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G-VIR® GLOVE

HEALTH TECHNOLOGY ASSESSMENT SECTION

MEDICAL DEVELOPMENT DIVISION

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EXECUTIVE SUMMARY

Health care workers are at increased risk of infection by blood-transmitted viruses, in particular human immunodeficiency (HIV) and hepatitis-causing viruses. Needle stick injuries reported in Ministry of Health Malaysia personnel for the year 2008 was 653 cases. 35% of the cases involved medical officers, 20% were seen in nurses and 12% were noted in assistant nurse or midwifes.

It is now standard practice for health care workers in medicine, dentistry, and blood banking to wear surgical gloves as a protective measure when dealing with contaminated fluids. A recent Cochrane Systematic Review has demonstrated that the addition of a second pair of surgical gloves significantly reduces perforations to innermost gloves.

G-VIR® is a surgical glove that is composed of three layers: 2 mechanical layers (inner and outer layers) and a middle layer containing microdroplets of disinfectant solution (chlorexidine digluconate and dimethyl didecyl ammonium chloride salts). Puncturing this glove then releases the agent, which can then help sterilize the puncture site or inhibit microbial growth at the puncture site. G-VIR® is both a latex free and powder free glove.

G-VIR® is classified as a class IIa medical device according to European Directive 93/42/CEE and has also been registered to be used as in China, Korea and Russia.

There was poor level of evidence that demonstrates that G-VIR ® gloves are safe and offer mechanical protection (glove barrier) especially in the surgical setting. There were no randomised controlled trials to demonstrate clinical tolerance and effectiveness of this device.

As for cost implications, this technology is reported to be more expensive than the current practice in high risk surgeries using double gloves.

This technology is not recommended until more clinical research is obtained.

MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA

TITLE: G-VIR ® GLOVE

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1. INTRODUCTION

Health care workers are at increased risk of infection by blood-transmitted agents, in particular, human immunodeficiency (HIV) and hepatitis-causing viruses. Virus infection can occur by contact with an infected body-fluid, where the person handling the sample has an area of broken skin, usually on the hands. Infection can also occur when a person receives a needle prick injury by a contaminated needle or other sharp instrument.[1]

The operating-room setting presents the greatest risk where these needle stick injuries occur in many countries.[2] Surgeons in training have the greatest risk of exposure to blood-borne pathogens, given their numerous encounters involving the use of sharp instruments on patients and the increased propensity for injury while learning new technical skill sets.[3]

653 cases of needle stick injuries were reported by the Ministry of Health Malaysia personnel for the year 2008. 35% of the cases involved medical officers, 20% were seen in nurses and 12% were noted in assistant nurse or midwifes.[4]

Because of the often severe consequences of accidental infection by an infectious agent it is now standard practice for health care workers in medicine, dentistry, and blood banking to wear surgical gloves as a protective measure.[5] Gloving practice varies between different countries and different surgical specialties. In the UK, Europe and the USA single gloving appears to be standard practice in all specialties except for orthopaedics and maxillofacial surgery where double gloving is employed.

Following the publication of the original Cochrane review of Tanner 2002, a number of professional organizations have issued guidelines or statements supporting or incorporating the Cochrane recommendations for practice. These include the Royal College of Surgeons of England, The National Association of Theatre Nurses, The Association of Perioperative Nurses and the Australian College of Operating Room Nurses. [6]

Double gloving has been recommended because it reduces the risk of glove barrier (GB) breaches when compared to single gloving. [7, 8] In a recent update of a Cochrane Systematic review it was demonstrated that the addition of a second pair of surgical gloves significantly reduces perforations to innermost gloves (OR 4.10, 95% CI 3.30 to 5.09).[6] The Association of periOperative Nurses (AORN's) Recommended Practices Task Force in 2007, revised the "Recommended practices on prevention of transmissible infections in the perioperative practice setting" to recommend that health care practitioners double-glove during invasive procedures. [9]

A variety of protective glove devices to prevent or reduce the risk of accidental blood transfer by puncturing have been designed. These include glove liners and cloth outer gloves [10.11] puncture-proof glove, latex inner with steel weave outer glove.[12]

A new surgical glove has been developed that has chambers within the glove's interior that will hold anti-microbial agents in solution form. Puncturing this glove then releases the agent, which can then help sterilize the puncture site or inhibit microbial growth at the puncture site. One such glove that has been innovated is G-VIR®.

The Director of the Medical Development Division has requested the Health Technology Assessment Section to carry out a technology review on **G-VIR ® glove**.

2. OBJECTIVE

To assess the safety, effectiveness and cost effectiveness of G-VIR ® glove.

3. TECHNICAL FEATURES

G-VIR® is a surgical glove made from thermoplastic elastomer. It is made of synthetic rubber (non latex) which has very good elasticity and good mechanical proprieties. The G-VIR® glove is composed of three layers: 2 mechanical layers (inner and outer layers) and a middle layer containing microdroplets of disinfectant solution. These microdroplets are very close to each other and are separated by fine elastomer walls. The resulting thickness is 500µm, equivalent to double gloving. [13]

There is between 5 and 8 ml of disinfectant liquid per glove depending on the size of the glove (approximately 8 ml for 8 ½ glove). The disinfectant solution used is a blend of chlorexidine digluconate and dimethyl didecyl ammonium chloride salts, which are known to be active against enveloped viruses. The disinfecting liquid cannot escape from the glove when the glove is intact. However, when there is perforation, only the disinfecting liquid located at the breakage site is expelled. The rest of the liquid remains inside the elastomer, as each droplet is separated by a fine elastomer wall. [13]

G-VIR® is a powder free glove. These gloves are sterilized using gamma rays and conforms with ISO 1137 and EN 552 standards. The shelf lives of these gloves are 24 months from the date of manufacture. This glove is recommend being stored in a dry and ventilated in a place where the temperature does not exceed 30 C.

The following are contra- indications in using G-VIR® gloves:

- Known sensitivity to quaternary ammoniums or chlorhexidine digluconate
- Use of chemicals (e.g. solvents) which are compatible with the material that make up the glove.
- The practice of certain medical act that requires high tactile sensitivity

4. SEARCH METHODOLOGY

4.1 Searching

Literature search was conducted using the following electronic databases: HTA sites like INAHTA, ANZHSN, EUROScan, ARSENIPS; EBM reviews; Cochrane Database of Systematic Reviews; Cochrane Database of Clinical Trial Register; Medline (1966- 25th October 2008), Current Contents, Cochrane Controlled Trials Registry and general databases like Google and Yahoo. The manufactures website was also searched for further information.

These databases were searched using the below search terms: glove; 'surgical glove; 'virus inhibiting'; 'HIV/HCV; protection; surgical glove; blood exposure accident; blood-borne viruses; blood exposure accidents; needle puncture; viral contamination. There was no limitation in the search.

4.2 Selection

All published articles related to safety, effectiveness and cost effectiveness of G-VIR® were included. Critical appraisal of relevant literature was performed and evidence was graded according to US/ Canadian Preventive Task Force (Appendix 1).

5. RESULTS AND DISCUSSION

5.1 SAFETY

G-VIR® is classified as a class IIa medical device according to European Directive 93/42/CEE, which falls under the category of standard surgical gloves. G-VIR® gloves are also licensed by the State Food and Drug Administration (SFDA) in China, Korean Food and Drug Administration (KFDA) and have received GOST certification in Russia.

The G-VIR® glove has been launched first in France in June 2004. Today G-VIR® glove is sold in around 200 French private and public hospitals and in more than 20 countries for e.g. Belgium, Brazil, China, Colombia, Egypt, Germany, Italy, Iran, Kuwait, Portugal, Qatar, Russia, South Korea, Spain, Turkey and Venezuela.

There was only one clinical trial with no controls looking into the clinical tolerance and ergonomics of G-VIR®. 100 surgical procedures were performed by six surgeons wearing G-VIR® on 100 patients. Procedures performed were on laparoscopic surgery (n = 28) and open surgery (n = 72). In the case of open surgery the cases were further subdivided either into superficial (n = 33) and deep (n = 39) or into hernia (n = 32) and non hernia (n = 40). There was no allergy or skin tolerance observed using G-VIR® on patients and/or surgeons during the six month study period. [14, Level 11-3]

In this same study, it was reported that integrity feeling and mechanical resistance was higher with G-VIR® compared to standard double latex glove ($p < 0.05$). As for tactile sensitivity, elasticity, movement fluidity, shape, hand fitting, gripping quality and surgeon hand sweating it was noted to be comparable with double latex glove. However, donning was reported to be more difficult using G-VIR® ($p < 0.05$). [14, Level 11-3]

5.2 EFFECTIVENESS

There have been two experimental studies looking at the efficacy of G-VIR®. In the first study, has been carried out both in vitro and in vivo. In this study a contaminated needle with various surrogate viruses like Herpes Simplex Virus 1, Bovine Viral Diarrhea Virus and Feline Immune-Deficiency Virus was passed through a glove. In the vivo component of this study, mice and cats were stuck with a contaminated needle through a glove. [15,Level III]

The in vitro data showed an approximately 15-fold or greater reduction in infection when using the G-VIR gloves compared with nonvirucidal gloves of the same thickness while the in vivo data showed 53% to 64% reduced infection in the animals. [15,Level III]

In more recent in vitro study comparing G-VIR® with blank gloves and standard latex gloves it was demonstrated that single glove reduced the volume of blood transferred by 52% to $0.12 \pm 0.03\mu L$ ($p<0.001$) compared with no glove. However double gloving offered no additional protection $0.12 \pm 0.03\mu L$ ($p=0.93$) against hollow-bore needle punctures. This study concluded that mechanical wiping is maximized with a single glove. [16, Level III]

This study went on to show that G-VIR® compared to the controls, the study showed that there was an 81% reduction in the amount of Herpes Simplex Virus 1 transmitted from 122 ±23pfu for single latex gloves and 121± 27pfu for blank (double latex gloves) to 19±6pfu($p<0.001$) which has been attributed to the virucidal disinfecting agent. [16, Level III]

Out of 834 G-VIR® gloves, 15 breaches were identified in the first clinical trial of 100 elective surgical procedures. The breaches were detected using the water leak test (WLT). These breaches were located on the finger (n=10), the palm (n=4) and the dorsal surface of the hand (n=1). Breaches were frequent on the non dominant hand (n=9). Of the 15 breaches, six were identified by the surgeon and 9 went unperceived. [14, Level 11-3]

According to breach rate per operator-hour (BRpOH), deep hernia (36.4%) was significantly higher than in superficial hernia (8.51%) ($z=2.80$; $p<0.05$). The remaining procedures (non-hernia and hernia superficial) formed the category of middle risk (BRpOH=4.28%) which is significantly distinct from the other two groups ($z=1.95$ and $z=5.10$, $p<0.05$). [14, Level 11-3]

5.3 COST IMPLICATIONS

It has been reported that the cost of production of G-VIR ® is higher than the cost of manufacturing single gloves. It has been estimated that double gloving in a French public hospital costs approximately 5 times less than G-VIR ®. [14, Level 11-3]

6. CONCLUSION

There is poor evidence that demonstrates that G-VIR ® gloves are safe and offer mechanical protection (glove barrier) especially in the surgical setting. There was no randomised controlled trials to demonstrate clinical tolerance and effectiveness of this device.

As for cost implications, this technology has been reported to be more expensive than the current practice in high risk surgeries to use double gloving.

7. RECOMMENDATION

This technology is not recommended until more clinical research is obtained.

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