Policy brief: draft for consultation

How to expand access to affordable hand hygiene products to prevent health care-associated infection and reduce the spread of antimicrobial resistance
Intended audience:

This policy brief is aimed at decision-makers responsible for the procurement of medicines and other health care materials considered essential for basic health care system functioning, namely ministries of health and ministries of finance.

Key messages:

“Hand hygiene is as effective as vaccines, even more than some vaccines”
Minister of Health, Libya (2016)

- Too many of the most vulnerable people in low- and middle-income countries (LMICs) develop a health care-associated infection (HAI) resulting in harm and sometimes even death. This could be prevented through simple, low-cost infection prevention and control (IPC) interventions, such as hand hygiene, performed at critical moments.
- Defects in IPC at the health facility level, particularly compliance with hand hygiene practice, increase the risk of outbreaks of highly transmissible diseases that can spread across borders. Poor IPC also contributes to the impact of antimicrobial resistance.
- Targeted use of low-cost alcohol-based handrub (ABHR) in health care has been a WHO guideline recommendation since 2009 and was reinforced in 2015 when ABHR was included in the WHO List of Essential Medicines.
- Since 2009 WHO has made available a formula and implementation guide to facilitate the local production of ABHR in any health facility, anywhere in the world.
- ABHR is a life-saving technology that can be manufactured locally in each country of the world and directly impacts patient outcome – it protects the vulnerable, stops outbreaks and prevents the spread of antimicrobial resistance (AMR).

Effective, timely hand hygiene is a central pillar of the international health regulations (IHR)

The scale of the problem and the role of hand hygiene

HAIs are a global problem that both contribute to and directly result in significant morbidity and mortality. The prevalence of HAI in high-income countries (HICs) is estimated to vary between 3.5% and 12%. However, in low and middle-income countries (LMICs) on average the prevalence is 15% according to most reliable data but can be up to 20%\(^1\). The increased burden of HAI in LMICs especially affects high-risk populations, such as patients admitted to intensive care units (ICUs) and neonates, with HAI frequency several-fold higher than in HICs, particularly for device-associated infections. The proportion of patients with an ICU-

\(^1\) WHO (2011) Report on the burden of endemic health care-associated infection worldwide
acquired infection, for example, can be as high as 1 in 3 in LMICs, with a general incidence of HAI of up to almost 90%.

**One in five patients in some LMICs develop a HAI**

At the global level, poor IPC can fuel outbreaks of highly transmissible infection and contribute to global epidemics and pandemic. Poor hand hygiene compliance is considered to be a critical example of defective IPC, compounded by weak infrastructures and the lack of access to affordable products that enable effective hand hygiene (i.e. water, soap and ABHR), putting patients, health workers and the wider population at risk of harm.

At the national level, defective IPC impacts a country’s ability to meet the International Health Regulations, contain the spread of AMR and ultimately adversely impacts on quality of care - an important consideration in the quest for quality universal health coverage (UHC). A recent situational analysis found that relatively few countries across all Member States reported having an IPC programme at the national level. At the health facility level, poor IPC places individual patients, their families and health workers at risk of harm and death, affecting community confidence in the health care available.

HAIs also have a significant economic impact at the patient and population level including the opportunity cost to health services due to increased length of hospital stay, unnecessary investigations and treatments and additional time to perform care and treatment. Private costs to patients and informal carers relate to out-of-pocket expenditure and other consequences (death, pain and discomfort). Societal costs incurred include lost productivity due to morbidity and mortality.

The action of hand hygiene by health workers is a health care intervention aimed at preventing HAI, and one that WHO is taking very seriously, namely through the WHO Clean Care is Safer Care programme launched in 2005. There is growing evidence that low-cost technologies that facilitate hand hygiene, such as ABHRs, play a crucial role in improving compliance with hand hygiene, reducing the likelihood of HAI and thus saving millions of lives. However, ensuring targeted and timely compliance with hand hygiene guidelines is a universal and complex challenge and remains sub-optimal in most health facilities. In many LMICs compliance is dangerously low, compounded by a lack of access to the right infrastructure and resources. ABHRs however, enable hand hygiene to occur even in situations of gross infrastructural constraints associated with lack of access to soap and running water.

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35% of health care facilities in LMICs do not have water and soap for hand washing\textsuperscript{11}

There is a strong economic case for investing in hand hygiene improvement by simply making ABHR more widely available, with some estimates suggesting that even a reduction of just 0.1% in the rates of HAI, through the implementation of ABHR at the point of care, is highly likely to generate cost savings over a five year period\textsuperscript{12, 13}.

Policy challenges

Despite some achievements in recent years it is clear that the proven interventions have not yet been fully implemented across all countries and that access to and use of ABHR across many LMICs remains very low. At the policy level, a focus on the selection, procurement, regulation and management of ABHR within national health plans, and the specific inclusion of ABHR within the basic package of essential health services is not that widespread.

At the health care facility level, access to commercially-available products is limited in LMICs. A survey conducted by WHO in 2011 reported on the volume sales of ABHR by a number of global commercial companies across the African Region\textsuperscript{14}. This survey found that 56,220 litres of ABHR has been sold in that year in the health care sector.

The total litre sales to the health care sector would fill only one fiftieth or 2\% of an Olympic-sized swimming pool.

Barriers to availability of commercial products are a result of a combination of issues relating to affordability, product import and licensing barriers, transportation and distribution.

What is WHO doing?

WHO has made efforts to promote and support the use of life-saving ABHR in LMICs by developing a simple formula that enables an affordable and achievable local production within hospital pharmacy departments. This is part of an overall multimodal hand hygiene improvement strategy. An increasing number of hospitals across the WHO African Region are now successfully undertaking local production using the WHO Formula\textsuperscript{15, 16, 17}. This formula is now also on the WHO List of Essential Medicines. A recent cost analysis from

\begin{itemize}
\item \textsuperscript{14} WHO (2013) WHO Private Organisations for Patient Safety (POPS) - Availability of Alcohol Based Handrub with the Aim of Improving Hand Hygiene and Patient Safety on a Global Scale. Unpublished.
\item \textsuperscript{17} Budd A, Lukas S, Hogan U, Piscicile K, Fanny K, Hill P, Edouard N, Byikukenge JB, Placide N, Aimable M, Rex Wong R (2016) A Case Study and the Lessons Learned from In-House Alcohol Based Hand Sanitizer Production in a District Hospital in Rwanda. Journal of Service Science and Management, 2016, 9, 150-159
\end{itemize}
Rwanda demonstrated a 71% financial saving when an in-house hand sanitizer was produced, rather than a commercially-available sanitizer being bought. Additionally, since 2012 WHO has facilitated an initiative called Private Organizations for Patient Safety (POPS), which aims to engage private industry companies, with a focus on corporate social responsibility in order to harness industry strengths to align and improve implementation of WHO recommendations in different parts of the world, including in least developed countries. The goal of the collaboration is to benefit patients, and not the participants in the platform. A number of projects have ensued in these years supporting increased access to products, education and awareness raising in the long-term.

Key policy points:

- ABHR is a health care technology that is considered the “gold standard” for hand hygiene and contributes to the reduction of HAI.
- ABHR is listed as critical at the facility level to strengthen preparedness efforts to mitigate future outbreaks of highly transmissible diseases.
- It is an affordable health care product listed on the WHO Essential Medicines List 2015 (average production cost per 100ml in LMICs is approximately US$ 0.40).
- It can be accessed and used rapidly and overcomes the infrastructural constraints to achieving timely hand hygiene, such as lack of access to running water and soap. It therefore offers an immediate, short-term solution to the problem of HAI and AMR prevention and enables limited water supplies to be used for sanitation and other general hygiene purposes.
- In settings benefiting from economies of scale, the cost of hand sanitizer has been estimated to be a few dollars per person per year for daily use - comparable to the per-person estimated annual cost of hand washing with soap in LMICs.
- A study conducted in a Russian neonatal ICU estimated that the excess cost of one health care associated blood stream infection (BSI) (US$ 1100) would cover 3265 patient-days of hand sanitizer use (US$ 0.34 per patient-day) and its use would be cost saving if it prevented only 3.5 BSIs per year.
- A Centers for Disease Control and Prevention (CDC), USA report, found that the overall annual direct medical costs of HAI to U.S. hospitals ranges from $28.4 to $33.8 billion and $35.7 billion to $45 billion. Adjusting for the range of effectiveness of possible infection control interventions, the described benefits ranged from a low of $5.7 to $6.8 billion to a high of $25.0 to $31.5 billion.
- Effective implementation at the facility level requires national political commitment to address the barriers outlined in this brief, but, in addition: some initial investment in the necessary hardware to manufacture the ABHR, including alcometers; training of a team of pharmacists in the local production according to the WHO Formulation and purchase of the raw materials (ethanol/i-propanol, glycerol, hydrogen peroxide), to ensure acceptability and sustainability of the intervention.

The work to promote ABHR over the last decade has resulted in improvements in some, but not all, of the world’s health care systems and where used there is a demonstrable impact on HAI. However, there remains a global inequity in availability, access and affordability of this basic product to support hand hygiene, when it is most needed to save lives and prevent...
harm, most starkly demonstrated by the recent outbreak of Ebola virus disease in West Africa.

Lack of access to and use of ABHR directly contributes to the global antimicrobial resistance (AMR) problem\(^{22}\), hampers the move to quality universal health coverage, where access to essential medicines and health technologies with the potential to save lives and improve quality of life, is a prerequisite. It also prevents the full attainment of health security according to the IHR\(^ {23}\), where an established and functioning IPC programme at the national and hospital level forms the basis of core capacity development.

**Policy options**

The control and prevention of HAI is dependent on timely hand hygiene by health workers which is itself dependent on them having increased access to ABHR. As an example, great efforts were made to increase access to ABHR during the Ebola virus disease outbreak response, particularly in Liberia where support was given for successful local production exercise. This supported the WHO Guideline on hand hygiene in health care in the context of Filovirus disease outbreak response\(^ {24}\) recommendations which highlighted the high quality evidence for the effectiveness of ABHR and the need to prepare implementation strategies to move from use of chlorine/bleach. This policy brief outlines policy options for governments to increase access to this technology across all government health care facilities, to strengthen IPC and IHR core capacity, prevent the spread of AMR, prevent outbreaks of highly transmissible diseases and contribute to the attainment of quality UHC. The policy options presented here could be adopted independently or complementary to each other to increase access to ABHR, compliance with hand hygiene practices and reduction in HAI, saving hundreds of thousands of lives and millions of US dollars annually.

NOTE: the options presented below are generic and are intended to provide a guide for country-level teams. Country teams may decide to develop their own policy brief which reflects local context, and addresses local constraints.

1. **Option 1: Building capacity at the facility level to enable local production of ABHR according to the WHO formulation to facilitate increased access and coverage across all public health facilities.**

This would require financial investment to bring ABHR into each public hospital at the point of patient care, such that they are available and accessible when needed, making health care safer and of higher quality in the short- and long-term. The purchase of equipment and raw materials together with the training of pharmacists would form the basis of the initial investment. This option will also require well planned and staged implementation, targeting a number of larger health facilities in the first instance to become production “hubs” with the option of distributing to more rural facilities.

- The evidence suggests an excellent return on investment, deeming ABHR an affordable health care product and this is reinforced via its inclusion within WHO’s

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\(^{23}\) IHR core capacity monitoring framework: Checklist and Indicators for Monitoring Progress in the Development of IHR Core Capacities in States Parties. WHO 2013
\(^{24}\) WHO (2014) Hand hygiene in health care in the context of Filovirus disease outbreak response: Rapid advice guideline
Essential Medicines List 2015 (average production cost per 100ml in LMICs is approximately US$ 0.40\textsuperscript{15}). In settings that enable economies of scale, the cost of hand sanitizer has been estimated to be a few dollars per person per year for daily use - comparable to the per-person estimated annual cost of handwashing with soap, in LMICs\textsuperscript{25}.

- In addition, the study already highlighted within the key policy points section estimated that the excess cost of one health care associated blood stream infection (BSI) (US$ 1100) would cover 3265 patient-days of hand sanitizer use (US$ 0.34 per patient-day) and its use would be cost-saving if it prevented only 3.5 BSIs per year\textsuperscript{26}.

2. Option 2: Investment at the national level to enable centralised production, according to the WHO formulation (e.g. in the national pharmacy/essential medicines plant) to enable coverage across all public health facilities.

This would require investment including:

- the purchase of equipment and raw materials
- training of a cadre of pharmacists, for example based on experiences shared by hospitals in African countries, 2-3 pharmacists
- plans at the national hospital pharmacy facility (or equivalent) level to enable it to mass-produce the WHO formulation for ABHR and to perform quality controls
- logistics capability to distribute AHBR to rural and other urban public hospitals.

Such an option, enabling economies of scale to be achieved, would be possible to implement and achieve based on experiences (see quote below), and would bring significant benefits at the population level. This option is also aligned with emerging international and national health policies.

"The impact\textsuperscript{27} is especially high in facilities where there are inadequate hand hygiene resources, such as functioning sinks, water, soap and paper towels\textsuperscript{28}.”

3. Option 3: Address the current barriers to access to commercially available products

Following work undertaken by WHO, it has been established that there are a number of barriers associated with access to commercial products which could be overcome through long-term planning by countries and other parties. Actions include:

- licensing products within countries;


\textsuperscript{26} This refers to the impact of local production of ABHR.

• addressing the costs that can be prohibitive to commercial production in country (the costs outweighing the benefits of production);
• addressing import permits and port access costs, shipping and subsequent transportation, and storage facilities;
• demonstrating political commitment, i.e. statements by ministers of health and of finance emphasising that ABHR is an essential health technology.

The existing POPS initiative has a potential role to play in addressing the identified barriers, without bias or self-interest, in collaboration with national and international bodies responsible for addressing the factors listed above.

Implementation considerations

1. Political commitment
   a. Inclusive policy dialogue at national level, including the ministry of finance, ministry of health and other relevant stakeholders (e.g. those in charge of implementation together with district and hospital managers) where relevant the Ministry of Industry and Technologies would also be required to address the issues described here.
   b. Integration of ABHR local production can be incorporated within the National Action Plan for AMR and the national IPC programme.
   c. Policy-level commitment is important to address ethical and good governance issues, regulatory frameworks and quality control, insurance and measurement issues.

2. Availability of raw materials
   a. One of the biggest challenges facing those involved in local production is the supply of plastic bottles which in many countries have to be imported due to lack of local suppliers.
   b. Reliable access to the raw materials for ABHR itself – affordability issues can be addressed through subsidies and in some cases the establishment of public-private partnerships working with local entrepreneurs and small- and medium-sized enterprises.

3. Storage facilities and safety aspects
   a. Securing an appropriate place for storage (e.g. cool, dry, theft-secure, pest-free) is an important factor.

4. Building local capacity
   a. The supply of local expertise is critical – the models used to date have involved local pharmacists, however, there is the possibility to train NGOs and local small enterprises. A recent unpublished model being piloted in Uganda involves local production through development of a social enterprise.
   b. Training and education are required for those who will manufacture the ABHR, including national and local pharmacy personnel to develop the necessary skills and competency to manufacture and distribute ABHR. WHO has a range of implementation aids available to support this and case study examples of successful training on local production.\(^6\), \(^7\), \(^8\), \(^9\), \(^10\)

5. Changing behaviour at the front line

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\(^6\) WHO Tools for System Change [http://www.who.int/gpsc/5may/tools/system_change/en/](http://www.who.int/gpsc/5may/tools/system_change/en/)
\(^7\) Alcohol-based handrub planning and costing tool [http://www.who.int/entity/gpsc/5may/Alcohol_based_Planning_and_Costing_Tool.doc?ua=1](http://www.who.int/entity/gpsc/5may/Alcohol_based_Planning_and_Costing_Tool.doc?ua=1)
a. The ultimate aim of successful multimodal implementation strategies is an increase in hand hygiene compliance i.e. health worker behaviour change, and to advocate for this practice through their direct connections with local communities. WHO's multimodal hand hygiene improvement strategy and associated implementation tools (including training and education materials, campaigning materials, hand hygiene tolerability and acceptability surveys) have demonstrated success in all regions of the world.

b. Establishment of a monitoring and evaluation framework forms part of the multimodal improvement approach with a specific focus on quality measurement and improvement.

c. Motivate hospitals to use WHO’s Hand Hygiene Self-Assessment Framework as a diagnostic tool that establishes a baseline and enables improvement to be tracked over time.

d. Include, at the facility level, tools for measuring the quality of hand hygiene interventions (e.g. patient and staff questionnaires and WHO's Hand Hygiene Self Assessment Framework).

6. Increasing community/civil society knowledge through effective communication

a. Use of local radio, TV, theatre, school, with health promotion strategies and programmes, for example at national level talking about the effectiveness of ABHR. Engage the local community to be a supporter and increase demand for this intervention at facility level.

Further information

Comments on the open consultation on this draft policy brief can be provided through a short survey, which can be accessed on the WHO web pages http://www.who.int/gpsc/en/. For any other information, please contact Dr Benedetta Allegranzi, WHO Infection Prevention and Control Global Unit, by emailing aqueelahb@who.int
