

The Fight against Bacterial Resistance - New Initiatives but Much Still Needed

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Editorial

Bacterial resistance is a global issue accentuated by growing migration and international travel. Resistant pathogens, which were once considered local phenomena, are now spreading around the globe with astonishing speed. The recent O'Neil report has predicted dire consequences unless we act soon and effectively. The scenario for 2050 is incredibly daunting with significant negative economic and mortality outcomes. The current and future prospects were discussed at a UN Summit in New York City on September 22 with the consensus agreeing that, indeed, this is a global crisis. However, there needs to be a concerted, harmonized effort to tackling the escalating problem. Perhaps projects supported by individual nations, or even continents could be better maximized if there was a singular body driving a coordinated series of programs. There are various agreements in place, supporting initiatives between USA and Europe and USA and Asia, but could we make even more progress if we actually all worked together. As I mentioned earlier bacterial resistance is a global crisis so why not combat it together? Perhaps the International Committee for Harmonization could assume a leadership role as they have done in establishing protocols for specific parameters as QT prolongation (ICH E14) or maybe the World Health Organization could step in to maximize the global resources which are, and could be available?

In addition to the recognized paucity of new antibiotics in development there are several contributing factors towards resistance emergence. These include a poor understanding by patients. There have been three publications in the past twelve months which highlight

this long-standing problem. Unless we better educate the end-user this problem will continue to selection for resistant pathogens. Secondly, there are multiple reports of substandard antibiotics being available in countries where there is uncontrolled access to these essential drugs. There are some antibiotic tablets which contain less than the "advertised" concentration then it is clear that resistance selection is inevitable. Generic versions containing lower concentrations of antibiotics have been reported to cause both resistance development and clinical failures.

The UN Declaration highlighted that inadequate access to quality antibiotics is a major factor in increasing resistance. However, in establishing that such reliable and affordable medications are a problem in many countries. Worryingly introduction of new antibiotics into even industrialized nations, such as Europe, can be limited by economic and reimbursement issues. This inability to prescribe new antibiotics due to formulary absence only continues the use of less active drugs, thus driving resistance further. The clinical trials of new antibiotics are non-inferiority by design by both FDA and EMA, however many reimbursement groups will only approve agents at higher prices if "superiority is shown". Thus, we have a paradox of a need for new antibiotics, but lacking a way to allow prescribing due to lack of formulary presence.

The clear and obvious dangers of antibiotic resistance are increasing, global awareness is growing, but there are several challenges, some of which I have mentioned, but overall there is little encouraging news.