Combined humanitarian aid drug research and development

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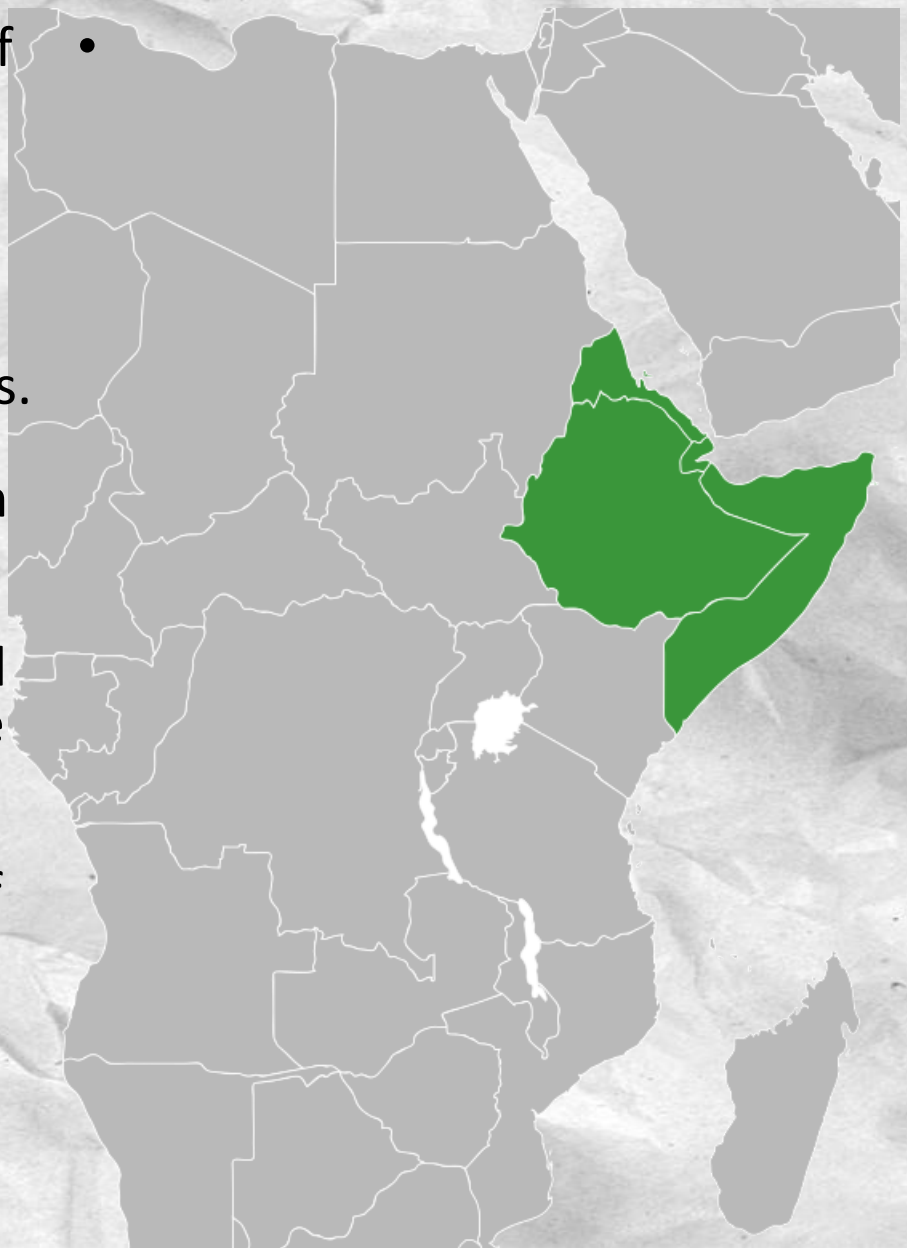
Relevance

East Aftica is one of the poorest regions of the world with massive insufficiency of trained medical personnel and medications. Lack of education amplifies the suffering of millions of people, who have no chance to acquire any kind of medical attention, especially in tribal areas. High risk of incoming large-scale military conflict around GER dam will induce even larger scale of humanitarian disaster and suffering. In such an environment, introduction of mass produced combined chemotherapeutical drug, aimed on ease of access and usage, may significantly affect the amount of human life and quality of life lost in the constant state of humanitarian disaster.



Aim

To develop and propose trials and usage of combined chemotherapeutical drug, aimed on mass usage among uneducated population of East Africa and other third world regions, based on free-of-charge distribution in mass numbers.

Goals

1. Collect and analyze data on the focus region for following info: doctor-to-patient ratio, prevalent diseases, GDP, political situation, any drug resistances of prevalent diseases.
2. Find out the best assortment of cheap and effective medicines against prevalent diseases, which may be taken by non-educated rural population.
3. Uncover any possible positive and adverse reactions, resistances and drug-on-drug interactions and assess their impact on general health of affected population.
4. Determine the best package method, price-per-pill and regimen for affected population.

Methods and materials

Statistical analysis of data listed in “Goals” section.

Analysis of available drugs based on criteria listed in “Choice of drugs” section.

Consultations with specialists of microbiology and pharmacology departments of BSMU.

Analysis of websites providing retail and en-masse price for medications.

Research of articles and textbooks concerning drug-on-drug interactions, effectiveness and adverse effects of picked or discarded medications.

Choice of drugs

Drugs were assessed and picked for the final formula according to following criteria:

- Price-per-pill
- General effectiveness vs. local pathogens
- Effectiveness among different gender and age groups
- Ease of access for testing and production
- Low-to-none drug abuse potential
- Liberal regimen
- Oral intake only
- Prolonged shelf life
- Low risk of AE
- Low negative drug-on-drug interaction risk

Drugs proposed and their retail price

Antifungal agent: Itraconazole (~$0.07 per pill from India, ~$0.33 in Belarus).

Broad spectrum antibiotic: Doxycycline (~$0.1 per pill from India, ~$0.067 in Belarus).

General antiviral drug: Ribavirin (~$0.1 per pill from India, ~$0.03 in Belarus).

Antimalaria drug: Chloroquine (~$0.11 per pill from India, no data on Belarus).

Overal price for retail-purchased combination is ~$0.5 per pill.

Drugs dosage and regimen

Itraconazole - 100 mg

Doxycycline - 50 mg

Ribavirin - 200 mg

Chloroquine - 300 mg

Capsule form, 650 mg + filler

2 times a day, per os.

Drug package and delivery

Humanitarian drug should be packed in pieces with 15 hard tablets for oral intake each, with provided instructions for use leaflet in at least three local languages and comic instructions variant for illiterate population.

It should be distributed in rural populations by international humanitarian aid organisations in large numbers, to prevent their deficit and black market trade.

Drug-on-drug interaction and adverse effects

Drug/drug's #	1	2	3	4
1. Itraconazole		N/A	N/A	**
2. Doxycycline	N/A		*	Potent positive synergy
3. Ribavirin	N/A	*		N/A
4. Chloroquine	**	N/A	N/A	

* - Doxycycline may reduce excretion rate of Ribaverin, which may result in higher serum level.
** - Chloroquine serum level and effect may be increased.

Suspected serious adverse effects of the combination:

Teratogenicity, potential liver damage, diarrhea, allergic reactions, development abnormalities.

Discussion

The listed criteria and AE risks were assessed and, compared with consequences of ongoing humanitarian crisis, were deemed acceptable.

Local population is mostly affected by HIV, TB, fungal infections, parasitic diseases (most of them – malaria), local viral infections, and bacterial wound infections. HIV and TB medications cannot be included because of their price and/or necessity for prolonged therapy, so following diseases were picked: malaria, fungal infections, bacterial wound infection, local viruses.

Discussion (cont.)

Rule “KISS” (Keep It Simple, Stupid), together with the low retail price were considered paramount, because target population (rural tribesmen) with extremely low level of education would not be able to keep strict regimen and dosage for prolonged period of time, so ”one size fits all” approach was enacted.

All age and gender groups were considered capable of receiving the medication, except for children up to 13 years of age and pregnant women.

Discussion (cont.)

Main problem of the formula, except for yet unknown drug-on-drug interactions and allergic risks, is continuously emerging malaria Chloroquine resistance across Sub-Saharan Africa. Unfortunately, even though there are better alternatives such as Artemisinin, the latter was forbidden for monotherapy by WHO, and other alternatives do not meet necessary criteria for inclusion in mass-distributed humanitarian drug.

Results

1. Socio-economic factors of the region and it's population were assessed, dictating the shape of idea and choice of medications.

2. Prevalent diseases of the region were analyzed, leading to the point 3.

3. List of drugs to be included in combined medication was selected, with alternatives considered.

4. Possible adverse effects and drug-on-drug interactions were analyzed and deemed acceptable.

5. Possible price-per-pill and methods of delivery were determined.

Conclusions

Although theoretical material suggests necessity and safety of usage, the next step is considered to be limited animal experimentation with prototype combination of drugs listed, to determine yet hidden factors.

In case of success of animal experimentation, contact should be established with concerned groups of interest, such as local healthcare authorities and international aid organisations.

Thanks for attention!