

### Why we need the further improvement of current standards?

Last time, we wrote about the **two most important standards for testing the efficacy of handrubs**; the European CEN **EN 1500** and the American **ASTM E-1174**. Now we summarize the main weaknesses of these standards.



The first issue with the EN 1500 and ASTM E-1174 is the cost. E-1174 needs a minimum of 54 test subjects for the *in vivo* test and another 54 for the positive control. In the case of EN 1500 the results could be intra-individually compared, thus reduce the sample size at the same statistical power [1].

The required hand treatments are 30 seconds for E-1174 and 30 seconds repeated twice in EN 1500. The actual average duration of a hand hygiene event is less than 15 minutes in most studies [1]. It means that almost no data exists regarding the efficacy values under conditions in which they are actually used. To prove non-inferiority in the efficacy is easier, if we examine longer skin contact. For shorter term, bigger sample size would be required [1].

ASTM E-1174 requires 2 log<sub>10</sub> reduction after the 1<sup>st</sup> use and 3 log<sub>10</sub> reduction after the 10<sup>th</sup> use. The 2 log<sub>10</sub> reduction is quite a low requirement that even unmedicated soap and water can fulfil. In health-care settings, strong and immediate effect would be necessary even after the first use [1].

Both EN 1500 and ASTM E-1174 use *Escherichia coli* for artificial had contamination, and E-1174 allows to substitute *E.coli* with *Serratia marcescens*. These organisms are Gram negative bacteria, however Gram positive pathogens, like MRSA and VRE (vancomycin-resistant enterococci) are big threats in hospitals. **Gorony-Bermes 2001** examined the handrub efficacy according to EN 1500 against *Micrococcus luteus*, as a representative of Gram positive bacteria, and compared it to the efficacy against *E.coli*. They did not found significant difference, but drew attention to the fact that the ethanol-based handrub (Desderman in their case) was significantly more effective against *E.coli* than against *M. luteus*, while there were no significant differences in the case of a propanol-based handrub (Desmanol) [2].

Both standard methods use unrealistic high level hand contamination, which necessitates the use of unrealistic volumes of product at excessive contact times [3]. Microbiological sampling also raises questions, we will discuss it later.

#### **New methods:**

ASTM developed new methods in recent years, including **ASTM E-2755** (for bacteria-eliminating effectiveness) and **ASTM E-2784** (for effectiveness of handwash formulations). **Edmonds-Wilson 2015** found that efficacy values are highly depend on the method applied, and efficacy value after the first use was not predictive for the result after the 10<sup>th</sup> use (see *Table 1*).



ASTM method	Mean log <sub>10</sub> reduction after the 1 <sup>st</sup> use	Mean log <sub>10</sub> reduction after the 10 <sup>th</sup> use
E-1174	2.69 ± 0.56	4.35 ± 1.38
E-2755	3.29 ± 0.94	4.06 ± 0.89
E-2784	4.57 ± 1.13	5.06 ± 0.46

*Table 1:* Effectiveness values of the same handrub measured according to different standards.

Source: [Edmonds-Wilson 2015 \[4\]](#)

These new standards were developed to make the hand contamination procedure more realistic [4]. ASTM E-2755 use *Staphylococcus aureus* for hand contamination, which is more representative of a hand transmitted pathogen in healthcare environments. It also applies lower level of artificial contamination [3]. A revised version of EN 1500 was released in 2013, which left untouched the key elements of the protocol despite the rising criticism. It may take several years before a new European Norm working group comes up with an alternative recommendation.

#### Conclusion:

**An ideal efficacy test of handrubs should focus on the condition used in healthcare settings; about 15 second application time, single use, and on germs representing well the typical pathogens in health-care setting. It should be carried out cost-effectively, to facilitate the development of new formulations. Such a new, internationally accepted standard would be a huge step-forward. Until then, keep in mind that different standards result different efficacy values, and try to choose a product that is tested with different test methods.**

#### References

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- 2: Goroncy-Bermes P.: *Hand disinfection according to the European Standard EN 1500 (hygienic handrub): a study with gram-negative and gram-positive test organisms*. International Journal of Hygiene and Environmental Health, 204(2-3):123-6. 2001. DOI: 10.1078/1438-4639-00093
- 3: Arbogast J.W. et al.: *Advancement of the standard in vivo hand rub test methods: a critical comparison of the health care personnel handwash (ASTM E1174) and the hygiene handrub (EN1500)*. BMC Proceedings 5(Suppl 6):P269. 2011. DOI: 10.1186/1753-6561-5-S6-P269
- 4: Edmonds-Wilson S. et al.: *Comparison of 3 in vivo methods for assessment of alcohol-based hand rubs*. American Journal of Infection Control, 43(5):506-9. 2015. DOI: 10.1016/j.ajic.2015.01.025