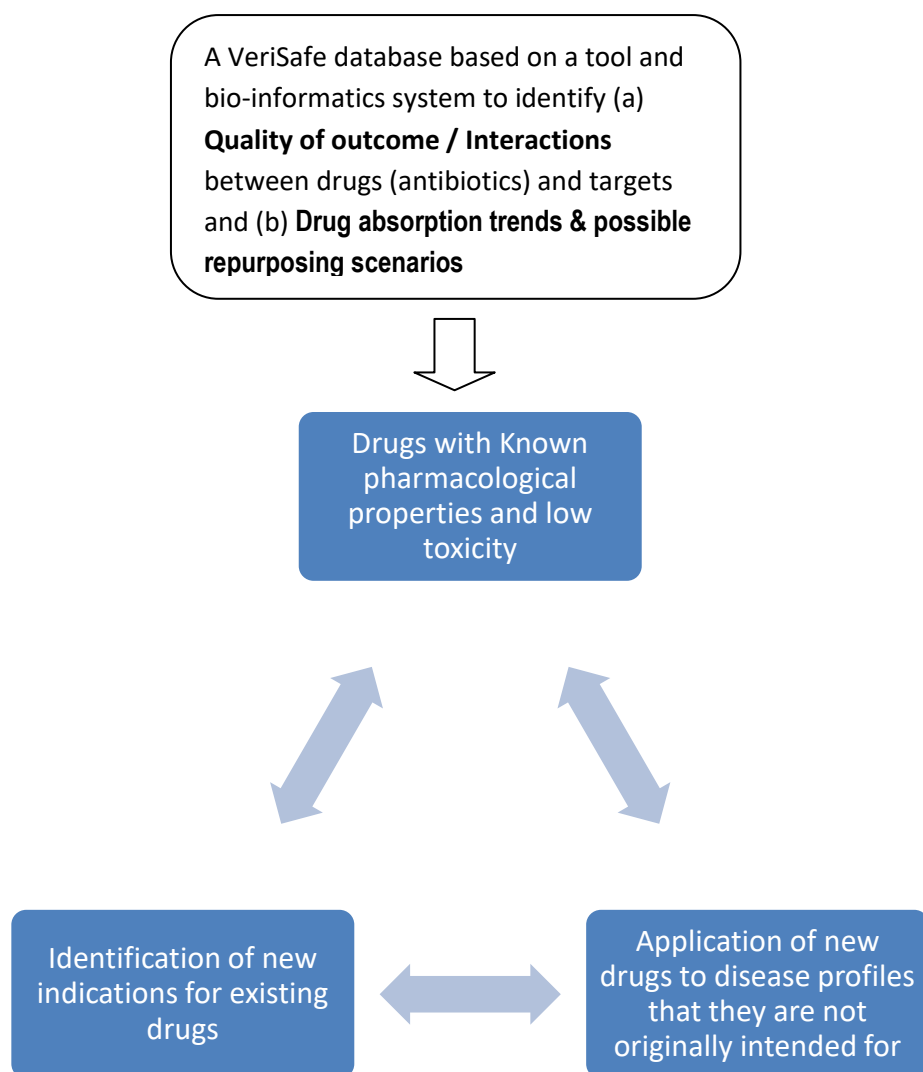
Project Proposal

The main focus is to develop a closed loop to (a) guide purchase or sale, (b) collect data about consumers, (c) guide and monitor use, (d) help return or issue recall, (e) collect and dispose of unwanted drugs without causing an adverse toxic effect or unwanted pharmacological effect that harms people and/or the environment.

This document includes a template for the Know Your Customer proposal.

The scope considered for Drug repurposing

This proposal considers the following illustration to be the background for its inferences



The consultant is also aware that mechanisms or techniques like screening of Electronic Health Records, Compound or Helper Compound Libraries, Drug Target interactions, Efflux pump inhibitors, Compound Active site predictors and more innovatively the use of bacteriocins (that are produced by bacteria to maintain their population & reduce competitors) and bacteriophages (that affect cellular processes on hosts where the drug is made available with high specificity and increased abundance) are growing in importance in the domain of future drug repurposing.

However, the proposal finds that **screening for known compound-new target scenarios and known target-new compound** scenarios forms the baseline for BRIC countries or developing countries reporting incidences of (a) issues in intensive care, (b) reducing oral treatment options and (c) increasing antibiotic drug resistance.

The proposal importantly highlights that understanding the Mechanism of Action of drugs that are therapeutically efficient and suitable for a location, state or country is an important step.

The proposal finds that drug manufacturers need to include more information about anti-microbial activity in their package inserts. The need to include information about how the antibiotic functions (to help drug discovery or drug repurposing) that is

- a. Its altering of bacterial cell permeability
- b. Its regulation of the efflux pump mechanism
- c. Its influence on the cross membrane ionization
- d. Its influence on the activity of membrane based enzymes
- e. Its modulation of microphage activity
- f. Its inclusion of any helper compounds in its formulation
- g. Its use of compound libraries or “need for” consideration of more information like chemical structure, purity, quantity & physiochemical properties from any compound libraries (that are being hosted by different companies and biotechnologists)

Enabling further development or looking past pure chemical formulation towards multi-therapy and poly therapy

There should also be a paragraph in the drug’s package insert on “suggested alternate anti-microbial(s) for patients or consumers reporting adverse drug events, severe side effects or even drug resistance for the drug being considered, where sufficient clinical trials or evidence is indicated for options like off label usage, use of bacteriophages (though they are still not proven or are known to be attacked by the immune system) and use of anti-bacterial(s) from natural products available in a region should be made available”.

The proposal exceeds the stipulated number of pages, as the consultant found the need to delve into specifics or practical illustrations was important given the nature of the solution.

The solution called “Veritable and Safe PharmaCare with new VeriSafe labelling and augmentation”, involves different stages like

Stage 1: Addition of VeriSafe labelling and augmentation to antibiotics primarily, thereon to life saving drugs and medicines

This is being taken up with the pharmaceutical businesses, chemists and druggists.

Step 2: Patients or consumers should complete the **VeriSafe KYC**

The “**VeriSafe KYC template**”

The KYC template avoids conflicts of interest and does comply with patient or consumer perspectives like

- a. Right to information
- b. Considerateness, respect and care while meeting needs
- c. Right to privacy and safety
- d. Right to choose and be heard
- e. Right to any available consumer education

Out-patient mode (For example)

The registration process expects the entry of information like the Consumer name, Sex, Date of birth (if known) Age (approximate number of years), Current Consumer Group during a first time registration.

If the Consumer has already registered, this process permits the consumer or user to update information.

If the Consumer expires or does not want to remain a part of the VeriSafe system, then this process permits the user to initiate an end-of-life standard operating procedure within the system and its associated sub-systems.

Consumer's Name:

Sex:

Date of birth:

Age:

Current Consumer group: Pregnant/Breast Feeding/Paediatric/Geriatric/Others

Current lifetime of account: Till end of life/ for a particular period

Current patient category: Out-patient/ In-patient/ Emergency patient/ Consumer/
End-of-life-status

Current data maintenance period:

Start date:

End date:

VeriSafe Id (secure read only field):

VeriSafe status (secure read only field):

Register

Update

End of Life

VERISAFE PROFILE

Consumer Name:

VeriSafe Id:

Place of residence:

Region:

City:

State:

Country:

Sex:

Age:

Current Consumer group: Pregnant/Breast Feeding/Paediatric/Geriatric/Others

Nationality:

Country of origin:

**[A] THIS SECTION HELPS UNDERSTAND LITERACY AND WORK BACKGROUNDS
TO IMPROVE ITS DIAGNOSTICS, CALL CENTRE, COMMUNICATIONS AND
INFORMATION**

Can you understand information communicated in English? Yes/No/Others

Can you read and write English? Yes/No/Others

Do you need help to read and write English? Yes/No

If English is a problem, what is the language of your choice?

Do you need help such as periodic brown bag inventory of your drugs, medications and pharmaceutical products? Yes/No

Nature of occupation: Unemployed/Employed/Self-employed/ Business/ Retired/Others

Do you work or study in less safe environments? Yes/No/Not applicable

Nature of work or study environment:

Do you travel frequently? Yes/No

Last country visited:

Date visited:

Did you suffer from any incidences during travel?

Yes/No/Not applicable/Do not know/Cannot comment

Did you rely on self-medication during these incidences?

Yes/No/Not applicable/Do not know/Cannot comment

If yes, did you consume antibiotics via some self-knowledge?

Yes/No/Not applicable/Do not know/Cannot comment

If no, did you seek professional advice or intervention?

Yes/No/Not applicable/Do not know/Cannot comment

If yes, provide possible details:

If no, did you meet a doctor on return to the country?

Yes/No/Not applicable/Do not know/Cannot comment

If yes, provide possible details:

[B] THIS SECTION HELPS UNDERSTAND CONSUMER BEHAVIOUR

Do you use medications or healthcare products purely on the advice of doctors or practitioners? Always/Yes/No/Not applicable

Nature of medications or healthcare products that you consume on advice of doctors or practitioners:

Nature of medications or healthcare products that you consume as self-medication or as self-guided care:

System of medicine availed of most often? Allopathy/ Ayurveda/ Homoeopathy/Mix or Polytherapy/ Others

System of medicine availed of sometimes? Allopathy/ Ayurveda/ Homoeopathy/Mix or Polytherapy/ Others

System of medicine that has not worked? Allopathy/ Ayurveda/ Homoeopathy

Any alternatives recommended by experts?

Do you alter medications sometimes (leading to cases of off-label usage of drugs)? Only on the advice of an expert/Self-guided/On the basis of availability/On the basis of costs/Other reasons

Benefits experienced:

OR

Issues faced:

VeriSafe brings to attention that unwanted (severe) side effects or Adverse Drug Events related to drugs mostly include some of the following:

Allergy/Arrhythmias/Bleeding/GI tract bleeding/Sudden Constipation/Convulsions/ Delirium/Electrolyte disorders/Signs of Hepatotoxicity/ Hepatic dysfunction/ Hypotension/Continued or sudden loss of appetite/Reduced urine output/Renal dysfunction/Severe acidity/Severe stomach upset or cramps/Sudden pain in the abdomen/Nausea or vomiting/Restlessness or profuse sweating/Uneasiness

[C] THIS SECTION IDENTIFIES INDIVIDUAL CHARACTERISTICS

State your constitution? Healthy/ Occasionally unwell/Recovering/Chronic condition/
Do not know

Weight: Normal/Under-weight /Overweight/Do not know

Blood sugar: Normal/Low/High/Under control/Do not know

Blood pressure: Normal/Low/High/Under control/Do not know

Do you suffer from or were you treated for any type of cancer (as this may affect the action of the drug due to possible DNA/RNA mutation, inflammation levels or changes in immune response)? Yes/No/Do not know

Do you suffer from any other Life-changing condition: Yes/No/Do not know

VeriSafe informs that for people suffering from HIV or auto-immune diseases, the benefit/risk ratio or drug-to-drug interactions vary and may even cause adverse effects. It is important to know whether a drug or medication is safe for such a person to reduce risks and ensure better quality of outcome.

If yes, provide possible details:

Do you take drugs (that need more careful monitoring for drug interactions) such as anti-diabetes, oral anti-coagulants, anti-epileptics, Digoxin variants for heart ailments, psychotropic & tri-cyclic anti-depressants, medication for insomnia, pain killers (NSAIDs):
Yes/No/Do not know

If yes, provide possible details:

Do you use medication or healthcare products regularly? Yes/No/Do not know

Are you on prescription medicines? Yes/No/Do not know

If yes, provide details:

If yes, provide details on the period for which you have been on prescription medicines:
Number of years: _____ Number of months: _____ Number of days: _____

Are you currently under treatment? Yes/No/On prescription medicines/Do not know

If yes, provide possible details:

Do you consume any Herb and Dietary Supplements (HDS)? Yes/No/Do not know

VeriSafe states that HDS intake along with certain drugs and medications can affect the outcome and also introduce new risks. It is important that a consumer discuss and confirm HDS purpose, safety and suitability with a medical practitioner or pharmacist.

If yes, provide details:

:

[D] THIS SECTION ASSESSES PARAMETERS FOR DRUG INTERACTION

Diet: Vegetarian/Non-vegetarian/Both/Others

Do you drink sufficient water or fluids every day (this is important for solid drug dispersion and solubility levels)? Yes/No/Do not know

Do you smoke or drink alcohol? Yes/No

Do you consume narcotic drugs (due to medical condition or other preferences)? Yes/No/Do not know

Do you suffer from any food allergies? Yes/No/Do not know

Do you suffer from any drug or medicine related allergies? Yes/No/Do not know

Do you suffer from pollen, smoke or dust allergies? Yes/No/Do not know

Do you know about your vulnerability or susceptibility to certain diseases? Yes/No/Do not know

Do you have more information about this?

Which method of antibiotic drug administration has worked for you mostly?
Oral/Sublingual (below the tongue)/Subcutaneous (SC)/Intra Muscular (IM)/
Intra Venous (IV)/Topical/Rectal/Not applicable/Do not know

Have you suffered any Adverse Drug Events? Yes/No/Not applicable/Do not know
If yes, provide possible details:

Have you been treated for drug overdose? Yes/No/Not applicable/Do not know
If yes, provide possible details:

[E] THIS SECTION IDENTIFIES DETAILS OF CHRONIC DISEASE OR MAJOR / RECENT INCIDENCES

Do you know about the nature of your problem? Yes/No/Not applicable/Do not know

Is clinical diagnosis available? Yes/No/Not applicable

Nature of your problem:

Care availed for problem: Not under treatment/Under treatment/Was treated but there is a reoccurrence/Was treated but cannot revisit that doctor or practitioner

Issues faced? Do not have medical records/Do not know enough/No expert opinion available/Suffered contra-indications/Medications costly/Medications not available/Fewer alternate medicines

System of medicine availed of specifically for problem?

Allopathy/Ayurveda/Homoeopathy/ Mix or Polytherapy/ Others

[F] THIS SECTION IDENTIFIES RISK FACTORS FOR VERISAFE

Can you read prescriptions or statutory healthcare information? Always/Yes/No/
Not applicable

Can you use associated statutory information or warnings to contact doctors or
practitioners when suffering from contra-indications? Always/Yes/No/Not applicable

Do you have a “safe and recommended for continued product quality” storage location
for your medications? Yes/No/Do not know

Do you have safe dispensing mechanisms and/or periodic brown bag inventory to take
your medications according to priority, dosage, timing or frequency? The mechanism
should help even if the consumer suffers from cognitive dysfunction, or failing eyesight or
other (label or text associated) reading problems. Yes/No/Do not know

Do you know how to dispose of the antibiotics/drugs that are unwanted or have expired
in a manner that is safe to everyone? Yes/No/Do not know

If relevant, is there a take back programme for unwanted or expired drugs by your
pharmacist or area associated community centre? Yes/No/Do not know

Are you under any trial for medications or healthcare products or plan of care?
Yes/No/Do not know

If yes, provide possible details:

Do you have a family physician or consulting doctor? Yes/No/Not applicable

Do you discuss your conditions or responses regularly with experts? Yes/No/
Not applicable

Do you discuss your condition or responses with other peer groups of people suffering
from the same diseases or illness? Yes/No/Not applicable

Do you rely on any source of information or marketing function to know more about the
drugs and products available for your condition (so you become a more aware
consumer)? Yes/No/Not applicable

Options available or improvements needed?

Step 3: Develop a **VeriSafe diagnostic system** that helps collect data on antibiotic consumption, results, incidences or failures with references to the nature of influences on the complete socio-economical model. Incorporate diagnostics for drug repurposing.

VERISAFE DIAGNOSTIC SYSTEM FOR CONSUMPTION

Consumer Name:

VeriSafe Id:

Sex:

Age:

Current Consumer group: Pregnant/Breast Feeding/Paediatric/Geriatric/Others

Current Weight: Normal/Under-weight /Overweight/Do not know

Current Blood sugar: Normal/Low/High/Under control/Do not know

Current Blood pressure: Normal/Low/High/Under control/Do not know

Do you mostly get enough or undisturbed sleep (typically 6-8 hours at night):
Yes/No/Do not know/Not applicable

Do you mostly eat and drink water or fluids at fixed times of the day (this typically means breakfast, lunch and dinner): Yes/No/Do not know/Not applicable

Current health condition: Unwell/Occasionally unwell/Under-treatment/
On other prescription medicines/Do not know

Nature of ailment (if details known):

Name of antibiotic or antibiotics currently being prescribed (details can be obtained from the prescription or hospital records):

If on other ailment related medication, provide possible details:

If on other prescription medicines, provide possible details:

If yes, provide details on the period for which you have been on prescription medicines:
Number of years: _____ Number of months: _____ Number of days: _____

Is there any dose staggering or ensuring of a gap of 1-2 hours between your current antibiotics and other medications? Yes/No/Do not know/Not applicable

Do you take a homoeopathic medicine called St John's Wort? Yes/No/Do not know/
Not applicable.

If yes, VeriSafe informs you that this can cause adverse effects in multi-therapy treatment or more particularly in treatment for cardio-vascular ailments.

Do you take products containing Psyllium? Yes/No/Do not know/ Not applicable.

If yes, VeriSafe informs you that this can alter the performance of particular drugs and antibiotics.

Fixed Dose Combinations

For VeriSafe consumers, it is important to know that

Fixed Dose Combinations or FDCs are a combination of 2 or more active drugs in a dosage form

OR

Fixed Dose Combinations or FDCs are a combination of a drug, or a device or a biological product.

Purpose of FDCs

FDCs are used for multi-targeting in treating infections.

Guidelines for FDCs

The World Health Organization (WHO) has released 18 FDCs that are part of the Essential Medicines list and recommends that these be prescribed to prevent rising incidences of antibiotic misuse or drug resistance.

If on FDCs, it is important to know that this could lead to drug resistance setting in

Have you been prescribed Fixed Dose Combinations (FDCs) of medicines to supplement an anti-biotic or to more effectively treat your health condition (like vitamins, iron supplements, antacids, analgesics, anti-diarrhoeal, cough suppressants)?
Yes/No/Do not know/Not applicable

If yes, provide possible details:

Herb and Dietary Supplements (HDS)

Do you consume any Herb and Dietary Supplements (HDS)? Yes/No/Do not know

VeriSafe states that HDS intake along with certain drugs and medications can affect the outcome and also introduce new risks. It is important that a consumer discuss and confirm HDS purpose, safety and suitability with a medical practitioner or pharmacist.

If yes, provide details:

Do you suffer from or were you treated for any type of cancer (as this may affect the action of the drug due to possible DNA/RNA mutation, inflammation levels or changes in immune response)? Yes/No/Do not know

Have you undergone any gastro-intestinal surgery (that has reduced motility or effective functioning)? Yes/No/Do not know

If yes, provide possible details:

Have you undergone any surgery related to the liver (that has reduced biliary function)? Yes/No/Do not know

If yes, provide possible details:

Have you undergone any renal surgery (that has reduced well-being or renal functions)? Yes/No/Do not know

If yes, provide possible details:

Have you undergone any heart surgery or cardio-vascular function based surgical procedure? Yes/No/Do not know

If yes, provide possible details:

Do you suffer from any other Life-changing condition: Yes/No/Do not know

If yes, provide possible details:

Do you take drugs (that need more careful monitoring for drug interactions) such as auto-immune modifiers or stabilizers, anti-diabetes, oral anti-coagulants, anti-epileptics, Digoxin variants for heart ailments, psychotropic & tri-cyclic anti-depressants, pain killers (NSAIDs)/medication for insomnia: Yes/No/Do not know

If yes, provide possible details:

Are you under any trial for medications or healthcare products or plan of care? Yes/No/Do not know

If yes, provide possible details:

Step 4: Generate VeriSafe reports, bulletins and notifications that can be used for drug utilization and/or repurposing analytics by drug manufacturing companies

The “VeriSafe reporting framework”

The work in progress framework will include different types of reports, bulletins and notifications.

A. VeriSafe Checker and All-clear

The VeriSafe checker (that will be available at a PharmaCare.Portal) will confirm rational use of antibiotics (that is their purpose & suitability) . The VeriSafe checker will help control morbidity & mortality, prevent or reduce harm to consumer, limits cases leading to drug resistance and regulates or limits socio-economic impact due to medication errors.

Rational use of an antibiotic confirms the following:

1. Appropriate patient information
2. Appropriate patient evaluation
3. Appropriate disease & purpose indication
4. Appropriate patient (Consumer group and individual characteristics)
5. Appropriate drug on the basis of Appropriate Costs
6. Appropriate VeriSafe acknowledgments of purpose and suitability

On confirming rational (veritable and safe) use, the Consumer or VeriSafe user is sent a VeriSafe all clear as an SMS on a registered mobile or as an email to a registered email account.

If the consumer is to start or continue long term medication, the Consumer or VeriSafe user will be able to register for VeriSafe bulletins and notifications.

B. VeriSafe Drug Absorption Report

The VeriSafe tool will report data on drug absorption results for its users with details on performance related to

- a. Gastro-intestinal tract functioning
- b. Intra-luminal pH impact on drug stability and degree of ionization
- c. Biliary function and influence on ability to solubilise or subsequently absorb (lipids related) lipophilic drugs
- d. Gastric emptying time or reduced motility that may retard drug passage into intestine
- e. Intestinal surface area or average intestinal length (effected by age-related or surgery related changes)
- f. Activity of intestinal drug metabolizing enzymes
- g. Availability of efflux transporters
- h. Cardiovascular changes
- i. Immune status
- j. Consumption of Herbs and Dietary Supplements

C. VeriSafe For Drug Repurposing Report

The VeriSafe tool will help drug repurposing by providing data on drugs/antibiotics (consumed by VeriSafe) users like

- a. Efficacy
- b. Known benefits or risks in Polytherapy
- c. Toxicity issues
- d. Mechanism of action (MOA)
- e. Incidences of drug resistance
- f. Incidences of psychosocial impact or socio-economic impact
- g. Recommended administration dose
- h. Recommended administration schedule
- i. Safe Fixed Dose Combinations
- j. Safe Poly therapy
- k. Evidence of any new/repurposed (agent?) due to nature of prescribing/off label usage/co-morbid and life changing conditions/impact of drug lag/