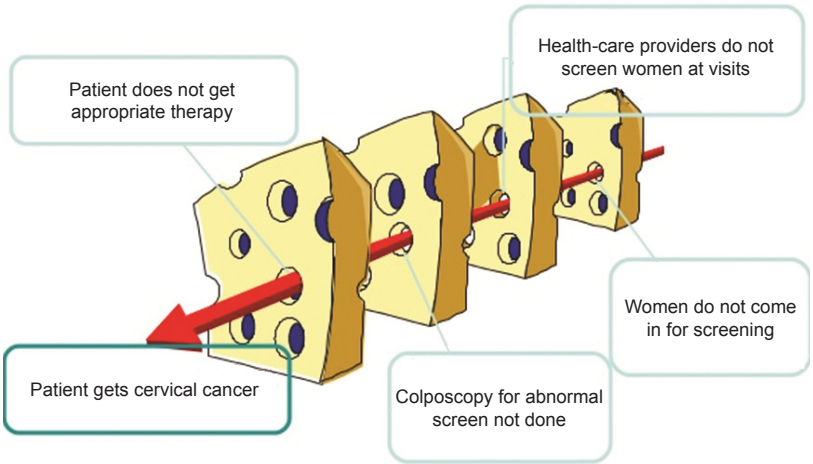
CHAPTER 18.

Quality assurance: fail-safe protocols and clean equipment

In tandem with a national HPV vaccination programme, a systematic, quality-assured call-and-recall system of cervical screening is the best way to reduce rates of cervical cancer and associated mortality. In an opportunistic programme, opportunities may be lost, leading to a diagnosis of cervical cancer (Fig. 18.1). For a screen-positive patient attending a colposcopy service, there is still potential for error. After proper training, a colposcopist will be able to competently perform colposcopic examination and undertake treatment for women with suspected cervical precancer. To deliver this service, the colposcopist needs a facility in which to provide the service as well as appropriate nursing and administrative resources and equipment. Once a service has been established, it is important that it be *quality-assured*. Every aspect of a cervical precancer screening programme needs to be included in a quality assurance programme, but the screening, organizational, and laboratory components of the programme are outside the scope of this manual. The interested reader is referred to the NHS Cervical Screening Programme website (https://www.gov.uk/guidance/cervical-screening-programme-overview) for a fuller description of

Fig. 18.1. In an opportunistic screening programme, lost opportunities may ultimately lead to cancer.



every aspect of the quality assurance system of the United Kingdom screening programme.

18.1 Standard operating procedures

It is possible to reduce the risk of mistakes in any clinical case by conscientious attention to detail. However, when a colposcopy service is managing large numbers of similar clinical presentations (i.e. screen-positive women) and dealing with large numbers of similar laboratory reports, it is easy for mistakes to happen.

The organizational aspects of a colposcopy service are as important as the diagnostic skill of the colposcopist. If a *system* of routine patient care and management of laboratory reports is established at the outset, failures and oversights will be much less likely to occur (Fig. 18.2). A manual of standard operating procedures (SOPs) of how to routinely manage every presentation will reduce the chance of mistakes happening. SOPs will contain the expected protocol for: how to deal with patient appointment default; how to arrange supply of disposable equipment; how to clean, disinfect, and sterilize reusable equipment; how laboratory reports should be filed and acted upon; and how samples should be routinely processed, labelled, and delivered on time. SOPs should be available and known to everyone in the clinic.

Auditing of how these SOPs are being adhered to and how effective they are will allow a centre of excellence to evolve (Fig. 18.3). Constant updating of the manual on the basis of changing evidence in the literature and review of the audit cycle will maintain excellence. Table 18.1 lists some of the issues that a quality assurance programme will attempt to maintain at a level of excellence, or at least competence.

Fig. 18.2. Some clinic management mistakes that may occur in a patient pathway through a colposcopy clinic service.

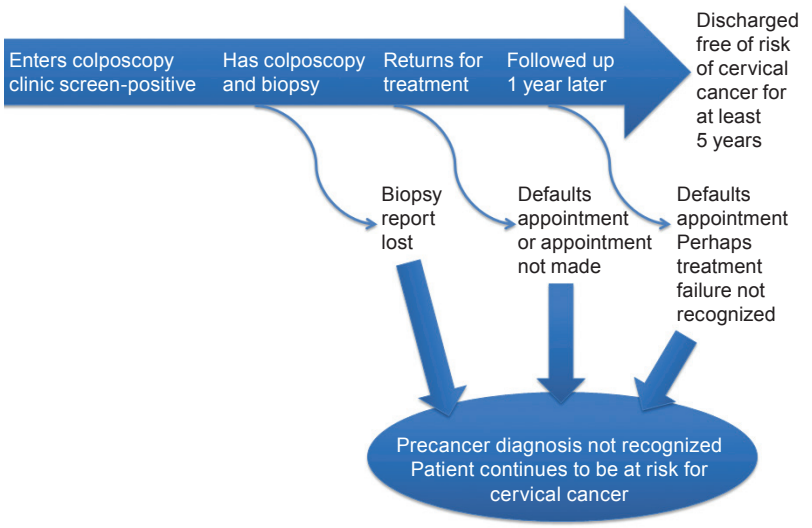
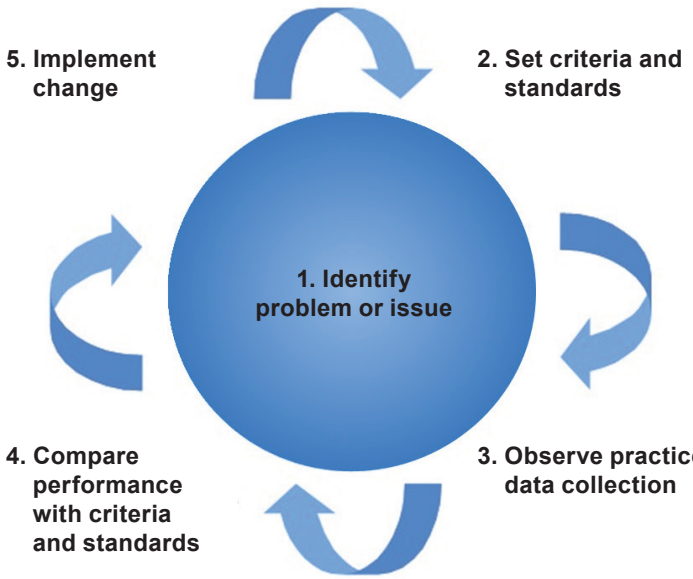


Fig. 18.3. The audit cycle: trying to achieve excellence.



18.2 Protection against infection

First, if a patient has a genital tract infection, it is almost always necessary to treat it before proceeding to colposcopic examination. Any degree of cervicitis will usually preclude an adequate examination. The treatment policies for pregnant and non-pregnant women diagnosed with reproductive tract infection are outlined in Table 9.1. Use of oral metronidazole is contraindicated during the first trimester of pregnancy, but it can be safely used during the second and third trimesters. Patients taking oral metronidazole should be cautioned not to consume alcohol while they are taking the drug or up to 24 hours after taking the last dose. Patients with advanced syphilis may

Table 18.1. Quality assurance issues

Issue	Explanation	Examples
Clinical guidelines	Details best practice according to best evidence and available local circumstances	NHS Cervical Screening Programme clinical guidelines (NHS, 2016) WHO comprehensive cervical cancer control guide (WHO, 2014)
Manual of standard operating procedures (SOPs)	Lists agreed clinic and service management protocols	Locally produced; includes how to process samples, ensure that laboratory reports are acted upon, ensure that appointment system is effective, etc.
Fail-safe protocols	Details strategies to prevent mistakes in patient and report management, particularly oversights in report management	Establish a tracking system for cytology and biopsy specimens and reports
Audit logs of colposcopic performance	Measures agreed parameters of clinical performance	• Cytology–histology correlation • Percentage treatment under local anaesthesia • Rate of false-negative histology at excisional histological examination
Waiting time for appointments Time to treatment when cancer diagnosed	Maximum time allowed for implementing management (e.g. for a cancer diagnosis)	Time from when cancer report is made until management is implemented should be < 2 weeks
Equipment log	Equipment maintenance and replacement arrangements	List all functional equipment failures and act to correct them
Information leaflets	Patient information Waiting-time lists Follow-up arrangements	Ensure that all information leaflets and other routine paperwork are up to date and available
Documentation	How records are collected	Standardized forms for colposcopic examinations (new visits, follow-up visits, treatment visits, etc.) Ideally, computerized
Cleaning, disinfection, sterilization	How patients and staff are protected from infection in the clinic	Equipment management before, during, and after an examination

require prolonged treatment with antibiotics. There is no known cure for genital herpes infections, but the course of symptoms can be modified if systemic therapy with acyclovir or its analogues is initiated.

Establishing a system of equipment management is fundamental to good practice. This is true for managing the equipment before, during, and after the colposcopic examination. Ideally, a clean room should house the clean equipment and a separate cleaning room (sometimes called a sluice room) should receive equipment after use in the clinic room, where it can be cleaned before disinfection and/or sterilization. SOPs for the care of equipment and disposable supplies are a crucial part of preventing systematic errors in the flow and use of safe equipment. For a new clinic or for new staff in an existing service, SOPs are particularly useful. There are three different infection risks to consider in the colposcopy clinic: (i) managing equipment before it enters the clinic room area; (ii) managing equipment in the colposcopy room and during colposcopy; and (iii) managing equipment after it has been used.

18.2.1 Managing equipment before it enters the clinic room area

Clean, disinfected, or sterile instruments and all disposable equipment should be stored in a clean, simple environment, preferably a dedicated room, which should be kept free of any used or clinically unclean equipment. The equipment should be accessible and organized, and the room should preferably be kept locked.

18.2.2 Managing equipment in the colposcopy room and during colposcopy

Establishing a system of equipment flow in the clinic room will reduce the risk of accidental infection. Such a system is both easy to arrange and ergonomically efficient. Given the repetitive nature of colposcopy, it is prudent to procure and stock a compartmentalized trolley to accommodate the reusable and disposable equipment needed for the clinic (see Chapter 5). Dirty or used equipment should never be placed on or in this trolley. Care should be taken to arrange the hardware used

in colposcopy so that the equipment and cables are not in the line of potential infection and will not trip anyone up. If possible, the monitor, computer, camera system, ESU, and ablative treatment equipment should be stacked on fixed wall-mounted shelving. The cables and tubes from this equipment should come from only one side of the colposcopist.

A simple layout illustrating the different parts that come together in the working interface is shown in Fig. 18.4. This interface is where the risk of contamination is greatest. The colposcopist should take care not to place used or dirty instruments back onto the clean supplies trolley. The flow of equipment should be in one direction: from the instrument trolley to the working interface area and then to the receptacle for used equipment. It is often useful to have a temporary storage bowl or dish just underneath the patient's perineum where instruments and swabs may be kept during the procedure until finished with (Fig. 18.5). Equipment may then be transferred to the receptacle for used equipment. There should be a hand wash basin for the patient to wash her hands and, ideally, a separate one for the colposcopist to do so after each procedure.

18.2.3 Managing equipment after it has been used

Before equipment may be used or reused, it needs to be decontaminated, cleaned, and then either sterilized or disinfected using high-level disinfection (HLD).

18.3 Decontamination

Decontamination comprises a series of steps to make a medical instrument or device safe for handling by reducing its contamination with microorganisms or other harmful substances. Usually, these procedures are performed by the nursing, technical, or cleaning staff, and decontamination protects these workers from inadvertent infection. If these procedures are carried out properly, decontamination of the instruments will be ensured before they are handled for cleaning. This step results in the inactivation of most organisms, such as hepatitis B virus and HIV. Further processing is needed to ensure that the object is cleaned and then sterilized.

18.3.1 Method of decontamination

Immediately after use, place instruments and other items, such as gloves, in a large clean plastic bucket containing a 0.5% chlorine solution for 10 minutes. The 0.5% chlorine solution can be prepared by adding 1 part of concentrated household bleach (sodium hypochlorite solution, 5% available chlorine) to 9 parts of water.

The general formula for making a dilute solution from a commercial preparation of any given concentration is as follows: total parts of water = [% concentrate/% dilute] − 1. For example, to make a 0.5% dilute solution of chlorine from 5% concentrated liquid household bleach, total parts of water = [5.0%/0.5%] − 1 = 10 – 1 = 9; hence, add 1 part of concentrated bleach to 9 parts of water.

If commercially available dry powder chlorine is used to make the solution, use the following formula to calculate the amount (in grams) of dry powder required to make a 0.5% chlorine solution: grams/litre = [% dilute/% concentrate] × 1000. For example, to make a 0.5% dilute solution of chlorine from a dry powder of 35% calcium hypochlorite, grams/litre = [0.5%/35%] × 1000 = 14.2 g. Hence, add 14.2 g of dry powder to

Fig. 18.4. Layout of equipment and cables relative to the working interface. The colposcopist should ensure that used equipment does not contaminate the permanently stacked hardware or the relevant cables, or the clean supply trolley.

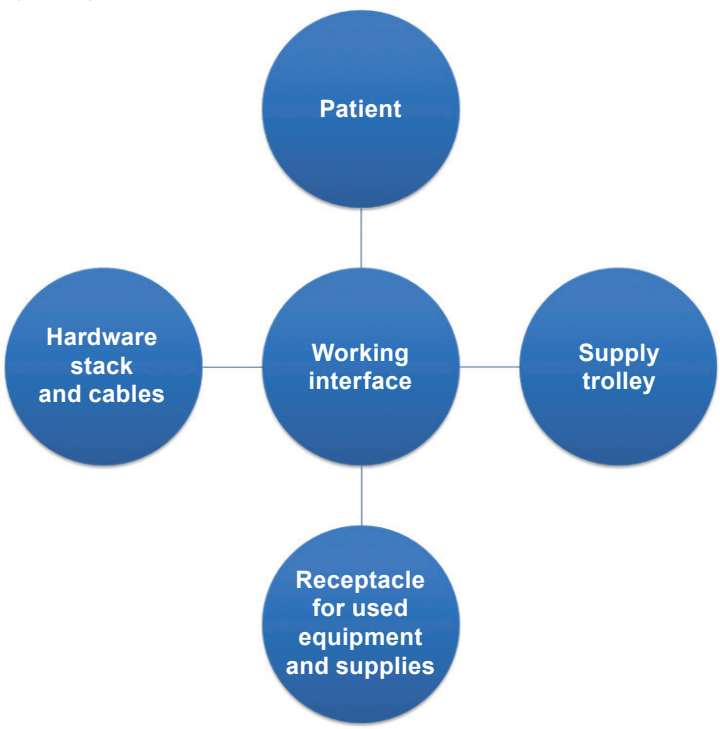
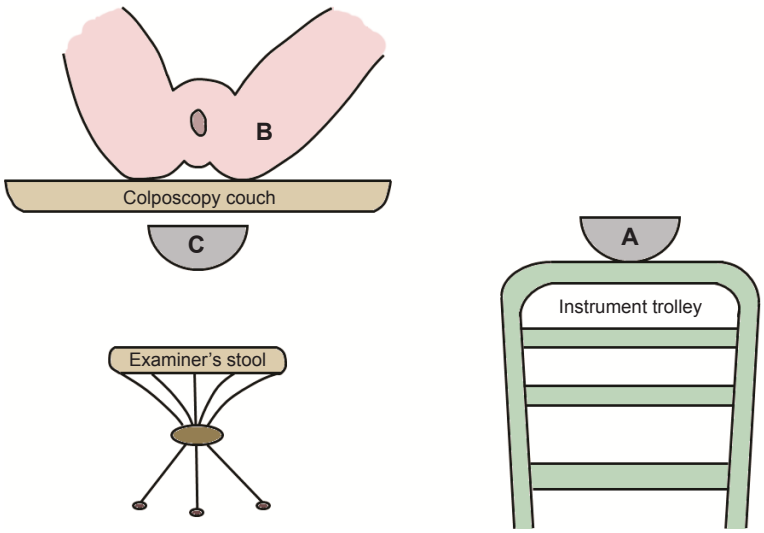


Fig. 18.5. The flow of instruments and equipment (reusable and disposable) should be in one direction: from the instrument trolley (A) to the working interface area (B) and then to the receptacle for used equipment (C) and never back to A.



1 litre of water or 142 g of dry powder to 10 litres of water.

The instruments should not be left in dilute bleach for more than 10 minutes and should be cleaned in boiled water immediately after decontamination to prevent discoloration and corrosion of metal.

18.4 Cleaning

Cleaning is a crucial step in providing safe, infection-free instruments. Vigorous manual cleaning with running water and liquid soap or detergent removes biological material such as blood, body fluids, and tissue remnants. Instruments should be cleaned as soon as possible after use.

If biological material is left behind, it can act as a sanctuary for residual microorganisms, protecting them from the effects of disinfection and sterilization.

18.4.1 Method of cleaning

Thorough manual cleaning of instruments with water and detergent to remove all organic material, after decontamination in 0.5% chlorine solution for 10 minutes, is of the utmost importance before sterilization or HLD. A brush should be used to scrub the instruments free of biological matter. Instruments should be cleaned as soon as possible after use, so that no organic material will dry and stick to the instruments, providing a sanctuary for microbes. The person cleaning should use utility gloves while washing the instruments.

Protective glasses or goggles should be worn by the cleaners to protect their eyes from contaminated water. Special attention should be given to instruments with teeth (e.g. biopsy punches) or joints and screws (e.g. vaginal specula), to which biological material can become stuck. After cleaning, rinse the instruments thoroughly with boiled water to remove detergent residue.

18.5 Sterilization or high-level disinfection

Sterilization is defined as the process of destroying all microorganisms on an instrument by exposure to physical or chemical agents. This process kills all forms of microbial life, including bacterial spores. In practice, sterility is considered to be achieved if the probability of a surviving microorganism is less than 1 in 1 million. The sterilization process is fundamental to the safe reuse of instruments in clinical care.

When sterilization equipment is not available or the instrument cannot be sterilized, HLD is used. Disinfection implies that the microbial burden of an instrument is reduced but is not entirely eliminated. The extent of this reduction depends on the disinfection process used and the resistance of the microbial forms present. In practice, however, HLD results in all forms of microbial life being destroyed except bacterial spores.

18.5.1 Methods of sterilization

Instruments that are considered critical (instruments that enter sterile body tissues or the vascular system, such as biopsy punches, surgical instruments, electrocautery tips, and vaginal specula; see Table 18.3) require sterilization before reuse. Two methods of sterilization are described here: steam sterilization and chemical sterilization.

High-pressure saturated steam sterilization using autoclaves is recommended for sterilization. Unwrapped instruments should be exposed for 20 minutes to temperatures of 121–132 °C at a pressure of 106 kPa (15 lb/inch^2). The manufacturer's recommendations should be followed, because pressure settings may vary slightly depending on the make of the autoclave. Small wrapped packs of instruments should be exposed for 30 minutes. The material used for wrapping should be porous enough to let steam through. Wrapped sterile instruments have a shelf life of up to 7 days, if kept dry

and intact. Unwrapped instruments should be placed in a sterile container. Small autoclaves are ideal for use in clinics.

Chemical sterilization by soaking in 2–4% glutaraldehyde for 8–10 hours or in 8% formaldehyde for 24 hours is an alternative to steam sterilization. This requires special handling with gloves, and the instruments thus sterilized should be rinsed with sterile water before use, because these chemicals form a residue on the instruments. Glutaraldehyde is very expensive, whereas formaldehyde is more irritating to skin, lungs, and eyes. Steam sterilization is preferred to chemical sterilization.

18.5.2 Methods of high-level disinfection

Two methods of HLD are described here.

Boiling plain tap water in a clean vessel offers a cheap and readily accessible form of HLD. The contact time for instruments should be at least 20 minutes after boiling has started. Water in the vessel should be changed daily. The vessel should be washed and kept dry every day.

Alternatively, HLD may be obtained by soaking instruments in one of the following solutions for 20–30 minutes.

- *0.1% Chlorine solution:* If boiled water is used to make the solution, 0.1% chlorine may be used for HLD. If not, 0.5% chlorine solution should be used. The contact time required is 20 minutes. The solution is very corrosive to stainless steel. After disinfection, instruments should be rinsed thoroughly with boiled water and then air-dried or dried with a sterile cloth before use. The shelf life of prepared solution is 1 week.
- *6% Hydrogen peroxide solution:* It can be prepared by adding 1 part of a 30% solution to 4 parts of boiled water. The contact time required is 30 minutes. After disinfection, instruments should be rinsed thoroughly with boiled water and then air-dried or dried with a sterile cloth before use. However, this solution will damage the external surfaces of rubbers and plastics and will corrode copper, zinc, and brass instruments after prolonged use.
- *2% Glutaraldehyde:* It must be prepared according to the manufacturer's instructions. Activated 2% solution in a covered container has a shelf life of 2 weeks. The contact time required is 20 minutes. Because glutaraldehyde forms a residue on instruments, which is toxic to tissues, the instruments must be rinsed thoroughly with sterile water and dried with a sterile cloth before use.

18.6 Quality assurance of equipment safety and sterility

Strict implementation of decontamination, cleaning, and sterilization or HLD of instruments according to a written manual is helpful in quality assurance of the procedures. The manual must be prominently displayed in the clinic for ready reference. The quality assurance process includes regular audits, analysis, system adjustments, and education. The audits should include: review of the methods of sterilization used, the items being sterilized, and the duration and temperature of exposure; identification of the person performing the sterilization; and periodic review and inspection of the equipment being used for sterilization. The frequency of pelvic infection after clinical procedures in this context (i.e. screening, early detection, and treatment of cervical precancer) is a good indicator of the quality of the sterilization process in place.

18.7 Spaulding's classification of medical instruments (modified)

Spaulding (1968) categorized medical instruments as critical, semi-critical, or non-critical, according to how they are used (Table 18.2). This classification is useful in guiding the processing of instruments for reuse.

Intermediate-level disinfection results in destruction of *Mycobacterium tuberculosis*, vegetative bacteria, most viruses (HIV, hepatitis B virus, and herpes simplex viruses), and most fungi (*Candida*, *Aspergillus*), but it does not kill bacterial spores. Low-level disinfection destroys most bacteria, some viruses, and some fungi, but not *Mycobacterium tuberculosis* or bacterial spores. Antiseptics such as 60–90% ethyl or isopropyl alcohol or iodophors such as 10% povidone iodine act as intermediate-level or low-level disinfectants. Alcohol does not leave a residue on instruments, but iodophors do.

A guide to the processing of instruments and materials used for screening of cervical neoplasia, colposcopy, and treatment of CIN is given in Table 18.3.

Table 18.2. Spaulding's categorization of medical instruments

Class	Use	Processing
Critical (C)	Enters sterile body site or vascular system	Decontamination and cleaning followed by sterilization
Semi-critical (SC)	Comes into contact with intact mucous membrane or non-intact skin	Decontamination and cleaning followed by high-level disinfection
Non-critical (NC)	Comes into contact with intact skin	Decontamination and cleaning followed by intermediate-level or low-level disinfection

18.8 Decontamination of surfaces in the screening clinic

Procedure tables, trolleys, and equipment (colposcope, cryosurgical equipment, ESU, smoke evacuator, halogen lamp, etc.) in the screening clinic may be contaminated with body fluids such as vaginal secretions, purulent discharge, and blood. The surface of the procedure table should be decontaminated after each patient procedure, and the other surfaces should be decontaminated daily by wiping with 0.5% chlorine solution, 60–90% ethyl or isopropyl alcohol, or other chemical disinfectants such as iodophors. The floor of the screening clinic should also be decontaminated daily.

Table 18.3. Guide to the processing of instruments and materials used for early detection and treatment of cervical neoplasia

Instrument/material	Category	Processing	Suggested procedure
Vaginal speculum, vaginal retractor, biopsy forceps, endocervical curette, endocervical speculum, needle holder, toothed forceps, vulsellum forceps, mosquito forceps, insulated speculum, vaginal sidewall retractor	C	Decontamination and cleaning followed by sterilization or HLD	Autoclaving or disinfection with boiling water
Gloves	C	Decontamination and cleaning followed by sterilization	Autoclaving as wrapped packs
Cryoprobes	SC	Decontamination and cleaning followed by HLD	Disinfection with 0.1% chlorine or 2% glutaraldehyde or 6% hydrogen peroxide
Colposcope head, stand LLETZ/LEEP equipment, cryogun and regulator, cryo gas cylinder, examination table, hand lens, handheld magnification device, torch lights, halogen lamp, instrument trolley, trays	SC	Intermediate-level or low-level disinfection	Wiping with 60–90% ethyl or isopropyl alcohol

C, critical; HLD, high-level disinfection; LEEP, loop electrosurgical excision procedure; LLETZ, large loop excision of the transformation zone; SC, semi-critical.

Key points

- The organizational aspects of a colposcopy service are as important as the diagnostic skill of the colposcopist.
- Contamination and cross-infection are risks for both patients and staff in a colposcopy clinic.
- Decontamination, cleaning, sterilization, and high-level disinfection are different terms with precise meanings.