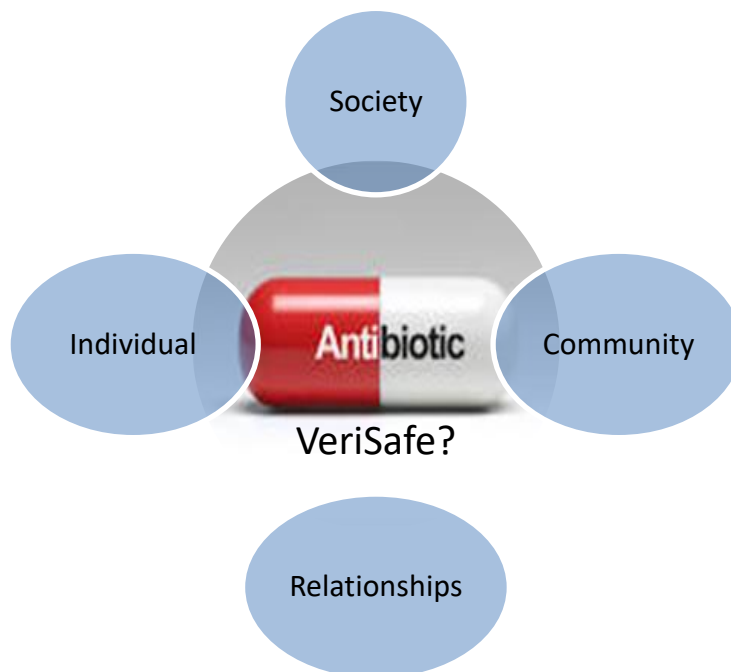


19-30 March 2018 17 June 2018



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 gathering information about a patient's pattern of antibiotic consumption.

[B] VERISAFE ANTIBIOTIC PROFILE

Have you been administered antibiotics earlier?

Yes/No/Do not know/Not applicable

If relevant, available for review are the following list of antibiotics that have been administered in the past. VeriSafe has collected this data via the consumer's or user's interactions with the VeriSafe tool.

Lookup past antibiotics:

Have you been told you cannot/could not be given any best (1st line of therapy) drug (antibiotic) due to other health issues? Yes/No/Not applicable/Do not know

Is Yes, provide possible details:

Have you been told you cannot/ could not be given a particular antibiotic due to an age restriction? Yes/No/Not applicable/Do not know

Is Yes, provide possible details:

Have you been told you cannot/ could not be given a particular antibiotic due to a weight restriction? Yes/No/Not applicable/Do not know

Is Yes, provide possible details:

If no, provide possible details as to why so (comments like discontinued due to costs, unavailability, adverse side effects, adverse drug reactions)?

Did you need to change any course of antibiotics (due to drug resistance or unsuitability)? Yes/No/Not applicable/Do not know

If relevant, have you suffered from any side effects but continued medication?

Yes/No/Not applicable/Do not know

If yes, provide possible details:

If relevant, have you suffered any Adverse Drug Events that needed immediate treatment and discontinuation of the antibiotic? Yes/No/Not applicable/Do not know
If yes, provide possible details:

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

Do you have any comment about the efficacy, safety and cost appropriateness of the antibiotic drug administered to you earlier? Yes/No/Not applicable/Do not know
If yes, provide possible details:

Have you suffered from any reoccurrence of the ailment (after completing or stopping the course of antibiotics)? Yes/No/Not applicable/Do not know

During the treatment, was there any unknown or unforeseen change in the prescribed course of medication (called medication error)? Yes/No/Not applicable/Do not know

If yes, provide possible details?

If no medication error has occurred in the prescribed course

(a) Whether the same medication is/was prescribed but with changes in dosage, potency or duration? Yes/No/Not applicable/Do not know

If yes, provide possible details?

Did this cure you satisfactorily? Yes/No/Not applicable/Do not know

(b) Whether there is/was a change in the type or dosage or method of administration (from oral or sublingual to injection/intra-venous) of antibiotics specifically for the problem? Yes/No/Not applicable/Do not know

If yes, provide possible details?

If the changed prescription has been followed

Has this cured you satisfactorily? Yes/No/Not applicable/Do not know

If no, have you started suffering or suffered from any new ailments?
Yes/No/Not applicable/Do not know

If yes, provide possible details?

(c) Whether there is/was a change in the system of medicine availed of specifically for the problem? Ayurveda/Homoeopathy/ Mix or Polytherapy/ Others

If yes, provide possible details?

Has this cured you satisfactorily? Yes/No/Not applicable/Do not know

If no, have you started suffering or suffered from any new ailments?

Yes/No/Not applicable/Do not know

If yes, provide possible details?

[C] VERISAFE ENTERAL DRUG RELEASE PROFILE

Have you taken antibiotics orally or via the sublingual mode earlier?

Yes/No/Not applicable/Do not know

What was the frequency?

Single rdose/Daily AM or PM/Daily AM & PM/Daily AM, Afternoon, PM/Others

Were you advised on what to do if you missed a dose?

Yes/No/Not applicable/Do not know

If relevant, what did you do mostly when you missed a dose?

Details related to improved drug absorption (as the performance of the drug depends mostly upon your other health conditions, sleep-wake cycle, food & fluid intake [easy to digest diet])

[

Were the antibiotics in the direct capsule form?

Yes/No/Not applicable/Do not know

]

OR

[

Were the antibiotics in the oral tablet or dissolved liquid form?

Yes/No/Not applicable/Do not know

Was the bitter or unpleasant taste of the antibiotic masked?

Yes/No/Not applicable/Do not know

If oral tablet form, was the antibiotic in a sugar bead form?

Yes/No/Not applicable/Do not know

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Did you need to take the oral antibiotic preferably with water?

Yes/No/Not applicable/Do not know

Were you told to take the antibiotic after (preferably easy to digest or regulated protein intake specific) food? Yes/No/Not applicable/Do not know

Were you told to take any specific (immediate or slow release) antacid before taking the antibiotic? Yes/No/Not applicable/Do not know

Do you know that you should not consume acidic fruit juices like grape fruit juice along with your medication? Yes/No/Not applicable/Do not know

If yes, VeriSafe informs you that you need to confirm or discuss this with a medical practitioner to ensure there is no effect on your medication's efficacy and outcome.

During recent time periods, have you consumed old prescription oral antibiotics (on a self-medication basis or self-preference basis) without clinical guidance? Yes/No/Not applicable/Do not know

If yes, provide possible details:

Due to the slow acting effect or non-performance, were any of the courses of oral antibiotics switched to the Parenteral method (that is SC/IM/IV) of drug administration? Yes/No/Not applicable/Do not know

If yes, provide possible details?

[D] VERISAFE PARENTERAL DRUG RELEASE PROFILE

Have you been administered antibiotics via the Subcutaneous (SC) or Intra-muscular (IM) or Intra-venous (IV) mode?

Yes/No/Not applicable/Do not know

What was the frequency?

Single dose/Daily AM or PM/Daily AM & PM/Daily AM, Afternoon, PM/Others

Was the antibiotic specific to your medical condition?

Yes/No/Not applicable/Do not know

(++) If answer to the previous question is not “Yes”, was the antibiotic **broad spectrum** (or meant to treat an infection about which there is “less knowledge or insufficient evidence of type of infection or confirmed indications”)?

Yes/No/Not applicable/Do not know

If the answer to the previous question (++) is “Yes”, did the broad spectrum antibiotic cure you satisfactorily? Yes/No/Not applicable/Do not know

If the answer to the previous question (++) is “No”, did you suffer from any side effects?

Yes/No/Not applicable/Do not know

If relevant, did you suffer from any Adverse Drug Events?

Yes/No/Not applicable/Do not know

Have you suffered from any re-occurrence, since any such antibiotic administration?

Yes/No/Not applicable/Do not know

Have you developed any new ailments, since any such antibiotic administration?

Yes/No/Not applicable/Do not know

[E] VERISAFE DRUG USAGE BY PREGNANT OR LACTATING MOTHERS

Have you been made aware that all medications are not safe for your condition?

Yes/No/Not applicable/Do not know

Does the drug's labelling or package mention the availability of a pregnancy drug registry that provides details on drug exposure, follow-up study, prospective epidemiologic study?

Yes/No/Not applicable/Do not know

Does the drug's labelling or package inserts include information about the summary of risks involved?

Yes/No/Not applicable/Do not know

Does the drug's labelling or package inserts include details on clinical considerations?

Yes/No/Not applicable/Do not know

Does the drug's labelling or package inserts provide data on the drug's positive and negative experiences, any identified foetal development influencers or abnormalities, other adverse effects?

Yes/No/Not applicable/Do not know

[F] VERISAFE OFF LABEL DRUG USAGE

VeriSafe thinks that as a consumer it is important to know that off-Label usage of drugs is very important in the development of newer, more effective and repurposed drugs.

The need of the hour is to consciously become aware, sensitized and prepared to note or record or report details on this manner of drug usage, where pharmacovigilant care is shown at the healthcare provider or medical practitioner level, the pharmaceutical network level, the local chemist or druggist level and last but not the least the consumer level.

Off-label usage of a drug involves changes in any or all of the following norms recommended in the administration or consumption of a particular drug, that is

- a. Changes in the indication for which the drug is being administered or prescribed
- b. Changes in the route of administration
- c. Changes in the age group or consumer group for which the drug is normally recommended
- d. Changes in the duration of administration or prescription
- e. Changes in the frequency of administration or consumption
- f. Changes in the dosage form
- g. Changes in the identified list of co-medications or list of co-morbid conditions for which the drug does have clinically tested benefits
- h. Changes in the usage or prescription of the drug due to issues like drug lag or unclear availability
- i. Changes in the usage or prescription of the drug due to Fast Track adoption

VeriSafe expects that as social responsibility, all concerned consumers or prescribers, need to be provided details on any pre-clinical trials or track records that assess (a) Tested efficacy of the drug (b) Toxicity levels (c) Mechanism of action (d) Recommended administration dose (d) Recommended administration schedule (e) Evidence of new or repurposed agents in the formulation

Details of any off label drug usage

(**) Have you been administered or prescribed any antibiotics “in an off-label manner”?

Yes/No/Not applicable/Do not know

If “Yes”, can you provide the name of the antibiotic with relevant details of any combined medication as indicated in your prescription or discharge summary?

If “Yes”, did you have clinical or consumer level access to published or current details on any pre-clinical trials or post-trial track records of the antibiotic or drug? Yes/No/Not applicable/Do not know

If the answer to the previous question (**) is “Yes”, did the off label usage cure you satisfactorily? Yes/No/Not applicable/Do not know

If the answer to the previous question (**) is “No”, did you suffer from any side effects?

Yes/No/Not applicable/Do not know

If relevant, did you suffer from any Adverse Drug Events?

Yes/No/Not applicable/Do not know

Have you suffered from any re-occurrence, since any such antibiotic administration?

Yes/No/Not applicable/Do not know

Have you developed any new ailments, since any such antibiotic administration?

Yes/No/Not applicable/Do not know

[G] VERISAFE SOCIAL RESPONSIBILITY

(Read only fields)

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

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

Pre-treatment Nature of ailment (if details known):

Name of antibiotic or antibiotics that was prescribed (details as in the prescription or hospital records):

If on other ailment related medication, previously provided details:

If on other prescription medicines, previously provided details:

(Entry to be made fields)

Current health condition or status: Normal with complete recovery/Well but still to recover completely/Still unwell/Occasionally unwell/Still under treatment/ On other prescription medicines/Do not know

Recommended Plan of Care or further treatment: Clinical tests advised/To follow particular diet, get enough rest and moderate level of exercise/On new or added antibiotics/On new or added prescription medicines/Periodic consultation & check up advised/To self-monitor specific health parameters and report regularly/Do not know

Is there feedback? Yes/No/Not applicable/Do not know

Feedback about antibiotic treatment:

Were there side effects? Yes/No/Not applicable/Do not know

Side effects if any:

Were there adverse drug events? Yes/No/Not applicable/Do not know

Adverse Drug Events, if any:

Are there any other complaints? Yes/No/Not applicable/Do not know

Other complaints, if any:

Are there any issues with the type and quality of product packaging, package inserts, slips, written material, printing of information or labelling, guidelines, clinically tested benefits, safety or tolerable side effects, pharmacovigilance notifications? Yes/No/Not applicable/Do not know

Other complaints, if any: