# Supplementary materials

A: Glossary

B: Guideline development and conflicts of interest

C: Consultation

## A: Glossary

**Cleaning:** Methods that physically remove soil, dust and dirt from surfaces or equipment.

**Colonisation:** Situation whereby micro-organisms establish themselves in a particular environment, such as a body surface, without producing disease.

**Decontamination:** a process where microbial contamination is removed to render an environment, the equipment, or an item safe. It encompasses methods for cleaning, disinfection, and sterilisation.

**Disinfection:** a process in which viable microorganisms are destroyed. The process may not necessarily kill and remove all microorganisms but reduces them to an acceptable level to prevent harmful effects on health.

**Flexible endoscope:** An instrument with flexible fibre optics, inserted directly into a body cavity and used to view an organ or area, that would otherwise be inaccessible.

**Infection:** Invasion by and multiplication of pathogenic micro-organisms in the body, producing tissue injury and disease,
requiring treatment.

**Outbreak:** At least two similar (i.e., not distinct) cases related in time and place.

**Pseudo-outbreak:** A situation where a microorganism is found in clinical samples at the rate higher than expected and patient are found not to be infected or colonised OR a situation when patients are infected/colonised with a microorganism at higher than usual rate but the genetic profiling shows that these infections did not originate from the same source.

**Sterilisation:** a process in which all microorganisms (including spores) are completely destroyed and removed.

**Waterborne microorganism**: a microorganism which contaminates a water supply. The term is usually associated with pathogenic and opportunistic microorganisms which have a potential to cause a waterborne infection.

## B: Guideline development and conflicts of interest

*Guideline development process*

The Working Party followed the guideline process described by the National Institute of Health and Care Excellence: Developing NICE guidelines: the manual. Process and methods; 2018. Available at: https://www.nice.org.uk/process/pmg20/chapter/introduction [last accessed September 2021].

**The Working party members declared following conflicts of interest:**

| **1. Member's details (some information in this section has been redacted from the original document)** | | | | | |
|---|---|---|---|---|---|
| **Name:**<br>CW | | | | | |
| **Primary employer and other paid positions:** | | | | | |
| **2. Pecuniary interests (amounts in GBP)** | **None** | **≤2500** | **≥2,500 - 5000** | **≥5000-25000** | **≥25000** |
| **Consultancy Work**<br>This refers to any paid retainer or agreement between the member and a company usually with a contract for a specific period and includes payment for attending Advisory Board meetings. | x ☐ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **Speaker fees**<br>This section mainly concerns fees (e.g. for lectures, commissioned articles, or other similar paid activity) received from a commercial sponsor and where the member has benefited personally. | ☐ | x☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| Gilead Sciences speaker fee | | | | | |
| **Company shares**<br>This section includes any shares held by the member in the biomedical industry (e.g., pharmaceutical, diagnostic, or similar companies). | x☐ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
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|---|---|---|---|---|---|
| **Other paid income**<br>This refers to patents or royalties, serving as an expert witness, or performing other activities for an entity with a financial interest in this area undertaken by the member. | x☐ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **Other relevant disclosures**<br>This refers to any other relationships which are financial or with an organisation that, if not disclosed by the member, could compromise the member or HIS as a charitable organisation. | x☐ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |

**3. Non-pecuniary interests**

You are required to declare any trusteeships in other organisations, other committee memberships or directorships, which have conflicting or competing interests.

**Trusteeships**

Give full name(s) of organisation(s) and information on term served to date and retirement date.

None

**Committee memberships**

Give full name of organisation(s) and indicate your role on any committees, giving details of term served to date and retirement date.

Are you:

- a member of an executive committee (or board) of another international organization (e.g. society, federation, association)?
- a member of the programme committee of another international congress?
- an editor-in-chief, senior editor or (associate) editor with any journal in the fields of CM/ID/IC?
- a member of an advisory board of a company involved in the medical field?
- taking up any other functions in an international organization?

No

**Directorships**

Give full name(s) of organisation(s) and information on term served to date and retirement date.

None

**4. Please indicate any potential future conflicts of interest.**

None

| 1. Member's details (some information in this section has been redacted from the original document) | | | | | |
|---|---|---|---|---|---|
| **Name:**<br>JW | | | | | |
| **Primary employer and other paid positions:** | | | | | |
| **2. Pecuniary interests (amounts in GBP)** | **None** | **≤2500** | **≥2,500 - 5000** | **≥5000-25000** | **≥25000** |
| **Consultancy Work**<br>This refers to any paid retainer or agreement between the member and a company usually with a contract for a specific period and includes payment for attending Advisory Board meetings. | ☐ | ☐ | ☐ | ☒ | ☐ |
| **Please provide further details** | | | | | |
| Consultancy work for "Idexx International" a microbiological company that produces culture media for a range of microorganisms | | | | | |
| **Speaker fees**<br>This section mainly concerns fees (e.g. for lectures, commissioned articles, or other similar paid activity) received from a commercial sponsor and where the member has benefited personally. | ☐ | ☒ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| Payments from Idexx International for presenting at international conferences. | | | | | |
| **Company shares**<br>This section includes any shares held by the member in the biomedical industry (e.g., pharmaceutical, diagnostic, or similar companies). | ☐ | ☐ | ☒ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| Shares held in GSK and Dechra Pharmaceuticals | | | | | |
| **Other paid income**<br>This refers to patents or royalties, serving as an expert witness, or performing other activities for an entity with a financial interest in this area undertaken by the member. | ☐ | ☒ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| Payments for decontamination books published through Elsevier | | | | | |

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|---|---|---|---|---|---|
| **Other relevant disclosures**<br>This refers to any other relationships which are financial or with an organisation that, if not disclosed by the member, could compromise the member or HIS as a charitable organisation. | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **3. Non-pecuniary interests**<br>You are required to declare any trusteeships in other organisations, other committee memberships or directorships, which have conflicting or competing interests. | | | | | |
| **Trusteeships**<br>Give full name(s) of organisation(s) and information on term served to date and retirement date. | | | | | |
| None | | | | | |
| **Committee memberships**<br>Give full name of organisation(s) and indicate your role on any committees, giving details of term served to date and retirement date.<br>Are you:<br>• a member of an executive committee (or board) of another international organization (e.g. society, federation, association)?<br>• a member of the programme committee of another international congress?<br>• an editor-in-chief, senior editor or (associate) editor with any journal in the fields of CM/ID/IC?<br>• a member of an advisory board of a company involved in the medical field?<br>• taking up any other functions in an international organization? | | | | | |
| No | | | | | |
| **Directorships**<br>Give full name(s) of organisation(s) and information on term served to date and retirement date. | | | | | |
| None | | | | | |
| **4. Please indicate any potential future conflicts of interest.** | | | | | |
| None | | | | | |

| **1. Member's details (some information in this section has been redacted from the original document)** | | | | | |
|---|---|---|---|---|---|
| **Name:**<br>ER | | | | | |
| **2. Pecuniary interests (amounts in GBP)** | **None** | **≤2500** | **≥2,500 - 5000** | **≥5000-25000** | **≥25000** |

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|---|---|---|---|---|---|
| **Consultancy Work**<br>This refers to any paid retainer or agreement between the member and a company usually with a contract for a specific period and includes payment for attending Advisory Board meetings. | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **Speaker fees**<br>This section mainly concerns fees (e.g. for lectures, commissioned articles, or other similar paid activity) received from a commercial sponsor and where the member has benefited personally. | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **Company shares**<br>This section includes any shares held by the member in the biomedical industry (e.g., pharmaceutical, diagnostic, or similar companies). | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **Other paid income**<br>This refers to patents or royalties, serving as an expert witness, or performing other activities for an entity with a financial interest in this area undertaken by the member. | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **Other relevant disclosures**<br>This refers to any other relationships which are financial or with an organisation that, if not disclosed by the member, could compromise the member or HIS as a charitable organisation. | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **3. Non-pecuniary interests**<br>You are required to declare any trusteeships in other organisations, other committee memberships or directorships, which have conflicting or competing interests. | | | | | |
| **Trusteeships** | | | | | |

| |
|---|
| Give full name(s) of organisation(s) and information on term served to date and retirement date. |
| |
| **Committee memberships**<br>Give full name of organisation(s) and indicate your role on any committees, giving details of term served to date and retirement date.<br>Are you:<br>• a member of an executive committee (or board) of another international organization (e.g. society, federation, association)?<br>• a member of the programme committee of another international congress?<br>• an editor-in-chief, senior editor or (associate) editor with any journal in the fields of CM/ID/IC?<br>• a member of an advisory board of a company involved in the medical field?<br>• taking up any other functions in an international organization? |
| Co-opted Board member Infection Prevention Society 2016-2018 |
| **Directorships**<br>Give full name(s) of organisation(s) and information on term served to date and retirement date. |
| |
| **4. Please indicate any potential future conflicts of interest.** |
| |

| **1. Member's details (some information in this section has been redacted from the original document)** | | | | | |
|---|---|---|---|---|---|
| **Name:**<br>GS | | | | | |
| **Primary employer and other paid positions:** | | | | | |
| **2. Pecuniary interests (amounts in GBP)** | **None** | **≤2500** | **≥2,500 - 5000** | **≥5000-25000** | **≥25000** |
| **Consultancy Work**<br>This refers to any paid retainer or agreement between the member and a company usually with a contract for a specific period and includes payment for attending Advisory Board meetings. | none | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
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| | | | | | |
|---|---|---|---|---|---|
| **Speaker fees**<br>This section mainly concerns fees (e.g. for lectures, commissioned articles, or other similar paid activity) received from a commercial sponsor and where the member has benefited personally. | none | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **Company shares**<br>This section includes any shares held by the member in the biomedical industry (e.g., pharmaceutical, diagnostic, or similar companies). | none | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| N/A | | | | | |
| **Other paid income**<br>This refers to patents or royalties, serving as an expert witness, or performing other activities for an entity with a financial interest in this area undertaken by the member. | none | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| None | | | | | |
| **Other relevant disclosures**<br>This refers to any other relationships which are financial or with an organisation that, if not disclosed by the member, could compromise the member or HIS as a charitable organisation. | ☐ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| None | | | | | |
| **3. Non-pecuniary interests**<br>You are required to declare any trusteeships in other organisations, other committee memberships or directorships, which have conflicting or competing interests. | | | | | |
| **Trusteeships**<br>Give full name(s) of organisation(s) and information on term served to date and retirement date. | | | | | |
| None | | | | | |
| **Committee memberships**<br>Give full name of organisation(s) and indicate your role on any committees, giving details of term served to date and retirement date.<br>Are you:<br>• a member of an executive committee (or board) of another international organization (e.g. society, federation, association)? | | | | | |

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|---|
| • a member of the programme committee of another international congress?<br>• an editor-in-chief, senior editor or (associate) editor with any journal in the fields of CM/ID/IC?<br>• a member of an advisory board of a company involved in the medical field?<br>• taking up any other functions in an international organization? |
| IHEEM chair of AE(D) registration board |
| **Directorships**<br>Give full name(s) of organisation(s) and information on term served to date and retirement date. |
| None |
| **4. Please indicate any potential future conflicts of interest.** |
| None |

| **1. Member's details (some information in this section has been redacted from the original document)** | | | | | |
|---|---|---|---|---|---|
| **Name:**<br>HG | | | | | |
| **Primary employer and other paid positions:** | | | | | |
| **2. Pecuniary interests (amounts in GBP)** | **None** | **≤2500** | **≥2,500 - 5000** | **≥5000-25000** | **≥25000** |
| **Consultancy Work**<br>This refers to any paid retainer or agreement between the member and a company usually with a contract for a specific period and includes payment for attending Advisory Board meetings. | ☐ | ☒ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| Undertake independent endoscopy related consultancy work for services in the acute and private sector, to help them achieve JAG accreditation. Paid and unpaid | | | | | |
| **Speaker fees**<br>This section mainly concerns fees (e.g. for lectures, commissioned articles, or other similar paid activity) received from a commercial sponsor and where the member has benefited personally. | ☐ | ☒ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| Lecture and chair at educational workshops and meetings for a number of commercial sponsors. Paid and unpaid | | | | | |

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|---|---|---|---|---|---|
| **Company shares**<br>This section includes any shares held by the member in the biomedical industry (e.g., pharmaceutical, diagnostic, or similar companies). | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| N/A | | | | | |
| **Other paid income**<br>This refers to patents or royalties, serving as an expert witness, or performing other activities for an entity with a financial interest in this area undertaken by the member. | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| None | | | | | |
| **Other relevant disclosures**<br>This refers to any other relationships which are financial or with an organisation that, if not disclosed by the member, could compromise the member or HIS as a charitable organisation. | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| None | | | | | |
| **3. Non-pecuniary interests**<br>You are required to declare any trusteeships in other organisations, other committee memberships or directorships, which have conflicting or competing interests. | | | | | |
| **Trusteeships**<br>Give full name(s) of organisation(s) and information on term served to date and retirement date. | | | | | |
| Decontamination and CJD advisor British Society of Gastroenterology 2014 to date | | | | | |
| **Committee memberships**<br>Give full name of organisation(s) and indicate your role on any committees, giving details of term served to date and retirement date.<br>Are you:<br>• a member of an executive committee (or board) of another international organization (e.g. society, federation, association)?<br>• a member of the programme committee of another international congress?<br>• an editor-in-chief, senior editor or (associate) editor with any journal in the fields of CM/ID/IC?<br>• a member of an advisory board of a company involved in the medical field?<br>• taking up any other functions in an international organization? | | | | | |
| IHEEM chair of AE(D) registration board | | | | | |
| **Directorships** | | | | | |

| Give full name(s) of organisation(s) and information on term served to date and retirement date. |
|---|
| None |
| **4. Please indicate any potential future conflicts of interest.** |
| None |

| **1. Member's details (some information in this section has been redacted from the original document)** | | | | | |
|---|---|---|---|---|---|
| **Name:**<br>LW | | | | | |
| **Primary employer and other paid positions:** | | | | | |
| **2. Pecuniary interests (amounts in GBP)** | **None** | **≤2500** | **≥2,500 - 5000** | **≥5000-25000** | **≥25000** |
| **Consultancy Work**<br>This refers to any paid retainer or agreement between the member and a company usually with a contract for a specific period and includes payment for attending Advisory Board meetings. | none | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **Speaker fees**<br>This section mainly concerns fees (e.g. for lectures, commissioned articles, or other similar paid activity) received from a commercial sponsor and where the member has benefited personally. | none | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **Company shares**<br>This section includes any shares held by the member in the biomedical industry (e.g., pharmaceutical, diagnostic, or similar companies). | none | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| N/A | | | | | |
| **Other paid income**<br>This refers to patents or royalties, serving as an expert witness, or performing other activities for an entity with a financial interest in this area undertaken by the member. | none | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| None | | | | | |
| **Other relevant disclosures**<br>This refers to any other relationships which are financial or with an organisation that, if not disclosed by the member, could compromise the member or HIS as a charitable organisation. | ☐ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| None | | | | | |
| **3. Non-pecuniary interests**<br>You are required to declare any trusteeships in other organisations, other committee memberships or directorships, which have conflicting or competing interests. | | | | | |
| **Trusteeships**<br>Give full name(s) of organisation(s) and information on term served to date and retirement date. | | | | | |
| None | | | | | |
| **Committee memberships**<br>Give full name of organisation(s) and indicate your role on any committees, giving details of term served to date and retirement date.<br>Are you:<br>• a member of an executive committee (or board) of another international organization (e.g. society, federation, association)?<br>• a member of the programme committee of another international congress?<br>• an editor-in-chief, senior editor or (associate) editor with any journal in the fields of CM/ID/IC?<br>• a member of an advisory board of a company involved in the medical field?<br>• taking up any other functions in an international organization? | | | | | |
| IHEEM chair of AE(D) registration board | | | | | |
| **Directorships**<br>Give full name(s) of organisation(s) and information on term served to date and retirement date. | | | | | |
| None | | | | | |
| **4. Please indicate any potential future conflicts of interest.** | | | | | |
| None | | | | | |

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|---|
| **1. Member's details (some information in this section has been redacted from the original document)** |
| **Name:**<br>WS |
| **Primary employer and other paid positions:** |

| 2. Pecuniary interests (amounts in GBP) | None | ≤2500 | ≥2,500 - 5000 | ≥5000-25000 | ≥25000 |
|---|---|---|---|---|---|
| **Consultancy Work**<br>This refers to any paid retainer or agreement between the member and a company usually with a contract for a specific period and includes payment for attending Advisory Board meetings. | ☐ | ☒ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| Payment by ASP Ltd for attending Global advisory Board in 2019. | | | | | |
| **Speaker fees**<br>This section mainly concerns fees (e.g. for lectures, commissioned articles, or other similar paid activity) received from a commercial sponsor and where the member has benefited personally. | ☐ | ☐ | ☒ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| Honorarium paid by Cantel Medical for speaking at a BSG sponsored study day, Honorarium paid by Im-Med for speaking at a endoscopy technician study day. Honorarium paid by Steris Ltd for speaking at a World Federation of Hospital Sterilization Sciences lunchtime seminar. Honorarium paid by ASP Ltd for speaking at a World Federation of Hospital Sterilization Sciences lunchtime seminar. | | | | | |
| **Company shares**<br>This section includes any shares held by the member in the biomedical industry (e.g., pharmaceutical, diagnostic, or similar companies). | ☐ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| N/A | | | | | |
| **Other paid income**<br>This refers to patents or royalties, serving as an expert witness, or performing other activities for an entity with a financial interest in this area undertaken by the member. | ☐ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| None | | | | | |
| **Other relevant disclosures**<br>This refers to any other relationships which are financial or with an organisation that, if not disclosed by the member, could compromise the member or HIS as a charitable organisation. | ☐ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |

| |
|---|
| None |
| **3. Non-pecuniary interests**<br>You are required to declare any trusteeships in other organisations, other committee memberships or directorships, which have conflicting or competing interests. |
| **Trusteeships**<br>Give full name(s) of organisation(s) and information on term served to date and retirement date. |
| None |
| **Committee memberships**<br>Give full name of organisation(s) and indicate your role on any committees, giving details of term served to date and retirement date.<br>Are you:<br>• a member of an executive committee (or board) of another international organization (e.g. society, federation, association)?<br>• a member of the programme committee of another international congress?<br>• an editor-in-chief, senior editor or (associate) editor with any journal in the fields of CM/ID/IC?<br>• a member of an advisory board of a company involved in the medical field?<br>• taking up any other functions in an international organization? |
| IHEEM chair of AE(D) registration board |
| **Directorships**<br>Give full name(s) of organisation(s) and information on term served to date and retirement date. |
| Director of Spencer Nickson Ltd from 2005 to present. They are my employer. |
| **4. Please indicate any potential future conflicts of interest.** |
| None |

| **1. Member's details (some information in this section has been redacted from the original document)** | | | | | |
|---|---|---|---|---|---|
| **1. Member's details** | | | | | |
| **Name:**<br>AB | | | | | |
| **Primary employer and other paid positions:** | | | | | |
| **2. Pecuniary interests (amounts in GBP)** | **None** | **≤2500** | **≥2,500 - 5000** | **≥5000-25000** | **≥25000** |
| **Consultancy Work**<br>This refers to any paid retainer or agreement between the member and a company usually with a contract for a specific period and includes payment for attending Advisory Board meetings. | ☒ | ☐ | ☐ | ☐ | ☐ |

| | | | | | |
|---|---|---|---|---|---|
| **Please provide further details** | | | | | |
| | | | | | |
| **Speaker fees**<br>This section mainly concerns fees (e.g. for lectures, commissioned articles, or other similar paid activity) received from a commercial sponsor and where the member has benefited personally. | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **Company shares**<br>This section includes any shares held by the member in the biomedical industry (e.g., pharmaceutical, diagnostic, or similar companies). | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **Other paid income**<br>This refers to patents or royalties, serving as an expert witness, or performing other activities for an entity with a financial interest in this area undertaken by the member. | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **Other relevant disclosures**<br>This refers to any other relationships which are financial or with an organisation that, if not disclosed by the member, could compromise the member or HIS as a charitable organisation. | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **3. Non-pecuniary interests**<br>You are required to declare any trusteeships in other organisations, other committee memberships or directorships, which have conflicting or competing interests. | | | | | |
| **Trusteeships**<br>Give full name(s) of organisation(s) and information on term served to date and retirement date. | | | | | |
| | | | | | |
| **Committee memberships**<br>Give full name of organisation(s) and indicate your role on any committees, giving details of term served to date and retirement date. | | | | | |

Are you:

- a member of an executive committee (or board) of another international organization (e.g. society, federation, association)?
- a member of the programme committee of another international congress?
- an editor-in-chief, senior editor or (associate) editor with any journal in the fields of CM/ID/IC?
- a member of an advisory board of a company involved in the medical field?
- taking up any other functions in an international organization?

**Directorships**

Give full name(s) of organisation(s) and information on term served to date and retirement date.

**4. Please indicate any potential future conflicts of interest.**

| **1. Member's details (some information in this section has been redacted from the original document)** | | | | | |
|---|---|---|---|---|---|
| **1. Member's details** | | | | | |
| **Name:** MG | | | | | |
| **Primary employer and other paid positions:** | | | | | |
| **2. Pecuniary interests (amounts in GBP)** | **None** | **≤2500** | **≥2,500 - 5000** | **≥5000-25000** | **≥25000** |
| **Consultancy Work** This refers to any paid retainer or agreement between the member and a company usually with a contract for a specific period and includes payment for attending Advisory Board meetings. | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
| | | | | | |
| **Speaker fees** This section mainly concerns fees (e.g. for lectures, commissioned articles, or other similar paid activity) received from a commercial sponsor and where the member has benefited personally. | ☐ | ☒ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
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| **Company shares**<br>This section includes any shares held by the member in the biomedical industry (e.g., pharmaceutical, diagnostic, or similar companies). | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
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| **Other paid income**<br>This refers to patents or royalties, serving as an expert witness, or performing other activities for an entity with a financial interest in this area undertaken by the member. | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
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| **Other relevant disclosures**<br>This refers to any other relationships which are financial or with an organisation that, if not disclosed by the member, could compromise the member or HIS as a charitable organisation. | ☒ | ☐ | ☐ | ☐ | ☐ |
| **Please provide further details** | | | | | |
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**3. Non-pecuniary interests**

You are required to declare any trusteeships in other organisations, other committee memberships or directorships, which have conflicting or competing interests.

**Trusteeships**

Give full name(s) of organisation(s) and information on term served to date and retirement date.

Healthcare Infection Society 2015-17

**Committee memberships**

Give full name of organisation(s) and indicate your role on any committees, giving details of term served to date and retirement date.

Are you:

- a member of an executive committee (or board) of another international organization (e.g. society, federation, association)?
- a member of the programme committee of another international congress?
- an editor-in-chief, senior editor or (associate) editor with any journal in the fields of CM/ID/IC?
- a member of an advisory board of a company involved in the medical field?
- taking up any other functions in an international organization?

Member of the Scientific Programme Committee, Infection Prevention Society 2017-present, Member of the HIS education committee 2019-present, member of the HIS scientific programme committee 2016-present

| **Directorships**<br>Give full name(s) of organisation(s) and information on term served to date and retirement date. |
| --- |
| None |
| **4. Please indicate any potential future conflicts of interest.** |
| None |

## C: Consultation

### Internal consultation

**List of stakeholders**: HIS council and guidelines committee members, IPS council, representatives of Public Health Wales, Scotland and Northern Ireland (individual names redacted), representatives of Authorising Engineers (individual names redacted).

| Section | Comments | |
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| Mr Peter Hoffman – full response with name | | |
| Title | "Rinse water quality for flexible endoscopy …." Could be "Final rinse water quality for flexible endoscopy …." – there are rinse stages within the wider process (e.g. rinsing detergent before disinfection) that are not as critical as the final one. | Thank you, this has been addressed |
| Recommendations | "EB1.1 Follow recommendations of the national guidance to ensure endoscopes are appropriately reprocessed." Delete "the" – there are distinct home nation guidance sets, not one national guidance set. | Thank you, this has been corrected |
| Evidence-based recommendations | "EB1.2 Continue to control the presence of microorganisms in the water system which supplies the final rinse water to endoscope washer disinfectors" If there are well maintained bacteria-retentive filters between the water system that supplies water and the EWD, then bacterial levels in, for example, the RO reservoir system are of minimal relevance. Saying that these levels should be controlled with giving no details of the levels is not helpful. | Thank you for this comment. We feel this is still important because it is virtually impossible to identify when the bacteria-retention filters are beginning to fail and this failure is frequently reported in the literature. We hope that this is another step that can be achieved relatively easily but can help the endoscope suites to control the problem of the contaminated final rinse water |
| Evidence-based recommendations | EB1.3 – essentially the same comment as for EB1.2 | Please refer to the comment above |

| Section | Comments | |
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| Evidence-based recommendations | EB1.6 & EB1.7 – Same context as for EB1.2 & EB1.3 but with the addition that this is general maintenance of the water supply system and of no real relevance to the focus of this guidance. | Please refer to the comment above |
| Evidence-based recommendations | EB1.7 "Where water usage is high (e.g. in units performing a high number of procedures) …. "In addition to my comment above, without some indication of what "high" usage constitutes, this recommendation is not helpful. | Thank you for this comment. We recognize that the recommendation was not clear and that the high usage is difficult to define. We therefore rephrased this recommendation and ask the units to consider doing this based on the number of procedures, which is easier to define. |
| Expert recommendations | "ER1.1 Test the final rinse water for Total Viable Counts and for the presence of Mycobacteria spp. and Pseudomonas spp." Mycobacteria in EWD final rinse water are variously referred to in this document as Mycobacteria spp., environmental Mycobacteria and NTM. Mycobacteria spp. and NTM are possibly too broad to be useful classifications. Suggest that environmental Mycobacteria, the term used in the HTM, is least problematic. | Thank you, this is now addressed. The term 'environmental mycobacteria is used throughout the manuscript as suggested. |
| Expert recommendations | "ER1.1 Test the final rinse water for Total Viable Counts and for the presence of Mycobacteria spp. and Pseudomonas spp." Whilst there is a reference to Pseudomonas spp in the HTM, this is an element that should have been edited out and should not be perpetuated in this HIS guidance. It is a term with no good laboratory methods or definition. In practice it would probably mean any Gram-negative oxidase positive colony, though this would vary from testing laboratory to laboratory, and reporting this to a clinical microbiologist would not help inform any risk assessment or actions. The species of predominant and specific interest is Pseudomonas aeruginosa and this should be the term used throughout this guidance. | Thank you for this useful comment. We agree and we have rephrased this as suggested. |

| Section | Comments | |
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| Expert recommendations | " ER1.2 Consider testing for other microorganisms of concern, as based on local circumstances, e.g. Legionella spp. or Enterobacterales spp. " This recommendation is perplexing for several reasons. 1) It is not clear what "local circumstances" means or what these could be. This does not help those at the sharp end. 2) "Legionella spp" is not a good description on which to commission external laboratory testing. I suspect this could be Legionella pneumophila or Legionella pneumophila serogroup 1. "Enterobacterales spp." is a vast group of bacteria to commission testing for. If these are of significance, it is from disinfection failures rather than from final rinse water. | Thank you for this comment. To address the first issue, we included an explanation in the paragraph describing the current recommendations in UK guidance documents and the rationale behind them. We hope it is now clearer what the local circumstances are.<br><br>We have addressed the issue of *Legionella* and only refer *to Legionella pneumophila*.<br><br>We think that it is important to keep the information about *Enterobacterale*s because, whilst these are mostly associated with the failure of decontamination, these are also sometimes present in the hospital water systems. If there is evidence of this, we suggest that the rinse water is tested to ensure that these microorganisms have not contaminated the AER and endoscopes. This is supported by the recommendation in the BSI ISO document. We acknowledged it in the manuscript and therefore suggest that this may need to be monitored. To ensure that there is not too much emphasis on this, we have removed this from the recommendation itself but mention the importance of this in the rationale for the recommendations. |
| Expert recommendations | "ER1.3 Continue monitoring endotoxin levels in final rinse water". There is no sound clinical basis in specifying endotoxin levels in EWD final rinse water. This was a highly arbitrary standard in early EWD guidance that was copied across to the 2013 CFPP 01-06 and then edited out of the 2016 HTM, apart from one mention in the Operational Management volume (not a volume where endotoxin requirement should be discussed) that failed to be edited out – that was an error (I was on that working group; that was our intent). Elsewhere in this draft (section 9.2) it says "For endotoxins, revised | Thank you. We have rephrased this recommendation and use the word 'consider' which gives the reprocessing units more flexibility to decide whether this indicator is important. More information was also added to the rationale section. |

| Section | Comments | |
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| | limit of 30EU/ml is advocated in England for non-invasive endoscopes" that is not an accurate reading of what is admittedly a confusing document. What it does say is (HTM 01-06 part B) "2.36 EWD final rinse-water should not contain more than 30 endotoxin units/ml. Above this level there is a small risk that the toxin may affect the patient after some procedures. Routine endotoxin testing is therefore not required unless there is evidence of a major water supply problem indicated by the TVC and TOC results …." It does not exclude sterile body cavity scopes from this generality. That endotoxin is not in the testing methods HTM volume E (Testing methods) reinforces the lack of a reason to look for it – look at chapter 6 "Water system" – no endotoxin testing requirement or inclusion in the testing schedule.<br><br>The specific section addressing endotoxin is in HTM 01-06 part B paragraphs 2.35 to 2.38 – there is no mention of a special requirement for "invasive" scopes there.<br><br>Throughout this guidance, could the approach be that stated in the most relevant section of the HTM (part B, paragraph 2.36) "EWD final rinse-water should not contain more than 30 endotoxin units/ml. Above this level there is a small risk that the toxin may affect<br><br>the patient after some procedures. Routine endotoxin testing is therefore not required unless there is evidence of a major water supply<br><br>problem indicated by the TVC and TOC results (see Table 3 in this document and Table 2 in HTM 01-06 Part E – 'Testing methods').<br><br>The approach only to test for endotoxin in exceptional situations only should apply throughout this guidance. | |

| Section | Comments | |
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| Expert recommendations | "ER1.4 Laboratories must use the methodology described in BS EN ISO 15883-1:2009+A1:2014 for Total Viable Counts (TVC) and endotoxins" - This is guidance – not "must".<br><br>What 15883-1 (2009) says is "6.4.2.3 Tests for bacterial endotoxins If a requirement for the level of bacterial endotoxins in the final rinse water is given in other parts of ISO 15883, determine the level by the limulus amoebocyte lysate (LAL) test with a sensitivity of 0,25 EU/ml, or better, using the method given in the European Pharmacopeia (EP) or United States Pharmacopeia (USP)." This just refers to other guidance – there is no methodology in the referenced source.<br><br>For TVC "6.4.2.4 Tests for microbial quality Make a total viable count by membrane filtration of not less than 100 ml final rinse water sample. Place the filter on R2A-medium in accordance with Annex D, or other suitable low nutrient medium and incubate at 28 °C to 32 °C for a minimum of 5 days to determine the aerobic mesophillic viable count. Other methods, including rapid methods such as ATP bioluminescence, that have been validated to be at least equivalent to the above method in terms of both specificity and sensitivity can also be used". There are variations in the UK guidance documents e.g. HTM 01-06 part E "6.80 Filter a 100 mL aliquot of the sample through a 0.45 µm filter. Aseptically transfer the filter to the surface of a R2A, TSA or YEA plate and incubate at 30±2ºC. Examine the plates after 48 hours' incubation and at five days. If an urgent report is required, preliminary readings could be made at 48 hours' incubation and a final report issued after five days' incubation" | Thank you, this is now rephrased. |

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| | There is no “must” about following the EN 15883 method. That statement should be modified. | |
| Expert recommendations | “ER3.2 Where TVC is >100cfu/ml or when indicator microorganisms are present, do not reprocess any endoscopes in an affected endoscope washer-disinfector.” I think there needs to be a more considered, more risk assessment based approach here. What the English guidance says is 01-06 part e, table 2 “Risk assessment required to consider taking EWD out of service until water quality improved”. This was carefully worded such that taking the EWD out of service was not mandatory. The counts are per 100ml. There is likely to be less than 1 mil final rinse water left on or in a processed scope – so if 100 cfu per 100m, that equated to 1 environmental bacterium per scope. If the choice is between compromising an important diagnostic service such as bowel screening and the introduction of 1 environmental bacterium the body’s most contaminated site, then the EWD should stay in service for those lower risk scopes. This needs to be a local decision but those making the decision need to have that level of comparative risk assessment set out as an example. “do not reprocess any endoscopes in an affected endoscope washer-disinfector …” is not a helpful requirement. | Thank you for this comment. This recommendation is in line of the Scottish recommendation and is in fact already relaxed; the Scottish guidance recommends that the AER is not used at the threshold level of 10-100cfu/100ml for high-risk endoscopes, which we do not think is necessary. We do agree that the risk is very low (as the responded noted, may be as little as 1 per 1ml), the experts agree that this is not an unreasonable standard to expect from the units. These standards have been in place for the last 20 years and working party believe that they helped in preventing rinse water related incidents which existed before they were in place. This rather restrictive standard ensures that action is taken before the level of microorganisms in the rinse water becomes unmanageable. As a result, this standard ensures that the rinse water quality does not achieve the cfu levels at which they are a risk to the patients. Thus, this standard helps us relax another recommendation which has been included in the Scottish guidance that the patients should be traced and followed. We think that maintaining consistently low TVC means that the endoscope suites will not be in a position that they will have to trace patients due to the contaminated rinse water. We provided more explanation in the preceding sections and make it clear that this recommendation is in line with the Scottish guidance. |
| Expert recommendations | “ER3.3 Where TVC is >100cfu/ml or when indicator microorganisms are present, recall and reprocess all unused reprocessed endoscopes” If | Please see the comment above, our experts agree that this is not an unreasonable standard to maintain. We have changed this to ‘consider reprocessing’ to allow for more flexibility for the units. |

| Section | Comments | |
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| | changes are accepted to ER3.2, this should be revised accordingly - here and elsewhere | |
| Expert recommendations | "ER4.1 Ensure that the final rinse water meets other (non-microbial) standards of safety for potable water". Drinking water has many criteria irrelevant to EWD final rinse water. These tests would be costly and irrelevant. The standards in HTM 01-06 and the home nation variants should suffice. | Thank you for this comment. We do not say that these are the indicators that need to be tested routinely. The paragraph above (section 9.4) makes it clear that we cannot make this recommendation. There are other ways of ensuring that the water is of sufficient quality without the routine testing. We refer to this in the Appendix. |
| Expert recommendations | "ER5.1 Ensure that microorganisms are not re-introduced during the drying and storing of the endoscopes." This is aspirational but not quantifiable. Open to varying interpretation. Not helpful in a guideline. | Thank you, we rephrased this recommendation that we recommend further actions we which do recognize are outside of scope of this guidance |
| Expert recommendations | "GPP5.1 For flushing the endoscope during the procedure, use sterile water if possible or use water which is at least the same quality as the final rinse water." This is off-topic and does not relate to the guideline intent. (+ what is "GPP") | Thank you. We think that despite being off-topic, this is a relevant point which should be addressed as a Good Practice Point (we have provided an explanation what GPP is in point 6.5). We feel that considering the vast resources spent on the rinse water monitoring (for a good reason as the literature indicates), its aim is weakened if the water of the lesser quality is introduced into the endoscope at this stage. |
| 8.1 | "In one of these studies,15 a new nurse accidentally reversed the taps in the endoscope reprocessing room, resulting in the filtered water being used for handwashing and the tap water being used for rinsing the endoscopes. This resulted in transmission of Legionella pneumophila to three patients undergoing endoscope-assisted transoesophageal echocardiography". I do not have access to the full paper but this appears to be just TOE/TEE, not endoscope assisted. The link is epidemiological and there could have been other sources – if there was Legionella in the tap water to the endoscopy unit, it was likely to have been present far more widely in the hospital's water | We appreciate this point and we do agree that *L pneumophila* could have been introduced via a different route. We have added a clarifying statement that this was authors' conclusions. Regardless of the results, we believe that our conclusions do not change – the evidence from the outbreak studies, which were published after the rinse water standards were introduced, demonstrates the clear reduction in the incidence of infections due to the contaminated final rinse water of AER. When these infections occur (and none did in the UK), these are now isolated incidents. Regardless of the results of this study, we consider the risk |

| Section | Comments | |
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| | system. Other routes more prone to aerosolization are more likely. Does a more critical analysis of the evidence really support "This resulted in transmission of Legionella pneumophila to three patients undergoing endoscope-assisted transoesophageal echocardiography"? | from the rinse water is now very low, thanks to the standards introduced 20 years ago. |
| 8.2 | "Furthermore, the Working Party concluded that untreated tap water, which is known to contain microorganisms is not suitable for the use of rinsing endoscopes after re-processing. The evidence suggests that filtered water cannot be assumed to be safe and that additional measures (e.g. disinfection and monitoring) are needed to ensure adequate quality." My understanding is that in Wales where water of adequate softness is supplied via mains, then that water is filtered and used for EWD process water – see Table 1 in WHTM 01-06 Part E. There are 2 points here 1) "untreated" is too vague and probably an inappropriate description – see my point about the WHTM standard. 2) Water filtered through microbial-retentive filters is microbiologically safe if no microbial recontamination occurs. Stored RO water can be microbiologically contaminated but will always pass through a bacteria-retentive filter before entering the EWD. The statement "filtered water cannot be assumed to be safe" is not helpful or accurate. | Thank you, this is a good point and we have rephrased the statement to make it clearer. We used the term 'unfiltered' water and we also clarified that there is no guarantee that having filtration in place results in microorganisms being retained. The evidence from this section demonstartes that the filter failures are frequently identified thanks to monitoring or because a pseudo-outbreak occured. |
| 8.3 | "……. reported that throughout the study period, Pseudomonas spp. and NTM were occasionally grown from rinse water samples " spell out NTM on first use (if used – see next). Use same term throughout – elsewhere "Mycobacterium spp" or "environmental mycobacteria" are also used – these are the same thing in this context. The term "environmental mycobacteria" is probably the most appropriate. | thank you, we have used your advice and are now referring to environmental mycobacteria in the entire document. |

| Section | Comments | |
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| 8.3 | "Upon the review of the above evidence, the Working Party emphasised that rinsing stage is not efficient in removing microbial contamination and that appropriate actions need to be taken to ensure that this contamination is removed at earlier stages, e.g., manual pre-cleaning/rinsing, disinfection." This is an odd statement. Washing removes contamination, not rinsing. A rinsing stage would never be reasonably considered to be a contamination removal step. For the final rinse, it is always purely to remove process chemicals. Specifying "e.g., manual pre-cleaning/rinsing, disinfection" also ignores the washing phase in the EWD. This statement devalues other, more considered recommendations. | Thank you, we have rephrased to make it clearer that we wanted to emphasise the importance of previous stages of decontamination. |
| Evidence based recommendations | "EB1.7 Where water usage is high (e.g. in units performing a high number of procedures) consider changing membranes/filters more frequently". This is difficult for users to interpret – what precisely is "high"? If this is not defined, how does this statement help? | Thank you, this comment was addressed (please see page 3) |
| Recommendations | "ER1.2 Consider testing for other microorganisms of concern, as based on local circumstances, e.g. Legionella spp. or Enterobacterales spp." For Enterobacterales, do not use "spp" (i.e. species of one genus) for a family of several bacterial genera. Just use "Enterobacterales" or "specific Enterobacterales". This needs to be thought through and I am not sure what the intent is. | Thank you, we have explained our position on this (and appropriately rephrased in the guidance), please see the comment on page 3 |
| Table 1 | "Compulsory indicator microorganisms" – guidance is not compulsory + these are microbes of significance, not indicators. Suggest use "Microorganisms of significance" | Thank you, we have used your suggestion. |
| Table 1, endotoxins | HTM 01-06 "<30 EU/ml for non-invasive endoscopes, <0.25 EU/ml for scopes passed into sterile body cavities". HTM 01-06 part c "3.10 In | This table only acts to support the summary of the recommendations listed in different guidance documents. This helps us articulate what |

| Section | Comments | |
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| | general: endoscopes that, in use, are passed into sterile body cavities are considered to be invasive and should be free of viable microorganisms and endotoxins …" This is an unfortunate copy from previous editions and does not relate to a clinical reality. The HIS guidance should not perpetuate this error. Elsewhere in the 01-06 series it is contradicted, in the section dealing specifically with endotoxin, by saying: HTM 01-06 part B "2.36 EWD final rinse-water should not contain more than 30 endotoxin units/ml. Above this level there is a small risk that the toxin may affect the patient after some procedures. Routine endotoxin testing is therefore not required unless there is evidence of a major water supply problem indicated by the TVC and TOC results …." | other experts are recommending but we make our conclusions and the rationale for this is explained in the main text. Unfortunately, we are not in a position to mention that this was an editorial error (as far as we know, there were no corrections to this document released after the publication). We follow the SB ISO recommendation for this. |
| 9.2 | "For the indicator organisms such as Pseudomonas spp., Mycobacteria spp., Legionella spp. or Enterobacterales spp., all guidance documents retain the previous standard that these microorganisms should be absent from the rinse water." Not legionella - HTM 01-06 part b "2.42 Subject to risk assessment, testing the final rinse-water for legionella may not required. If the detection of legionella is considered necessary, the method described in Health Technical Memorandum 04-01 should be applied."<br><br>Enterobacterales – not referenced as required to be absent from final rinse water in the HTM | Thank you, we have addressed this in the previous comments above. *Enterobacterales*, which are not referenced in the HTM, are mentioned in BSI ISO standards as potential microorganisms that need to be tested (not routinely). |
| 9.2 | "For endotoxins, revised limit of 30EU/ml is advocated in England for non-invasive endoscopes.3 However the guidance also states that endoscopes which are introduced into sterile body cavities should be free of endotoxins. From this recommendation, a presumption must | Thank you, We have addressed an issue of endotoxins previously, please see our response above. |

| Section | Comments | |
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| | therefore be made that the previous limit derived from Sterile Water for Injection of 0.25EU/ml should apply in such cases. This infers that if an EWD is used for processing invasive endoscopes (which is a common practice for many endoscope reprocessing suites), the facility needs to apply a more stringent threshold for endotoxin level to ensure patient safety." Not specified - HTM 01-06 part B "2.36 EWD final rinse-water should not contain more than 30 endotoxin units/ml. Above this level there is a small risk that the toxin may affect the patient after some procedures. Routine endotoxin testing is therefore not required unless there is evidence of a major water supply problem indicated by the TVC and TOC results …." It does not exclude sterile body cavity scopes from this generality. This is the main endotoxin guidance in the HTM – a poorly edited minor reference in another volume does not negate this more detailed consideration. For context: There will often be low numbers of bacteria in the bladder (a "sterile" body cavity). These will contain and release endotoxin. This is clinically insignificant. The HTM is not a perfect document and this HIS guidance should not perpetuate its editing errors. All references to endotoxin free water for "invasive" scopes in the 2013 CFPP 01-06 were edited out for the 2016 HTM except one inadvertently missed. | |
| Figure 1 | "Figure 1. Actions required for EWD following the results of rinse water testing". Where does "stop reprocessing endoscopes" if >100 cfu come from? The HTM requires consideration of EWD use cessation, it does not mandate it. | This recommendation is in line with the Scottish guidance, which we do mention in the section above and we provide an explanation why we align this recommendation with their document. |
| 9.3 | "9.3 Actions for the management of endoscopes and patients: Some endoscopes are considered to present a higher risk than others, e.g. those used for more invasive procedures such as ERCP or endoscopies | Thank you for this. The stratification into high and low risk endoscopes is also recommended in other UK guidance documents. |

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| | that breach the mucous membranes". Any biopsy, one of the main purposes of endoscopies, will breach mucous membrane e.g. colonoscopies where a biopsy is taken breach the mucous membrane – colonoscopes are not high risk. Duodenoscopes for ERCP travel through a contaminated body cavity – these are only of particular risk in their structural challenges to effective decontamination, not in their use application. | We do acknowledge that this statement is correct. However, for most endoscopes we are not talking about sterility but minimising the risk of introducing non-commensal microorganisms from instruments that have a complex structure and are difficult to clean. For this reason, clinically, we always stratify e.g. ERCP as high-risk procedure (or high-risk device for those which are used in ERCP) as we know that there is a high risk of introducing an infectious microorganism. Specifically for ERCP, pancreatitis (5-15%), which results in hospitalisation and which in 20% of cases results in necrosis of pancreatic tissue and or multi-organ failure is a concern. Although we recognise and manage this risk pre- and post-procedure, stratification into high-risk devices allows an appropriate recognition and minimising the risk by taking these extra precautions.<br><br>Similarly, cystoscopes, bronchoscopes, which also go through a non-sterile area, also fall into the same category. |
| 9.3 | "When the water quality test returns unacceptable results (>100cfu/100ml or indicator microorganisms are present), the EWD must be taken out of action for all endoscopes." Same point as for Figure 1 and where this is repeated elsewhere. | Please see our response above. |
| Table 4 | "High risk for introducing microorganisms: …….. Duodenoscopes used for ERCP " On what basis are ERCP duodenoscopes, scopes that pass through contaminated body cavities, deemed high risk? Yes, there are problems with duodenoscopes but these are not rinse water related. | Please see our response above. |
| Table 4 | Should "Urethroscopes" be ureteroscopes? | Thank you for this comment, we have made a suggested correction. Urethroscopes (those passed into the bladder) should be considered |

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| | | low risk while ureteroscopes (those passed into kidneys) should be considered high risk |

**Please note:** A total of five responses were received at the internal consultation stage. Some responses were not included either because the respondents did not wish their comments to be public or because the respondents did not provide a signed conflict of interest form (COI). According to our policies, the responses received without a completed COI will be addressed at the Working Party's chair. Respondents who were involved in the internal stage and whose comments were not included in this table can request the Working Party's response (to their comments only) by emailing consulations@his.org.uk.

## External consultation

TBC