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Research article

Galenic Hospital Laboratory during COVID-19 emergency - A practical experience in an advanced country

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ABSTRACT

In the actual Covid-19 emergency, as pandemic disease, in many countries at the same time, there was the rapid need to use preventive and therapeutic measures to control the diffusion of infection. In PC Area (Italy North) during the period between March and May 2020, there were observed about 1000 deaths related to Covid-19 (in March 2020 +271% death vs 2019). Between all the measures submitted by a public international institution like WHO, OMS, CDC and many others, the deeply use of disinfectants product became a crucial fact in safety procedure and protocols. The high amount of these disinfectants and antiseptic was needed especially in hospital settings or assimilates structure (named as the Covid-19 hospital) but also for territorial healthcare need. So, it was needed to buy these products from industries but also to start an internal production in Galenic Laboratories. This was because of pharmaceutical industries were not provided, in some cases, the requested amount of these safe life products. In this work, we reported a practical experience in a public hospital, PC area related galenic extra-ordinary production of disinfectants and antiseptics. The result of this local experience can be easily translated to other advanced and developing countries in the world.

INTRODUCTION

In the period observed, starting from February to March, Italy was deeply affected by covid-19 pandemic like other countries in the world. This created a real new complex situation for the hospital organization dues to the need to treat a high amount of patient in a limited time and related to a limited industry production availability. In the same time, many hospitals required a high amount of disinfectants and antiseptics. To prevent the diffusion and spread of coronavirus disease (Covid-19), many measures were proposed by public national and international health organizations like WHO, CDC, OMS, ministry of health and so on. Measures adopted also by the Italian Ministry of Health from lockdown to social distancing, to masks use, to a diagnostic test, medical devices as individual protective dispositive and many other since strictly use of antiseptic and disinfectant for hands and closed environment and related sanitation need).

This severe disease was characterized by high diffusivity and high mortality rate especially in some world region (for example Wuhan, North Italy and other). But not in all countries was seen the same mortality rate: it was related to a different kind of measure adopted (Luisetto and Latyshev, 2020). Between the various public health measures adopted to prevent diffusion of this severe disease one of the most important were the antiseptic and disinfectant policy. Disinfectants are used to treat the environment and antiseptics for patients and healthcare professional. Antiseptics were also used to clean and disinfect hands in public places like train, station, metro, office, and any other situation.

All the measures adopted like mask use, social distance, lockdown, disinfectant use, informatic retracement diagnostics, individual protective products and many others produced a reduction of RT (Contagious Index). The high distribution of the disease in the population required in a short time a lot of amount of all these products and measures. Hospitals and institutions needed to get these

products from the pharmaceutical industry but the high level of requests by many hospitals at the same time created a situation of lack of product. In this situation, there was the need to auto-product the disinfectants in a galenic lab.

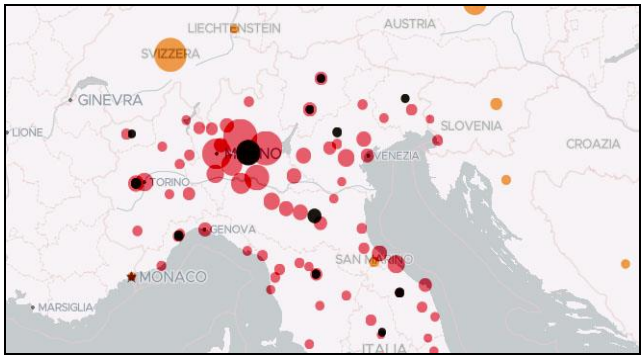


Fig. 1. Diffusion of Covid-9 in Italy during March 2020

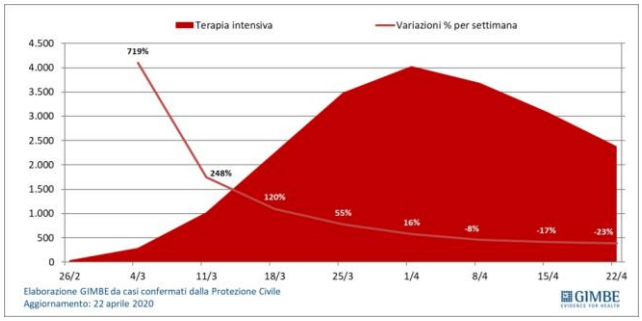


Fig. 2. Confirmed cases of Covid-19 in Italy upto 22 April 2020 (Source: Gimbe)

HYGIENE PRODUCTS FOR SANITIZATION

It is fundamental to know that if alcoholic-grade is expressed in volume of alcohol in 100 volume (V/V) in the weight of alcohol in 100 weight (m/m). The 2 values are not the same when added water to alcohol due by a volume-contraction, in ex. alcohol 62.5% (m/m) (=62.5°), will have an alcoholic grade > if expressed in volume V/V. So, it is crucial in some hygiene products that the alcoholic-grade is clearly expressed in weight or volume. The Ministry of Health Communication regarding alcohol-solution has recommended a concentration of 70 or 75 grades (SIFAP, 2020). The diagnostic availability, ICU beds, right number of the pulmonary ventilator, availability of drugs (including experimental trial), DPI medical devices, disinfectants, and oxygen are required for the management of Covid-19 (Luisetto and Latyshev, 2020). Observing the results obtained in other kinds of scientific or organizational settings (military strategy, Aereo-spatial nuclear settings, insurances and other), it is clear that introducing in day-by-day activity in emergency settings makes possible to achieve the best results. Using a prospective instrument is the real tool to be added to the classic risk-analysis management procedure. The historical data can not be the only one correct to be used. So, it is strictly needed to share translate the real good practice from one discipline (such as insurance settings, industries, Aereo-spatial and other) to another (like emergency settings). The multi-disciplinarity (with the presence of a clinical emergency pharmacist in the medical team), sharing of knowledge, introducing the best-practice, and also if typical of other scientific disciplines produce a good organization whit real useful results. In a real emergency, only one failure in the organization process can produce death of a patient, so, it is crucial to adopt this instrument also whit a prospective-point of view (Luisetto, 2019).

The hospital organization is fundamental to contain the diffusion of the novel coronavirus. In a recent blog post by Santilli (2020) about Sichuan Provincial People's Hospital during covid-19 epidemic stated that six groups were working to manage the pandemic situation in the hospital which include emergency team, prevention and control team, medical emergency team, material security team, publicity and education team and information and updating team. The author of this blog also analysed some managerial and organization hospital aspects that could be crucial to overcoming emergency in this epidemy.

According to Kampf (2018), ethanol is used world-wide in healthcare facilities for hand-rubbing. It has been reported to have a stronger and broader virucidal activity compared with propanols. This report described the spectrum of virucidal activity of ethanol in solution or as commercially available products. This study comprised of the data on the reduction of viral infectivity from suspension tests (49 studies) and contaminated hands (17 studies). Ethanol at 80% was highly effective against all 21 tested; enveloped viruses within 30 s. Murine and adenovirus type 5 was usually inactivated by ethanol between 70-90% in 30 s whereas poliovirus type 1 was often found to be too resistant except for ethanol at 95% (all test viruses of EN 14476). Ethanol at 80% is unlikely to be sufficiently effective against polio-virus, calicivirus (FCV), polyoma-virus, hepatitis A virus (HAV) and foot and mouth disease virus (FMDV). The spectrum of virucidal activity of ethanol at 95% covers the majority of clinically relevant viruses. Additional acids can substantially improve the virucidal activity of ethanol at lower concentrations against, poliovirus, FCV, polyoma-virus and FMDV although selected viruses such as HAV may still be too resistant. The selection of a suitable virucidal hand-rub should be based on the viruses most prevalent in a unit and on the user acceptability of the product under frequent-use conditions.

WHO (2019) has suggested the composition of alcohol-based hand-scrub formulations for local production. The choice of components for the WHO recommended hand-scrub formulations takes into

account cost constraints and microbicidal activity. The following 2 formulations have recommended for local production with a maximum of 50 litres per lot to ensure safety in the production and storage.

Formulation I

To produce final concentrations of 80% ethanol v/v, 1.45% glycerol v/v and 0.125% v/v hydrogen peroxide (H_2O_2), pour 833.3 ml of 96% ethanol v/v, 41.7 ml of 3% H_2O_2, and 14.5 ml of 98% glycerol into a 1000 ml graduated flask. Top up the flask to 1000 ml with distilled water or water that has been boiled and cooled; shake the flask gently to mix the content.

Formulation II

To produce final concentrations of 75% isopropyl alcohol v/v, 1.45% glycerol v/v and 0.125% H_2O_2 v/v, pour 751.5 ml of 99.8% isopropyl alcohol, 41.7 ml of 3% H_2O_2 and 14.5 ml of 98% glycerol into a 1000 mL graduated–flask. Top up the flask to 1000 ml with distilled water or water that has been boiled and cooled; shake the flask gently to mix the content.

Only pharmacopoeial quality reagents should be used (The International Pharmacopoeia) and not technical grade products. The alcohol for the chosen formulation is poured into the large bottle or tank up to the graduated mark to make above formulations. H_2O_2 and glycerol must be added using a measuring cylinder. As the glycerol is very viscous and sticks to the walls of the measuring cylinder, it can be rinsed with some sterile distilled or cold boiled water to be added and then emptied into the bottle tank. The bottle/tank is then topped up to the corresponding mark of the volume (10 litres or 50 litres) to be prepared with the remainder of the distilled or cold, boiled water. The lid or the screw cap is placed on the bottle/tank immediately after mixing to prevent evaporation. The solution is mixed by gently shaking the recipient where appropriate (small quantities) or by using a wooden, plastic or metallic paddle. Electric mixers should not be used unless EX protected because of the danger of explosion. After mixing, the solution is immediately divided into smaller containers (1000, 500 or 100 ml plastic bottles). The bottles should be kept in quarantine for about 72 hours. This allows time for any spores present in the alcohol or the new or re-used bottles to be eliminated by H_2O_2.

Quality control

If concentrated alcohol is obtained from local production, verify the alcohol concentration and make the necessary adjustments in volume to obtain the final recommended concentration. An alcohol-meter can be used to control the alcohol concentration of the final use solution. H_2O_2 concentration can be measured by titrimetry (oxide-reduction reaction by iodine in acidic conditions). A higher level of quality control can be performed using gas chromatography and the titrimetric- method to control the alcohol and the hydrogen peroxide content, respectively. The absence of microbial contamination (including spores) can be checked by filtration, according to the European Pharmacopeia specifications.

Labelling of the bottles

The bottles should be labelled under national-guidelines. Labels should include the information about the name of the institution, date of lab production, batch number and composition (i.e. % of ethanol or isopropanol, glycerol and H_2O_2). Besides, other statements like WHO recommended hand-rub formulation, for external use only, avoid contact with eyes, keep out of reach of children, use (apply a palmful of alcohol-based hand-rub and cover all surfaces of the hands. Rub hands until dry), and flammable (keep away from flame and heat) should also be included in the label.

Alcohol disinfectant effectiveness in the ABHRs depends on the type of alcohol, concentration, the quantity applied on hands and time of exposure. Isopropanol, ethanol, n-propanol, or combinations of these alcohols are most commonly used in hand-rubs. Unlike other antiseptics, these alcohols do not have the potential for acquired bacterial resistance. None of these alcohols is effective against bacterial- spores. When used at the same concentration, ethanol seems to have a lower bactericidal activity than propanols. Ethanol has superior viricidal activity than propanols against non-enveloped viruses. Also, skin tolerance is better with ethanol compared to n-propanol or isopropanol, thus ethanol is often the alcohol of choice in the ABHR preparations.

Ethanol concentrations of 60-95% (v/v) are deemed safe and effective for disinfection by the United States Food and Drug Administration, CDC and the WHO including for use against SARS-CoV-2. The antimicrobial activity of the ABHRs is highly dependent on the choice of formulation (excipient) rather than on the concentration of alcohol. The liquid, gel and foam-based products can all be equally effective if the ethanol content is within the 60–95% standard range. However, increasing ethanolic concentrations of hand rubs from 80-85% (v/v) can reduce the contact time necessary to achieve an efficient bactericidal activity. The WHO, US FDA and CDC still maintain their recommendations of 60-95% ethanol content in ABHRs. An analysis of some currently marketed products reveals indeed that ABHRs, sold in Italian pharmacies as biocides, contain percentages of ethanol between 62-74% (w/w)/ (70-80% v/v). This goes in line with the standard WHO, US FDA and CDC guidelines. It is worth highlighting that ethanol, unlike water, has a density <1 g/cm^3,

which means that percentages of ethanol in water by weight (w/w) and by volume (v/v) can be significantly different and must be specified on the label. A useful comparison between % by weight and by volume of ethanol in ABHRs is also suggested by BDC. Although this concept might seem trivial, there are cases of published works, where the concentration expression (w/w or v/v) was not specified, as indicated by Kampf (2018), ultimately presenting ambiguous information. In compounding and manufacturing, it is recommended to specify the concentration units of alcohol used in ABHRs (Berardi et al., 2020).

The recommendation of 0.1% (1000 ppm) in the context of Covid-19 is a conservative concentration of chlorine-based products that will inactivate the vast majority of other pathogens that may be present in the healthcare setting. However, for blood and body fluids large spills (more than about 10 mL), a concentration of 0.5% (5000 ppm) is recommended. Hypochlorite is rapidly inactivated in the presence of organic material; therefore, regardless of the concentration used, it is important to first clean surfaces thoroughly with soap and water or detergent using mechanical action such as scrubbing or friction. High concentrations of chlorine can lead to corrosion of metal and irritation of skin or mucous- membrane, in addition to potential side-effects related to chlorine smell for vulnerable people such as people with asthma (WHO, 2020a).

As per the WHO (2020b), in healthcare settings, environmental surfaces include the surfaces of furniture and other fixed items (tables, chairs, walls, light switches, computer peripherals and others) as well as the surfaces of non-critical medical equipment (equipment that only comes into contact with intact skin, such as blood pressure cuffs, wheel-chairs, incubators). These surfaces should be frequently cleaned with water and detergent and followed by the application of disinfectants. Among the most common disinfectants used which have been demonstrated to be effective against SARS-CoV-2 are ethanol 70-90% and chlorine-based products (hypochlorite) at 0.1% (1000 ppm) for general environmental disinfection or 0.5% (5000 ppm) for blood and body fluids large spills; or hydrogen peroxide >0.5-6%. The minimal time recommended of exposition to the surface for these disinfectants is 1 minute or according to the manufacturer instructions. In non-healthcare settings, environmental surfaces include furniture and other fixed items, such as countertops, stairway rails, as well as floors and walls. Disinfectants should be applied to high- touch surfaces to reduce potential SARS-CoV-2 contamination in community settings where the risk of contamination is unknown (gyms, offices, restaurants, accommodation sector and other) as well as in households and non-traditional facilities where individuals with suspected or confirmed COVID-19 disease are accommodated.

The WHO ethanol-based hand-rub (EBHR) formulation contains 1.45% glycerol as an emollient to protect healthcare workers (HCWs) skin against dryness and dermatitis. However, glycerol seems to negatively affect the antimicrobial efficacy power of alcohols. The minimal concentration of glycerol required protecting hands remains unknown. In a tropical climate setting, the WHO-modified EBH-R formulation containing 0.5% glycerol led to better ratings of skin tolerance than the original formulation, and, may offer the best balance between skin tolerance and antimicrobial efficacy (Menegueti et al., 2019).

PRACTICAL EXPERIENCE OF PRESENT STUDY

The place of observation was PC area having about 700 beds, 6 hospitals (presidium) (but also territorial need). The time of observation was from 1 March to 15 May 2020. The manpower involved in Galenic Lab is including two hospital pharmacist managers and one pharmacist. The observation was done under the director of the hospital pharmacy and responsible of Galenic non-sterile lab.

The need for disinfectants and antiseptics for this hospital was verified by hospital pharmacist director, medical devices responsible and another manager also from health central office of the hospital. The formulation adopted was the WHO formula and approved by infectious disease physicians' director (also under the responsibility of the pharmacist manager of lab and director chief pharmacist of the hospital).

Procedure

The procedure was adopted as use in Galenic Lab, and according to FU XII ED, EP and other normative rules. The product was produced according to the WHO formula and other industrial products as per following details.

Hand disinfectant alcoholic gel composition	
Ethanol 96%	623 mL
Hydroxyethyl cellulose	10 g
Depurated water	q.b. 1000 mL
Hand alcoholic disinfectant composition	
Ethanol 96%	833.3 mL
Hydrogen peroxide 3%	41.7 mL
Glycerol 98%	14.5 mL
Depurated water	q.b. 1000 mL
Alcohol 70-75 grades solution composition	
Alcohol 96%	733 mL
Depurated water	q.b. 1000 mL
Amuchina hand solution composition	
From industrial products	Bottle of 500 mL

Raw materials

Ethanol (94-99%), glycerol (98% FU), hydrogen peroxide (3%), depurated water, hydroxyethyl

cellulose, containers, bottles, dispenser and other closing system were used to prepare the sanitizers and disinfectants. In addition, calibrated lab glassware to measure accurate volume, beaker, bottleneck and other necessities were also used. Single used mask, sterile gloves, caps, lab coats and protective glasses were used as usual.

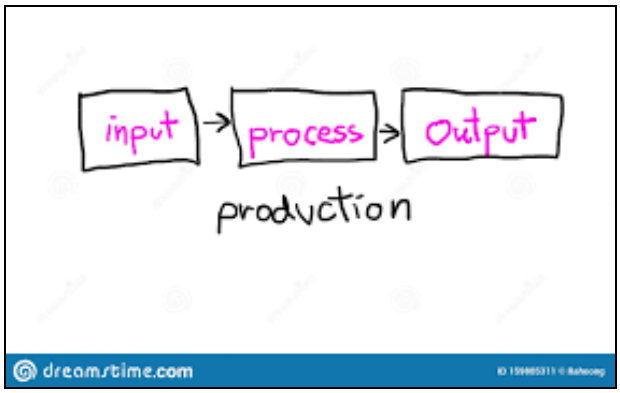
The amount was produced according to the daily working schedule signed in the lab. The medium week production was approximately 600 flac. da 500 mL of hand disinfectant (periods emergency COVID-19) and 600 x 500 mL = 300000 mL for a week. The alcoholic gel was prepared 400 flac. for a week and amuchina x-germ 200 flac per week. The packaging of the bottles is shown in Fig. 3 and 4.

Fig. 3. Bottles of disinfectants produced in hospital

Fig. 4. Production of disinfectant in hospital

Management of production system

The rapid supply chain systems of raw material and bottles from producers, verify of real availability from different providers, costs analysis, benchmark, emergency need, clinical need viz. high need of disinfection procedures dues to severe pandemic level and high amount of production to cover hospital and territorial need are the key points for successful management of production system. The process of the production can be shown as per Fig. 5



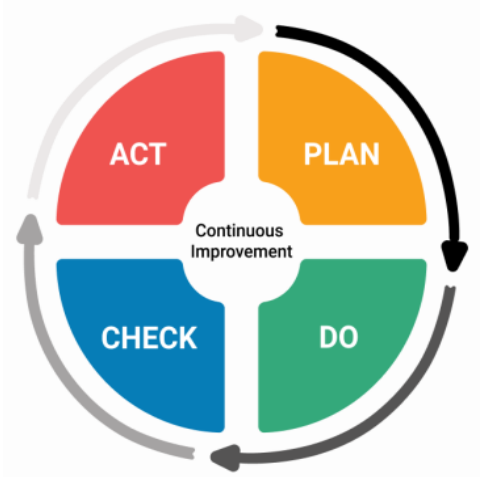


Fig. 5. Images based on production of sanitizers

Ordering procedure

A buying office was established inside the hospital, after encoding and cost evaluation. The effective availability was verified from different providers in order to be sure of the supply of the products. The record has been maintained in the office (Fig. 6).

Fig. 6. Buying and record office

Practical procedure

Due to the high amount of raw material was needed, a special system to bring this high amount of raw material into the Galenic Lab was established. Before start, it was needed to put on gloves, protections DPI, and others according to safety rules to protect pharmacists but also the product from any kind of contamination, according to the pharmacopoeia in use. Right labelling according to safety international rules (CLP REGOL.), name of the galenic product and added risk logo (hazard) and prudence phrases were included in the label. An advice of usage, date of expiry, name of the pharmacy, the label of shake before use, general conservation suggestions like not near the heat source and pay attention to product based on alcohol as are easily flammable.

Expiration data

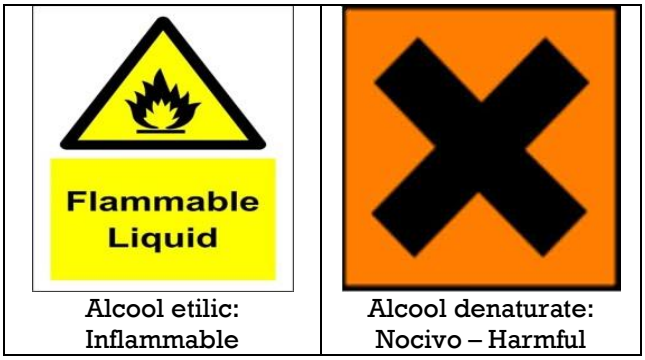
The expiry date was 2 months for hand alcoholic gel and 3 months for ethanol 75%. In the end, the pharmacist writes a working document and then after the control signs this. Then an evaluation of global costs was performed based on raw material, bottles, and any other products used in order to have a cost by 1 bottle of 500 mL to be compared with industries products. To obtain the right price was used the official formulary of the pharmacist in Italy with the cost for kind of products. The expiration of other data was 60–90 days according to the kind of galenic product.

Risk analysis

All pharmacists were correctly trained to all kind of procedure used, according to the preventing risk rules and quality management policy by the chief of the laboratory. The packaging comprised of the sign of both chemical and biological risks as per the symbols given in Fig. 7.

Quality control

After all daily production, batches were performed quality control according to pharmacopoeia need. This step included correct procedure, general aspect, verify of the closing system, a number of preparations by single lot, labelling correct, the sign of the pharmacist on the scheme of preparation and on the label.



Alcool etilic: Inflammable

Alcool denaturate: Nocivo – Harmful

Fig. 7. Chemical and biological risks symbols

Economic evaluation

From industry

The cost of alcohol 70% was about 1,2 euro for 1 litre and 0,6 euro for 500 mL whereas, at central buying centre, the cost was 3,5 euro per 500 mL in commerce out of the hospital. The cost of amuchin gel hand was 1,5 euro for 80 mL and 2,3 euros for 500 mL. The cost of septaman gel hand 100 mL was 0,72 euro and 500 mL was 3,6 euros whereas, in commerce, 500 mL cost was about 6 euros.

From our production

Alcol ethylic 75% flac 500 mL costs 2,5 euro (raw material not easily available form commerce), cost of alcoholic hand gel flac 500 mL was 5,23 euro, cost of alcoholic hand solution flac 500 mL was 7,43 euro whereas the cost of amuchine gel hand product was determined from dividing procedure (of tanks 5 litres).

Registration of production data

All disinfectants manufactured in Galenic lab were registered in an official way for pharmacopoeia need, normative rules, quality procedure and to make possible also recall if needed. In the period observed, no ADR adverse event reaction related to galenic lab disinfectants produced was registered in an official way including skin reaction or other adverse reactions. There was no need for a recall of any product as no toxic issues involved with the same.

Distribution of product

All products prepared in the Galenic Lab as disinfectants were distributed to the inside hospital (covid ward or other) or outside the hospital for territorial health use.

DISCUSSION

In the WHO recommended hand-rub formulations, the efficacy is the consensus opinion of the WHO expert group that the WHO recommended hand-rub formulations can be used both for hygienic hand antisepsis and for pre-surgical hand preparation. The production and storage of the hand-rub are depended on the formula used, pharmacopoeia and other rules. With regards to skin reactions, hand-rubbing with alcohol-based products is better tolerated than handwashing with soap and water. In a recent study conducted among ICU HWs, the short-term skin tolerability and acceptability higher than those of a reference product.

The covid-19 mortality rate in PC hospital was zero in 10 may, and a high mortality rate due by a coronavirus in PC area was registered in the period from March to May (like in another city like Lodi, Cremona, Brescia, Parma, Alessandria). The cumulative mortality in Piacenza was 258,5 deaths per 100000 people living in the area. The covid-19 emergency showed clearly the need in the pandemic situation of Galenic Hospital Laboratory with high productivity to guarantee the high amount in little time to control the diffusion of disease. All this show that corrected measure was introduced and also in the field of disinfectants used.

The global safety of galenic products comes from pharmacopoeia rules and all normative of lab galenic added to the formulary adopted as per WHO formula. So we can assume equal safety of industrial products for the same pathology need. A good management system of the laboratory makes it possible to do it. Related the costs of this production it is needed to explaining that in this period the global amount of disinfectant by industry was reduced using galenic production. The high amount of raw material not used for the acute time of pandemic can be used next. The total cost takes into consideration: time of pharmacist, raw material, bottle costs, and fixed cost of the laboratory. In the observed period was reduced the amount of product form industry and stokes of raw material will be used in the next 6 months to 1 year.

CONCLUSION

As observed, mortality was highly reduced after 2-3 months after the COVID-19 start in PC area, this means that a complexive number of deaths of about 900-1000 death become about zero in the first day of March. This means that all measure introduced where correct, and also the disinfectants and antiseptic policy adopted of the industrial origin or by internal hospital galenic laboratory production. The results of the literature review added to the result of our practical experience show that the hospital Galenic laboratory played a crucial role in emergencies like the covid-19 pandemic.

In this situation, it has been seen in March 2020 pharmaceutical industry was not able to produce the right amount of disinfectants and antiseptic for the need of some hospital in the red zone. In this situation, the high performance of hospital pharmacy organization makes possible an efficacy response and to achieve great clinical outcomes. Disinfectants are products that make possible to control infectious disease in the hospital setting and other assimilated structure, protect healthcare professionals and patients in the same way.

Hand washing and antiseptic procedure, disinfection of surfaces medical devices and other instrument were into the main preventive and contro-measure. High production added to the limited time of response was the keyword. The same it was relevant also the buying procedure to buy in a few days all raw material to produce this. In the period March 2020 was also needed to produce disinfectants not only for internal hospital but also to the territorial need based on physicians ambulatory of all province.

As the conclusion of this work, it is possible to say that hospital galenic laboratory and the managerial abilities of hospital pharmacist contribute in a high way to the global result. This experience was obtained in advanced countries but it can be exported also in another situation to cover the need for disinfectants and antiseptic. What is relevant is that an approach like what, if analysis in a prospective way can help in disaster emergency like pandemic situation. The internal galenic lab production was a winning strategy in this emergency event and contributes to the global result. The ability to adapt to a new situation is a great instrument to be used as a common way of work.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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