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Abbreviations

ASERNIP-S	Australian Safety and Efficacy Registry of New Interventional Procedures – Surgical
COPD	chronic obstructive pulmonary disease
CT	computed tomography
DALY	disability-adjusted life-year
MeSH	medical subject heading
MRI	magnetic resonance imaging
NHMRC	Australian National Health and Medical Research Council
PET	positron-emission tomography
PICO	population, intervention, comparator and outcome
TNM	tumour–node–metastasis
WHO	World Health Organization

Overview

Across the World Health Organization (WHO) Western Pacific Region, as in most parts of the world, the population is rapidly ageing. This is likely to place additional burdens on the provision of health care services to this demographic. Many medical devices are available that may benefit elderly people, although these devices may be expensive or may not be available in all countries. These factors impede equitable access to medical devices.

The clinical focus of this report has been defined as the five health conditions that cause the greatest loss of disability-adjusted life-years (DALYs) for older people (defined as people aged 60–79 years) in the Western Pacific Region. Five main health conditions, with 19 associated sub-topics, were identified:

- cardiovascular diseases;
- malignant neoplasms;
- respiratory diseases;
- sense organ diseases;
- neuropsychiatric conditions.

This report provides a literature-based review of medical devices needed by older people. The results have been used to create lists of devices categorized in terms of whether they are preventive, diagnostic or therapeutic. Broad clinical safety and effectiveness information has also been provided when available, although the volume and quality of this information vary widely between each device. Detailed information on the safety, efficacy and cost–effectiveness of each device was beyond the scope of this report. Where possible, all identified medical devices were categorized according to the definitions presented by the Global Harmonization Task Force.

The methodology used for this report was a rapid systematic review and so was limited in one or more areas in order to shorten the time for its completion. Modifications have been made in at least one of the following areas: search strategy, inclusion criteria, assessment of study quality and data analysis. It is considered that these amendments do not significantly alter the overall findings of a rapid review when compared with a full systematic review. These limitations have been adhered to mainly by restricting the specific clinical questions asked. These limits were applied following the requirements of the specific review, in agreement with WHO. For a more comprehensive understanding of this topic, a broader analysis of the literature may be required. As such, readers should be aware of the limitations of this review.

Of the 3278 articles retrieved in the searches, 1535 have been included in this report. Some topics were highly represented in the literature, for example topics related to cardiovascular diseases. In these cases, criteria (limiting to high-quality levels of evidence and more recent publications) were applied to increase the overall quality and relevance of the pool of literature. Other topics were less highly represented, for example cancers of the mouth and oropharynx, and lymphoma; these topics were not limited to study type. This variability between the 19 independent searches reflects the differences in the research and publication focus of certain specialties, and shows a certain level of publication bias. Some medical devices, such as magnetic resonance imaging scanners and endoscopes, were commonly identified across many studies and many conditions, but other devices, such as diagnostics, especially in vitro diagnostics, were identified infrequently. Basic medical devices, such as scalpels and other surgical instruments, surgical tables, anaesthesia machines and physiological monitors, were usually not reported in the included studies; this is probably related to the use of these standard pieces of equipment being well established. This may reflect the fact that medical devices reported in the peer-reviewed literature are generally used in locations of medium- or high-resource settings, and there is an assumption

that these basic devices are readily available and highly diffused across all jurisdictions.

Care was taken not to overinterpret search results, and information was provided as identified from the source publications. Some devices were explained in detail in terms of their use and clinical utility, but other devices were described very briefly; some devices were described in a generic manner but others according to their trade name. It is likely that for each example identified, a number of alternatives are available in addition to the specific devices that were mentioned, and the results of this report are not intended to be a comprehensive list. In many cases, the specific use of a medical device, how and why it was used, and its clinical significance were not clear from the information provided in the published study. Many studies report a range of similar types of devices, including tests used during the course of the study. In many cases, there may be a range of options of devices for a specific indication. The clinical application of the information from these studies in a real-world context may not always be clear, and a specific comment on the comparative safety and effectiveness of the alternative devices was not possible.

Although the list of topics was based on the top five causes of losses of DALYs for older people in the Western Pacific Region, regionality has not been a constraint in the search methodology; therefore, the outcomes of searches reported here may be broadly applicable to any country. The specific health problems in ageing populations within the Western Pacific Region, and the way in which they are treated, will be highly varied because the region includes a large number of countries over a wide area. The majority of studies were done in high-resource settings, and no studies provided information on devices and outcomes specifically related to low-resource countries. There is a lack of studies reporting on the clinical outcomes of basic or essential devices associated with service delivery, perhaps because the utility of these has been established through historical experience.

Clinical issues of safety and effectiveness are likely to be cross-jurisdictional. Cost-effectiveness for each device would be procedure-based where relevant and would likely vary from country to country, and will be the focus of future research. The basic elements of service delivery would remain similar, although the availability and cost of different parts of the service could vary widely and be dependent on current skills and infrastructure in each country. It is intended that this report will inform future research, with the aim of improving access to devices of elderly people across the different countries of the Western Pacific Region.

To achieve effective clinical management of any health condition, all aspects of the management pathway must be considered. The true clinical effectiveness of an individual device or intervention can be established only within the framework of preventive, diagnostic and therapeutic strategies.

1. Introduction

A strategic objective of the World Health Organization (WHO) plan for 2008–2013 *(1)* is to ensure the improved access, quality and use of medical products and technologies. Furthermore, WHO recognizes the important role that medical devices play as a crucial component of health care delivery.

Consequently, WHO has established a new initiative to facilitate the development and access to appropriate medical and assistive devices at a lower cost for ageing populations (defined as people aged over 60 years) to enable them to remain healthy, active and independent for longer.

With financial support from the Japanese Ministry of Health, Labour and Welfare, WHO has begun research regarding this initiative in the Western Pacific Region. To prepare a foundation for future decisions, a detailed mapping of the need for medical devices for older people in the region is to be conducted. This will determine the technological needs for diagnosis and treatment of the diseases of this population. Further research and surveys will be conducted at a country-by-country level to ascertain the availability and affordability of these devices. For low-income countries and low-resource settings, needs of priority core devices will be defined, especially for devices that may not be available. The initial work will allow WHO to develop preferred product profiles for devices identified as essential, but not currently available, to facilitate the development and transfer of suitable technologies to produce devices at lower costs. Finally, centres of excellence for medical and assistive devices for ageing populations in the Western Pacific Region will be strengthened or created to ensure that these devices are used in a clinically appropriate manner.

This initial report is a literature-based systematic review of needed medical devices. It is intended that this report will inform future research, with the aim of determining the need for medical devices and thus improving access of elderly people to needed devices across the Western Pacific Region.

1.1 THE GLOBAL AND REGIONAL CHALLENGE OF AN AGEING POPULATION

The proportion of the population classified as older is growing worldwide. Current data suggest that approximately one in nine people is aged 60 years or over. The global population is ageing as a consequence of increased life expectancy at birth and declining fertility rates. Developing countries across the world are expected to experience accelerated rates of population ageing compared with developed countries *(2)*. The rate of population ageing in the Western Pacific Region is expected to be faster than in almost any other WHO region. It is estimated that approximately 23% of the Western Pacific population will be over 65 years of age by 2050. The proportion of the population aged over 60 years in Cambodia, the Lao People's Democratic Republic and Papua New Guinea is expected to double in less than 30 years, a process that took over 50 years in Australia and New Zealand *(3)*.

In Japan, the challenge of population ageing is particularly pronounced, as people over the age of 65 years account for 23% of the population while people under the age of 15 years only account for 13% of the population *(4)*. This is attributed to a combination of low birth rates and the longevity of the population in Japan, which has the world's highest life expectancy. Consequently, the most common causes of death in Japan have shifted from infectious diseases to malignant neoplasms, heart diseases and cerebrovascular diseases *(5)*.

The aged population is also characterized by an overrepresentation of women. In the Western Pacific Region there are approximately 90 men for every 100 women over the age of 60 years. The preponderance of women in the aged population has increased with the reduction in maternal

mortality and drop in overall fertility rates, which means that a greater number of women reach older age *(3)*.

1.2 AGE-RELATED DISEASE IN THE WESTERN PACIFIC REGION

Global improvements in medical care, the ageing of the population and increased provision of public health interventions such as vaccinations have caused changes in the types of disease that affect populations. In the past, infectious diseases were the primary causes of mortality; now, the primary causes of global mortality are noncommunicable diseases such as cardiovascular disease and neoplastic disease. In 2012, it was estimated that approximately half of the global burden of disease was attributable to noncommunicable diseases. In the Western Pacific Region in 2012, noncommunicable diseases accounted for 84% of estimated all-cause mortality and 76% of all projected disability-adjusted life years (DALYs) *(6,7)*. People over the age of 60 years accounted for 82% of all mortality due to noncommunicable diseases.

The leading causes of mortality in the Western Pacific Region are represented in Table 1. Communicable, maternal, perinatal, and nutritional conditions accounted for 8% of all-cause mortality, injuries accounted for 8% of all-cause mortality, and noncommunicable diseases accounted for 82% of all-cause mortality. Only causes that account for more than 10% of all mortality are included in Table 1. Table 2 includes the major causes (10% or more) of projected DALYs for 2008 in the Western Pacific Region. The largest proportion of mortality due to noncommunicable diseases occurred in people over the age of 60 years.

Table 1 Estimates of death by cause,[a] Western Pacific Region, 2012 (published in 2014) *(7)*

Cause of mortality	All ages		Age > 60 years: total estimated deaths	Age > 60 years vs all ages: estimated deaths (%)
	Total estimated deaths	All causes of mortality (%)		
All causes	12 960 505	NA	9 933 496	77
Noncommunicable diseases	10 896 059	84	8 981 580	82
Cardiovascular disease	5 371 830	41	4 688 555	87
Malignant neoplasms	2 900 829	22	2 131 683	73
Cerebrovascular disease	2 703 356	21	2 375 306	88
Ischaemic heart disease	1 831 039	14	1 597 367	87
Respiratory diseases	1 302 109	10	1 220 781	94

[a] Major causes of death; figures numbers should not sum.

Table 2 Major contributions to projected disability-adjusted life-years (DALYs), Western Pacific Region, 2012 *(6)*

Cause of DALY	All ages		Age > 60 years: total estimated DALYs	Age > 60 years vs all ages: estimated DALYs (%)
	Total estimated DALYs	All causes of DALYs (%)		
All causes	496 817 257	NA	213 449 156	43
Noncommunicable diseases	376 359 807	76	191 851 690	51
Cardiovascular disease	112 302 635	23	80 421 955	72
Malignant neoplasms	74 241 072	15	40 188 854	54
Communicable diseases	65 774 588	13	9 869 564	15
Cerebrovascular disease	55 121 610	11	41 084 201	75
Injuries	54 682 868	11	11 727 900	21

NA: not applicable.

Cardiovascular disease and malignant neoplasms account for a large proportion of mortality in both men and women aged 60 years and over, but cancer mortality rates are much higher for men than for women. Age is a non-modifiable risk factor for age-related diseases, and some health conditions are strongly associated with ageing, including atherosclerosis, hypertension, diabetic complications, cancer, benign prostatic hyperplasia, Alzheimer's disease, Parkinson's disease, age-related macular degeneration, osteoarthritis, osteoporosis and seborrhoeic keratosis *(8)*.

The leading conditions that bring about death from cardiovascular disease are ischaemic heart disease and cerebrovascular disease. Approximately 57% of deaths from cardiovascular disease are associated with at least one of the following risk factors: high blood pressure, high cholesterol, high blood glucose, physical inactivity, being overweight or obese, and low fruit and vegetable intake. Of these risk factors, high blood pressure is the leading cause of cardiovascular deaths *(9)*.

Risk factors for specific cancers vary, and risk factors for certain cancer sites remain poorly defined. Lung cancer is the leading cause of mortality due to cancer among both men and women, and tobacco use is associated with the majority of all deaths from lung cancer. High body mass index, low fruit and vegetable intake, physical inactivity, tobacco use, alcohol use, unsafe sex, urban and indoor air pollution, and unsafe health care injections are risk factors attributing to 35% of all cancer mortality. Infections such as viral hepatitis, liver flukes, human papillomavirus infection and *Helicobacter pylori* infection are responsible for 18% of mortality from cancer *(9)*.

Vision and hearing problems are also more likely in older age. In the Western Pacific Region, 44% of people aged 60 years or over experience vision loss and 26% experience hearing loss. Of those people, 10% will become blind and 25% will experience severe hearing loss or deafness. The majority of people affected by vision or hearing loss live in low- and middle-income countries *(3)*.

Many risk factors for the conditions of interest are associated with modern lifestyle and dietary choices. As societies depart from more traditional modes of living, the risk factors for these conditions may become more prevalent across the population. Another consideration is that in older patients comorbidity is almost always present *(10)*, and this may affect the quality of life and choice or availability of treatment. The health problems in ageing populations within the Western Pacific Region, and the way in which they are treated, are highly varied, as the region accounts for a large number of countries over a wide area and at different stages of development. There is increasing recognition of the role that lifestyle factors play in the development of disease later in life; the prevalence and distribution of risk factors such as poor nutrition, physical inactivity,

tobacco use and high alcohol consumption varies considerably between countries in the Western Pacific Region.

1.3 DEFINING OLD AGE

There is no clear, universally accepted definition of "elderly" or "aged". The concept of ageing encompasses chronological age, changes in social roles, and changes in physical, mental and functional capabilities. The age at which someone is considered elderly varies between countries and is often associated with the age at which a person becomes eligible for pension schemes or retirement: this is usually between 60 and 65 years *(11)*. Ageing is a diffuse biological process that can be described as the accumulation of deleterious changes in cells and tissues that occur with advancing age. Defining old age is challenging as its onset is not defined by a single physiological phenomenon and its manifestation varies across individuals. The process of ageing involves physical, physiological and social changes and is considered by many to be a stage of life in which a person's functional, mental and physical capacity decline *(2)*. Old age is also associated with an increased propensity to disability and disease as a consequence of the cumulative effect of a range of deleterious changes in the body. Although chronological age is the common basis for determining old age by governments, demographers and researchers, it may not be equivalent with an individual's biological age *(12)*. An increase in a person's chronological age does not necessarily lead to ill health.

The United Nations applies 60 years as the cut-off for older people, so the health conditions that are the subject of this project were identified by examining the top five causes of loss of DALYs in people aged 60–79 years in the Western Pacific Region.

1.4 AGEING AND DISEASE

Damage at the cellular level that is attributed to the process of ageing has been linked to the pathology of certain diseases associated with the ageing population, such as atherosclerosis and cancers *(13)*. The relationship between the aetiology of age-related diseases and the physiological processes that underpin ageing is not well understood. The process of ageing, like all biological processes, is regulated by molecular signalling pathways and genetic transcription factors. There is a research focus on identifying familial aspects to ageing and longevity, including specific genetic mutations that may confer a longer lifespan and slow the onset of age-related disease *(14)*.

The development of age-related diseases reflects the cumulative effect of the ageing process as well as the impact of lifestyle and environmental factors over many years. Strategies to lower the risk of developing many age-related diseases may be focused on modifying lifestyle or environmental factors, the early initiation of which may help to promote healthy ageing.

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2. Methods

This project was requested by WHO to inform a consultation process on the need for medical devices in the ageing population in the Western Pacific Region. The work was focused on five main health conditions and 19 specific topics. The methodology in this report is not comprehensive. Rather, this is a rapid systematic review in which the methodology has been limited in one or more areas in line with the requirements of the report. Thus, modifications have been made in at least one of the following areas: search strategy, inclusion criteria, assessment of study quality, data analysis, and limitations pertaining to the questions of the review. It is considered that these amendments do not significantly alter the overall findings of the rapid review when compared with a full systematic review.

This rapid review is a limited evidence-based assessment based on a restricted systematic search of studies published in the peer-reviewed literature on the specific review topic. As a result, this rapid review may be used to inform certain questions on the topic. For a more comprehensive understanding of the topic, a broader analysis of the literature may be required. As such, readers should be aware of the limitations of this review.

The project methodology was arranged with reference to the population, intervention, comparator and outcome (PICO) criteria *(1,2)*.

2.1 POPULATION

The populations of interest were defined through the health conditions that were the top five causes for loss of DALYs in 2010 for older people (aged 60–79 years) in the Western Pacific Region:

- cardiovascular diseases:
  - ischaemic heart disease
  - cerebrovascular disease
  - hypertensive heart disease
- malignant neoplasms:
  - trachea, bronchus and lungs
  - colon and rectum
  - prostate
  - lymphoma
  - breast
  - stomach
  - liver
  - oesophagus
  - mouth and oropharynx
- respiratory diseases:
  - chronic obstructive pulmonary disease (COPD)
- sense organ diseases:
  - glaucoma
  - cataracts
  - refractive errors
  - adult-onset hearing loss
  - macular degeneration
- neuropsychiatric conditions:
  - Alzheimer's disease and other dementias.

Therefore, there were 19 groups of populations associated with the above topics, broadly grouped within five major health conditions.

2.2 MEDICAL DEVICES

Medical devices are required in all aspects of clinical practice, and many are the focus of a substantial commitment in terms of research and development worldwide. Effective medical devices are needed in the management of many chronic health conditions and, if selected, purchased and used appropriately, may be instrumental in addressing the priority health care needs of a population. Medical devices are also a source of cost to health care systems, however, and their regulation and assessment require a significant investment of time and resources. The utility of a particular device to a specific population is influenced by a number of factors, including:

- the priority health care needs of the population, which may be informed by population health issues or by broader policy commitments;
- the level of public health infrastructure available in the country, which may vary widely between

different towns or between rural and urban areas;
- the availability of resources to purchase needed devices and complementary technologies;
- the cost of the medical device (including purchase cost and ongoing costs);
- the skill and experience level of the end user of the device;
- regulatory issues and ease of access to the market, and other issues of relevance to the device manufacturer.

Thus, the need for a particular medical device is highly context-specific. As the global population ages, the priority health care areas of the population also change. There is now a growing need associated with the global burden of disease to prevent, diagnose and treat chronic diseases such as cardiovascular disease and neoplastic diseases. As the intended treatment population changes, there may also be shifts in research priorities to accommodate the aged population, such as towards minimally invasive technologies or home and self-care devices *(3)*.

New medical devices are frequently developed and tested in high-resource settings, and hence their applicability to low- or medium-resource settings needs to be considered. The factors involved in setting priority health care areas and identifying the medical devices needed to address them are many and complex. The focus of this project is to identify medical devices used in the prevention, diagnosis and treatment of several health conditions that affect the ageing population, including cardiovascular diseases, malignant neoplasms, respiratory conditions, neuropsychiatric conditions and sense organ diseases.

The term "medical device" covers a broad range of medical equipment, from highly sophisticated diagnostic machines to simple implements. Medical devices are essential for patient care and are defined as:

> …any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
>
> - diagnosis, prevention, monitoring, treatment or alleviation of disease;
> - diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
> - investigation, replacement, modification, or support of the anatomy or of a physiological process;
> - supporting or sustaining life;
> - control of conception;
> - disinfection of medical devices;
> - providing information by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means (4,5).

2.3 INTERVENTION

The intervention for this project is defined as "needed devices". The devices were categorized as:

- preventive
- diagnostic
- therapeutic.

2.4 COMPARATOR AND OUTCOME

As the aim of this project is to inform on needed devices, no specific comparator and outcome have been defined. These criteria would probably vary widely between the different conditions and topics under investigation.

2.5 LITERATURE SEARCH

A systematic approach was taken to identify relevant literature. PubMed (http://www.ncbi.nlm.nih.gov/pubmed) was used as the primary search engine, mainly because it accesses a range of databases (including Medline and others) and its indexing is frequently updated.

2.6 SEARCH STRATEGY

The searches were undertaken in two steps. A core search strategy was developed to identify non-disease-specific devices used for the prevention, diagnosis and treatment of older people. A wide range of Medical Subject Heading (MeSH) terms and keywords were used. This strategy was consistently applied to each of the 19 topics and was built as follows:

#1	aged [MeSH terms]
#2	health services for the aged [MeSH terms]
#3	aged
#4	senior
#5	elderly
#6	geriatric
#7	#1 OR #2 OR #3 OR #4 OR #5 OR #6
#8	equipment and supplies [MeSH terms]
#9	assistive devices [MeSH terms]
#10	surgical instruments [MeSH terms]
#11	device*
#12	aid*
#13	equipment
#14	armamentarium
#15	appliance*
#16	instrument*
#17	apparatus
#18	good*
#19	implement*
#20	material*
#21	machine*
#22	#8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21
#23	diagnosis [MeSH terms]
#24	rehabilitation [MeSH terms]
#25	primary prevention [MeSH terms]
#26	secondary prevention [MeSH terms]
#27	after treatment [MeSH terms]
#28	therapeutics [MeSH terms]
#29	diagnos*
#30	therap*
#31	treatment*
#32	prevention
#33	monitoring
#34	screening
#35	rehabilitat*
#36	alleviat*
#37	#23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36
#38	#7 AND #22 AND #37

For each of the 19 separate topics, a range of keyword and MeSH terms were used to create a disease- or condition-specific search that was applied to the above core strategy. The specific search strategy used for each of the 19 conditions is provided in the relevant section of this report.

Using this methodology we identified a range of devices associated with the older population, focused on each of the 19 topics of interest.

2.7 ADDITIONAL SEARCH CRITERIA AND FILTERS

In order to focus the literature search results to the most relevant and high-quality literature, a small number of additional criteria were applied to the initial search results:

- languages:
  - limit to English language only
- publication date:
  - limit to the past five years
  - limit to the past 10 years
- publication type:
  - limit to randomized controlled trials
  - limit to systematic reviews.

These criteria were applied to individual topics following the initial consideration of preliminary search results. The specific criteria used for each topic are given in the relevant sections.

No specific ages were used in the search terms or in any additional search criteria. The population is primarily defined through the 19 conditions and topics, which have been identified as being

associated with older people (aged 60–79 years). The search terms were deliberately kept broad so as not to inadvertently exclude relevant studies associated with each topic in a broad or non-age-specific manner; however, any specific devices associated more commonly with the specific aged population identified as a result of the literature search have been highlighted.

2.8 STUDY INCLUSION CRITERIA AND PRESENTATION OF RESULTS

The results for each topic describe the total number of studies identified in each search. Any studies of no relevance to the condition under investigation were excluded. The number of references relevant to the project (that is, referred to a device in the title or abstract) was recorded. No studies were excluded based on study quality or design as there was no qualitative evaluation of study outcomes.

Where possible, studies were categorized according to their design. This was done according to the Australian National Health and Medical Research Council (NHMRC) levels of evidence (see Annex 1) *(6,7)*. There were two exceptions to the application of these levels of evidence:

- Literature reviews or clinical practice guidelines that did not explicitly report the use of a systematic methodology, or that may comprise non-randomized controlled trial data: these literature reviews could not be allocated a level I level of evidence (systematic review based on randomized controlled trial evidence). This exception also included evidence-based clinical practice guidelines. Evidence hierarchy was "not applicable" to these study types.
- Randomized controlled trials of diagnostic outcomes: to be classified as level II, these trials need to use an appropriate and valid reference standard. Due to the significant clinical input required to establish the reference standard for each device, and the fact that this standard may vary between the countries in the Western Pacific Region, the evidence hierarchy of these studies was "not able to be determined".

Two levels of results are provided for each main health condition. The first table provides a description of key studies identified through the literature review as providing the most representative information of the main devices and interventions relevant to the topic of interest. Where possible, these studies were designated a level of evidence. The first table also provides the primary device or procedure associated with the study and any secondary devices that may have been within the study focus (for example, information regarding the comparator arm in a randomized controlled trial). This first table is informed through a review of the full text of the identified study.

The second table includes a comprehensive list of all devices identified through a search of the title and abstract of all relevant studies from the search. A full text review of each study was not undertaken to inform this table, and each device is not cited according to the study from where it was identified. Where relevant, devices with the same clinical objective were grouped together. Devices were listed in a generic manner and trade names of specifically marketed products were provided as examples; trade names were provided when identified in the literature as it was unclear without subsequent research whether these devices were similar to, or significantly different from, other devices available for the same service. The tabulated information should not be interpreted as an exhaustive list of all marketed devices; nor should it be taken as an indication of a device's safety, efficacy or cost-effectiveness.

The level of detail regarding devices presented in the tables is reflective of the level of detail provided in the literature in order to avoid potential misinterpretation of the information as provided. In some instances medical devices or interventions were described in broad terms, but in other cases very specific trade names or device specifications were mentioned. The tables are intended to reflect the characteristics of the literature identified; for this reason, disparities in the level of detail, range of devices and nature of

descriptive data provided across and between topics are observable.

The complete bibliography of the results for each topic was recorded using Endnote X4 (1988–2010 Thompson Reuters).

2.9 CATEGORIES OF MEDICAL DEVICES

Where possible, the identified devices were categorized using the following nomenclature as informed by the Global Harmonization Task Force definition of a medical device:

- appliance (a large instrument for a particular purpose or use with associated console, accessories, attachment and consumables);
- instrument (a mechanical tool or implement, for example surgical instrument);
- implant (a device used for repairing or replacing part of the body, including medication or radioactive material inserted into tissue for sustained therapy);
- prosthesis (a device, either external or implanted, that substitutes for or supplements a missing or defective part of the body);
- material (an inert substance used for repairing or replacing part of the body);
- apparatus (a group or combination of instruments, machinery, tools, materials, etc., having a particular function or intended for a specific use);
- in vitro diagnostic (a medical device intended to perform tests out of the body for diagnostic purposes);
- software (the programs used to direct the operation of a computer, as well as documentation giving instructions on how to use them);
- other (devices which do not fit to any of the above categories. Techniques or procedures which play a key role in the provision of services for the condition, but have no explicit medical device associated with them have been provided under this category for comprehensiveness) *(5)*.

For clarity and comprehensiveness, the terms "consumable", "chart" and "aid" were also used for categorization purposes where these were identified as being reported distinctly from other medical devices. The term "consumable" indicates that the device will be depleted or "consumed" after use. An example of a consumable is a single-use syringe. Procedures, interventions and tests (such as questionnaires) that did not explicitly report the use of a defined medical device are discussed narratively.

The term "appliance" was used to describe devices such as ultrasound machines. The term indicates that the device is comprised of several components such as probes, processing units and consoles (display units). The term also indicates that consumables such as a gel may be involved in the operation of the device. When specified in the primary literature, the components of the device of interest may also be listed.

2.10 SUPPLEMENTARY RESOURCES

The results of the literature search were considered from a clinical perspective in order to establish the role of each device within the overall management of a specific condition. In certain cases, clinical practice guidelines were used to confirm these issues (http://bestpractice.bmj.com/best-practice/welcome.html). The use of supplementary resources is clearly explained in the methods and results of each topic where relevant.

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3. Cardiovascular diseases

3.1 INTRODUCTION

Cardiovascular disease is a broad term encompassing diseases of the heart and blood vessels *(1)*. These diseases commonly also involve the brain and kidney. The underlying aetiologies are varied and include congenital diseases, inflammatory diseases, rheumatic diseases, atherosclerosis, cardiac functional insufficiencies and disease of other body systems. Atherosclerosis is the major cause for ischaemic heart disease. Hypertension and atherosclerosis are the leading causes for cerebrovascular disease. Hypertensive diseases are often associated with pathology of kidney function. In general, multiple organs and systems are involved with cardiovascular pathologies.

The WHO estimated global burden of death due to cardiovascular disease in 2012, both worldwide and in the Western Pacific Region, is summarized in Table 3. Of the burden of disease caused by cardiovascular disease, heart attack and stroke account for a significant proportion of the mortality. In terms of overall mortality, cerebrovascular disease is overrepresented in the Western Pacific Region compared with rates worldwide.

3.2 ISCHAEMIC HEART DISEASE

Introduction

Ischaemic heart disease, or myocardial ischaemia, is characterized by reduced blood supply to the heart muscle, usually due to coronary artery disease. As a consequence of reduced blood supply, the heart muscle may become damaged, commonly resulting in heart attack and death *(3)*. The risk of developing ischaemic heart disease increases with age, smoking, high cholesterol level, diabetes and high blood pressure. It is more common in men and people with close relatives with ischaemic heart disease *(4)*. Although ischaemic heart disease usually develops over several decades, clinical complications such as heart attack and stroke are mainly observed in middle-aged and elderly people *(5)*.

Table 3 Mortality due to cardiovascular disease, worldwide and Western Pacific Region, 2008[a] *(2)*

Cause of death	Worldwide		Western Pacific Region		Percentage of worldwide death from cardiovascular diseases attributable to Western Pacific Region (%)
	Total (millions)	Percentage of deaths (%)	Total (millions)	Percentage of deaths (%)	
All deaths	55.86	NA	12.96	NA	23
All cardiovascular disease	17.52	31	5.37	41	31
Rheumatic heart disease	0.34	1	0.08	1	23
Hypertensive heart disease	1.14	2	0.30	2	26
Ischaemic heart disease	7.36	13	1.83	14	25
Cerebrovascular disease	6.67	12	2.70	21	41
Inflammatory heart diseases	0.47	1	0.07	1	15
Other cardiovascular diseases	1.54	3	0.39	3	25

NA: not applicable.

[a] Percentages calculated from raw data and rounded.

Ischaemic heart disease is the most common cause of death for all cardiovascular diseases. It is a major cause of mortality in developed countries and is a chief health concern worldwide. In 2012, 7.4 million people worldwide had ischaemic heart disease, with 13% of total deaths that year attributable to the disease. More specifically, 14% of total deaths in the Western Pacific Region were attributed to ischaemic heart disease *(2)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH to identify devices that could be used in the prevention, diagnosis or treatment of ischaemic heart disease. The following filters were applied to the search results: English language and published within the past five years and systematic reviews. Additional searching was conducted online to confirm the surgical devices related to some procedures.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	myocardial ischaemia [MeSH terms]
#3	coronary artery disease [MeSH terms]
#4	ischemic heart disease
#5	ischaemic heart disease
#6	myocardial ischemia
#7	myocardial ischaemia
#8	(((((#2) OR #3) OR #4) OR #5) OR #6) OR #7
#9	(#8) AND #1

Results

The strategy yielded 269 results. On the title and abstract screen, 88 studies were identified that reported the use of a device for the diagnosis or treatment of ischaemic heart disease. The details of the key studies retrieved for full text review are summarized in Table 4. A broader list of identified devices was obtained through title and abstract review of all included studies (Table 5).

A review of the literature identified a focus on diagnostic machines and procedures as well as therapeutic procedures. The search identified two tests for genetic markers, *LRP6* and cardiac troponin-T, which may be relevant for screening and diagnosis, respectively. The test for *LRP6* was categorized as "preventive" because identifying ischaemic heart disease through gene technology before symptoms arise may prove to be a powerful preventive mechanism in future years. Additional screening methods for ischaemic heart disease included blood tests and assessment of blood pressure.

The main therapeutic procedures identified for the treatment of ischaemic heart disease included angioplasty, coronary artery bypass grafting and cardiac resynchronization therapy. Other therapeutic procedures identified in the search included coronary revascularization, hybrid revascularization, thrombectomy, reperfusion therapy and cardiogoniometry.

Table 4 Ischaemic heart disease – key studies

Study	Level of evidence	Primary focus	Secondary focus[a]
Bavry et al 2008 *(6)*	I	Embolic protection device	Thrombectomy Reperfusion Revascularization Percutaneous coronary intervention Catheter thrombus aspiration Mechanical thrombectomy Syringe Saline jet Rotating catheter Occlusive balloon Guide-wire
Biondi-Zoccai et al 2008 *(7)*	I	Drug-eluting stent	Cardiac surgery Bare-metal stent Balloon angioplasty Coronary artery bypass grafting Restenosis Surgical revascularization Coronary angiography
Byrne et al 2009 *(8)*	IV	Drug-eluting stent	Restenosis Bare-metal stent Drug-eluting stent CYPHER™ drug-eluting stent Taxus paclitaxel-eluting stent angiography Cine-angiogram balloon Balloon angioplasty Palmaz–Schatz stent Percutaneous coronary intervention Revascularization Stirolimus-eluting stent
Chander et al 2008 *(9)*	IV	Electrocardiographically gated Rb PET Contrast-enhanced CT ventriculography	CT coronary angiography 64-slice scanner Nuclear imaging Echocardiography Cardiac MRI Contrast ventriculography Discovery STRx PET/CT system equipped with integrated lutetium yttrium orthosilicate crystal PET component and 64-slice CT component CT topogram
Suyker and Borst 2008 *(10)*	I	Coronary connector device	Anastomotic connector Angiography Multi-detector CT MRI anastomotic device Anastomotic connector Graft thrombosis Proximal anastomosis devices: Symmetry™, SJM prox-II, CorLink™ PAS-Port®, Spyder® Distal anastomosis devices: MVP-4000/6000, C-Port®, Converge Coupler™, SJM distal 2.5 mm, SJM distal Easyload, automated anastomotic distal device
Thavapalachandran et al 2009 *(11)*	IV	Heart failure	Implantable cardioverter defibrillator device Cardiac resynchronization therapy by biventricular pacing electrocardiogram

CT: computed tomography; MRI: magnetic resonance imaging; PET: positron-emission tomography.

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 5 Ischaemic heart disease – devices identified for prevention, diagnosis and treatment

Device[a]	Description	Function
Prevention		
LRP6 gene	IVD	Encodes member of low-density lipoprotein receptor gene family in genetic marker testing
Diagnosis		
Cardiac troponin	IVD	Biomarker testing in diagnosis of heart failure
Echocardiogram machine	Appliance	Diagnosis, management and follow-up of patients with any suspected or known heart diseases
Electrocardiogram machine	Appliance	Transthoracic interpretation of electrical activity of heart over period of time, detected by electrodes attached to outer surface of skin and recorded by device external to body
Cine-angiograph	Appliance	Motion-picture recording of blood vessel or portion of cardiovascular system obtained after injecting patient with non-toxic radio-opaque medium
PET system	Appliance	Nuclear medicine imaging modality using positron-emitting radionuclide tracers to generate three-dimensional images of metabolic processes within body, e.g. in the heart
Computed tomography 64-slice system	Appliance	Medical imaging modality using computer-processed X-rays to generate cross-sectional images of specific areas of body, e.g. the heart. May involve intravenously injected contrast agents
Intravascular ultrasound	Appliance	Medical imaging methodology using specially designed catheter with miniaturized ultrasound probe attached to distal end of catheter
X-ray machine	Appliance	Uses penetrating electromagnetic radiation to visualize anatomical structures. Part of angiography procedure
Treatment		
Balloon catheter	Consumable	Empty and collapsed balloon on endovascular guide-wire
Ventricular assist device[b]	Implant/ appliance	Mechanical circulatory device that partially or completely replaces function of failing heart
Embolic protection device	Consumable	Captures and removes debris that becomes dislodged during interventional procedure
TandemHeart™ system[b]	Implant/ appliance	Extracorporeal circulatory assist device that drains blood from left atrium and pumps it back into femoral artery to bypass left ventricle
Impella® device	Implant	Ventricular assist device that helps patient tolerate procedures such as angioplasty by relieving heart's pumping function and providing time needed to perform life-saving procedures
Cyanoacrylate glue	Consumable	Medical adhesive
40 MHz intravascular ultrasound catheter	Consumable	Thin tube used in ultrasound
Cardiac resynchronization therapy device	Implant	Treatment for congestive heart failure caused by dilated cardiomyopathy
Implantable cardiodefibrillator	Implant	Small battery-powered electrical impulse generator implanted in patients at risk of sudden cardiac death due to ventricular fibrillation and ventricular tachycardia
Intra-aortic balloon pump[b]	Instrument	Increases myocardial oxygen perfusion and increases cardiac output
Impella® recover pump	Implant/ appliance	Pulls blood from left ventricle through inlet area near tip and expels blood from catheter into ascending aorta
Wire	Consumable	Stainless-steel pin used in surgery
Stents: drug-eluting; bare-metal; titanium-nitride oxide-coated bioactive; polymer-free rapamycin-eluting	Implant	Mesh tube used to open arteries

IVD: in vitro diagnostic; PET: positron-emission tomography.

[a] Proprietary marks have been included where this information was readily identified through source material.

[b] May be implantable or extracorporeal.

3.3 CEREBROVASCULAR DISEASE

Introduction

Cerebrovascular disease is a cardiovascular disease that incorporates a number of conditions caused by problems with blood vessels in the brain. The most common cerebrovascular diseases include ischaemic stroke, transient ischaemic attack, subarachnoid haemorrhage, intracranial aneurysm and vascular dementia (covered under Alzheimer's disease) *(12)*. Some of the more common risk factors for developing cerebrovascular disease include smoking, high blood pressure, diabetes, high cholesterol level, obesity and age.

Cerebrovascular disease is the second most common cause of death from cardiovascular disease. In 2012, 6.7 million people worldwide had cerebrovascular disease, and it accounted for 12% of total deaths. A similar trend is observed in the Western Pacific Region, with 21% of total deaths in the region attributed to cerebrovascular disease *(2)*.

Ischaemic stroke is the main cause of death and disability from cerebrovascular disease.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of cerebrovascular disease. The following filters were applied to the search results: English language and published within the past five years and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	cerebrovascular disorders (MeSH terms)
#3	cerebrovascular disorders
#4	cerebrovascular disease
#5	stroke
#6	transient ischaemic attack
#7	transient ischemic attack
#8	subarachnoid haemorrhage
#9	intracranial aneurysm
#10	#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9
#11	#10 AND #1

Following review of the search results, resources consulted included clinical practice guidelines *(13)* and the Best Practice website of the BMJ Evidence Centre *(14)*.

Results

The strategy yielded 250 results. On the title and abstract screen, 77 studies were identified that reported the use of a device for the prevention, diagnosis or treatment of cerebrovascular disease. The details of the key studies retrieved for full text review are summarized in Table 6. A broader list of identified devices was obtained through title and abstract review of all included studies (Table 7).

The results of the search identified a number of devices for the diagnosis and treatment of cerebrovascular disease. It should be noted, however, that although no devices for the prevention of cerebrovascular disease were identified, the management and prevention of extracranial carotid disease and hypertensive and ischaemic heart disease may be considered preventive measures for cerebrovascular disease.

Treatments for stroke or transient ischaemic attack included carotid endarterectomy, carotid stenting, endovascular mechanical clot disruption, endovascular thrombectomy, surgical intervention and medical management. Treatments for cerebral aneurysm included endovascular coil treatment and surgical clipping, with the aim of excluding the aneurysm from intracranial circulation.

Table 6 Cerebrovascular disease – key studies

Study	Level of evidence	Primary focus[a]	Secondary focus
Argawal et al 2012 *(15)*	I	Transcatheter closure coil embolization	Pretreatment shunt
Aqel et al 2009 *(16)*	ND	Stent placement of introducer catheter Stent	Cerebral angiogram Blood pressure monitor Electrocardiogram SPECT Doppler ultrasound
Brinjikji et al 2009 *(17)*	IV	Two-dimensional digital subtraction angiography Detachable coil Guiding catheters Guiding sheaths Micro-catheters, coil	Balloon remodelling Balloon Guiding catheter Stent Sheaths Angiogram
Fraser et al 2011 *(18)*	ND	Vascular plugs Balloon test occlusion with angiography Doppler ultrasonography Stump pressure measurements Radiographic/nuclear perfusion scans Intracranial bypass and subsequent coil embolization Saphenous vein or radial artery graft for high- or low-flow bypass Shunt Craniotomy and resection Endoluminal flow-diversion with stent Balloon-assisted liquid embolization	None
Nagy et al 2012 *(19)*	IV	Gamma-knife radiosurgery Thrombo-obliteration	Software for dose planning Stereotactic catheter angiography MRI Magnetic resonance digital subtraction angiography
Ottomeyer et al 2012 *(20)*	IV	Intravenous thrombolysis Intra-arterial therapy Intravenous thrombolysis with intra-arterial therapy Endovascular mechanical therapy (AngioJet®, Penumbra™, Phenox®, Amplatz GooseNeck® snare)	None
White et al 2010 *(21)*	IV	Mini-craniectomy Burr holes Diathermy Bridging of veins	Subdural drain Cannula aspiration

CT: computed tomography; MRI: magnetic resonance imaging; ND: not able to be determined; SPECT, single photon-emission computed tomography.

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 7 Cerebrovascular disease – devices identified for diagnosis and treatment

Device[a]	Description	Function
Diagnosis		
MRI system	Appliance	Medical imaging modality using magnetic fields and radiowaves to visualize anatomy, in particular soft tissue, organs and muscle. Characterizes aneurysm properties; evaluates extent of damage from stroke; diagnoses aneurysm and stroke. Functional MRI has applications in assessing level of rehabilitation following stroke. Techniques include functional MRI, contrast-enhanced MRI, 3 tesla MRI, diffusion-weighted MRI and magnetic resonance angiography
CT system	Appliance	Medical imaging modality using computer-processed X-rays to generate cross-sectional images of body. May involve intravenously injected contrast agents. Characterizes aneurysm properties; evaluates extent of damage from stroke or transient ischaemic attack. May also be used for CT angiography
SPECT system	Appliance	Medical imaging modality using gamma rays to generate three-dimensional images of anatomical and functional processes in body. Characterizes aneurysm properties. Also evaluates extent of damage from stroke or transient ischaemic attack
Tests:[b] serum electrolytes; clotting profile; full blood count; troponin I	IVD	Diagnosis of SAH
Electrocardiogram machine	Appliance	Diagnosis of SAH
Lumbar-puncture needle[b]	Instrument	Diagnosis of SAH and cerebral aneurysm
Treatment		
MRI system	Appliance	Contrast-enhanced magnetic resonance angiography for planning surgical approaches, and diagnosis of aneurysm and SAH
X-ray machine	Appliance	Uses penetrating electromagnetic radiation to visualize anatomical structures. Used for angiography procedures with contrast agent
CT system	Appliance	Medical imaging modality using computer-processed X-rays to generate cross-sectional images of body. May involve intravenously injected contrast agents. Used in CT angiography
Intra-arterial cerebral catheter	Consumable	Angiography that characterizes aneurysmal remnant
Syringe	Consumable	Administration of contrast agents
Inflatable balloon	Instrument	Balloon test occlusion angiography
Ultrasound	Appliance	Diagnosis and treatment planning
Electrocardiogram machine	Appliance	Evaluation of patient's status
Blood pressure monitor	Appliance	Diagnosis, treatment planning and risk assessment
Stump pressure monitor	Appliance	Evaluation of treatment (carotid occlusion)
Serum BNP and inflammatory markers (IL-6, CRP, fibrinogen tests) test	IVD	Prognostic factor: BNP levels are associated with functional outcome after ischaemic stroke. May also be used to predict mortality
Shunt	Instrument	Carotid endarterectomy (revascularization therapy), embolizing procedures, surgical procedures
Clamp	Instrument	Carotid endarterectomy (revascularization therapy)
Patches: autologous; bovine; Dacron	Material	Patch angioplasty and carotid endarterectomy
Closed-suction drain	Instrument	Carotid endarterectomy (revascularization therapy)
Stents: balloon-expandable; self-expanding	Implant	Carotid stenting (revascularization therapy), embolization of intracranial aneurysm
Guide-wire	Consumable	Carotid stenting (revascularization therapy)
Catheter	Consumable	Carotid stenting and mechanical clot disruption using angioplasty, intravenous thrombolysis, embolization of intracranial aneurysm
Antibiotic-impregnated catheter	Consumable	Treatment of SAH
Sheath	Consumable	Delivery of stents

Continues…

Device[a]	Description	Function
Balloon	Instrument	Carotid stenting and mechanical clot disruption using angioplasty, balloon-remodelling procedures for embolization of intracranial aneurysm
Clot-retrieval systems: Penumbra®; AngioJet®; Phenox®; Amplatz GooseNeck® snare	Instrument	Endovascular thrombectomy (revascularization of intracranial arteries)
Hypobaric oxygen therapy unit	Appliance	Treatment of stroke following cardiac surgery
Robot	Appliance	Rehabilitation and lower-limb movement following stroke
Virtual reality system	Appliance	Rehabilitation following stroke
Coils: detachable; Cerecyte®; bare-platinum	Consumable	Embolization of intracranial aneurysm
Clip	Consumable	Open surgical clipping of intracranial aneurysm
Vascular plug	Instrument	Embolization of intracranial aneurysm
Autologous tissue	Material	Embolization of giant intracranial aneurysm
Drill	Appliance	Creation of burr holes in treatment of subdural haematoma
Diathermy unit	Instrument	Treatment of subdural haematoma
Subdural drain	Instrument	Treatment of subdural haematoma
Cannula	Instrument	Drainage of subdural haematoma
Coronary artery bypass machine	Appliance	Stabilization of SAH
Gamma knife	Appliance	Treatment of arteriovenous malformations (radiosurgery)

BNP: brain natriuretic peptide; CRP: C-reactive protein; CT: computed tomography; IL-6: interleukin-6; IVD: in vitro diagnostic; MRI: magnetic resonance imaging; SAH: subarachnoid haemorrhage; SPECT, single photon-emission computed tomography.

[a] Proprietary marks have been included where this information was readily identified through source material.

[b] Identified via search of Best Practice database.

3.4 HYPERTENSIVE HEART DISEASE

Introduction

Hypertensive heart diseases are heart problems that occur due to high blood pressure (hypertension). These problems include coronary artery disease, chest pain (angina), heart failure and thickening of the heart muscle. Characteristically, chronic high blood pressure causes the heart muscle to thicken because the heart is required to pump harder due to the high pressure in the arteries. Similarly, high blood pressure also leads to thickening of the blood vessel walls, which can increase the risk of heart attack and stroke when combined with cholesterol deposits in the vessels. As a result of these factors, hypertensive heart disease has become the leading cause of illness and death from high blood pressure *(23)*.

Hypertensive heart disease is the third most common cause of death from cardiovascular disease. In 2012, 1.1 million people worldwide had hypertensive heart disease, and it was the cause of 2% of total deaths in that year. A similar trend is observed in the Western Pacific Region, with 2% of total deaths attributed to hypertensive heart disease. *(2)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of hypertensive heart disease. The following filters were applied to the search results: English language and published within the past five years and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	hypertension [MeSH terms], cardiac output, high [MeSH terms] OR cardiomegaly [MeSH terms] OR cardiomyopathies [MeSH terms] OR heart aneurysm [MeSH terms] OR heart failure [MeSH terms] OR heart rupture [MeSH terms] OR diseases, heart valve [MeSH terms] OR cardiac hypertrophy [MeSH terms]
#3	heart* OR cardi*
#4	hypertens* OR pressure
#5	#3 AND #4
#6	#2 OR #5
#7	#1 AND #6
#8	#1 AND #6 Filters: systematic reviews, published in the past five years, English

Results

The strategy yielded 186 results. On the title and abstract screen, 67 studies were identified that reported the use of a device for the prevention, diagnosis or treatment of hypertensive heart disease. The details of the key studies retrieved for full text review are summarized in Table 8. A broader list of identified devices was obtained through title and abstract review of all included studies (Table 9).

After reading the study titles and abstracts, studies were excluded if they did not include the targeted population or had not specified devices in the abstract. Among the excluded 113 studies, 11 studies focused only on ischaemic heart disease and another seven focused only on cerebrovascular diseases. Hypertensive renal diseases were included in the search results, although the identified literature focused predominantly on the cardiac consequences of hypertension, which include heart failure and cardiomyopathy. The preventive, diagnostic and therapeutic devices related to ischaemic heart disease and cerebrovascular disease are discussed separately in this report.

The search identified preventive, diagnostic and treatment modalities for hypertensive heart disease.

In addition to the medical devices listed in Table 9, a number of cardiovascular risk assessment tools were identified, including the Framingham Heart Study Model, the Cardiovascular Life Expectancy Model, the United Kingdom Prospective Diabetes Study Model and the Symptoms Causes Output Resources Effects Model, which are often used in the diagnosis of hypertensive heart disease *(24)*.

3.5 CONCLUSION

The searches identified devices related to the diagnosis and treatment of ischaemic heart disease, cerebrovascular disease and hypertensive heart disease. No specific screening methods were identified, although genetic marker testing may be used in screening for hereditary factors associated with an increased risk of cardiovascular conditions. Prevention is usually associated with lifestyle-modification devices. Risk assessment tools are used in the early identification of potential complications.

Table 8 Hypertensive heart diseases – key studies

Study	Level of evidence	Primary focus[a]	Secondary focus
Alexis 2009 *(25)*	ND	Sphygmomanometer	Cuff, stethoscope, observation charts
Padwal et al 2009 *(24)*	I	Risk-assessment tools: Framingham Heart Study Model, cardiovascular life expectancy model, United Kingdom Prospective Diabetes Study model, Symptoms–Causes–Output–Resources–Effects model	Global risk assessment tool, ambulatory blood pressure monitor, stethoscope, sphygmomanometer, manometer echocardiography, electrocardiography, computed tomography, iodine-131 metaiodobenzylguanidine scintigraphy, nuclear imaging IVD: blood chemistry (potassium, sodium, creatinine), fasting blood glucose, fasting serum total cholesterol and high-density lipoprotein cholesterol, low-density lipoprotein cholesterol and triglycerides, urine albumin Screening for hyperaldosteronism: plasma renin concentration, plasma aldosterone concentration, saline loading tests, fludrocortisone suppression test, captopril suppression test Screening for renal vascular disease: (duplex) Doppler sonography, magnetic resonance angiography, CT angiography, captopril-enhanced radioisotope renal scan
Raphael et al 2012 *(26)*	I	Lifestyle-modification devices: RESPeRATE (InterCure Ltd), Interactive music device, Usual Care device	Grab It! (Datatrend Software), standard blood pressure monitor
Dickstein et al 2010 *(27)*	ND	Implantable cardiac devices: pacemaker (conventional and CRT), defibrillator (including ICD)	Electrocardiography, echocardiography, hybrid therapy combining CRT, atrioventricular node ablation, biventricular stimulation, left ventricular assist device, continuous-flow device (HeartMate II), pulsative device
Thavapalachandran et al 2009 *(11)*	III	Implantable cardiac devices: ICD, CRT with defibrillator (CRT-D), CRT with pacemaker (CRT-P), permanent pacemaker, biventricular pacemaker	Electrocardiography

CRT: cardiac resynchronization therapy; CT: computed tomography; ICD: implantable cardioverter defibrillator; ND: not able to be determined.

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 9 Hypertensive heart diseases – devices identified for prevention, diagnosis and treatment

Device[a]	Description	Function
Prevention		
Biofeedback device	Appliance	Improves cardiac performance by assisting maintenance of blood pressure
Diagnosis		
Haemodynamic monitoring system	Implant	Implantable cardiac pressure monitoring device
Electrocardiogram machine	Appliance	Monitors and diagnoses cardiac pathology
Ultrasound machines and their modes: echocardiograms; three-dimensional echocardiography; pocket-sized echocardiography Duplex ultrasound; Doppler cardiac ultrasound system acoustic cardiography	Appliance	Views cardiac anatomy and assesses cardiac function in the monitoring and diagnosis of cardiac pathology
INR blood test	IVD test	Monitors effects of warfarin (anticoagulation therapy) and assesses risk for cerebrovascular disease
MRI system	Appliance	Medical imaging modality using magnetic fields and radiowaves to visualize anatomy, in particular soft tissue, organs and muscle. Measures heart, cardiac vasculature and function

Device[a]	Description	Function
CT system	Appliance	Medical imaging modality using computer-processed X-rays to generate cross-sectional images of body. May involve intravenously injected contrast agents. Measures heart and cardiac vasculature function
X-ray machine	Appliance	Uses penetrating electromagnetic radiation to visualize anatomical structures. Measures heart and major cardiac vasculature
Electro-anatomical mapping system (EnSite NavX™)	Appliance	Rapid, high-density atrial mapping. Cardiac chambers are mapped during rhythm of interest, and patterns of atrial activation are analysed to identify wavefronts of electric propagation
20-pole penta-array catheter	Consumable	Rapid, high-density atrial mapping. Part of electro-anatomical mapping system
Treatment		
Endoscope	Instrument	Assists endoscopic submucosal dissection
External ventricular support device: HeartNet; CorCap	Implant	Management of cardiac aneurism, hypertrophy and cardiomegaly
Implantable cardioverter-defibrillator	Implant	Detects cardiac arrhythmia and corrects by delivering jolt of electricity
Cardiac resynchronization therapy device	Implant	Resynchronizes contractions of heart's ventricles by delivering electrical impulses to heart muscle
Ventricular assist device and left ventricular assist device[b]	Implant/ Appliance	Assists maintenance of ventricular output
Dual chamber implantable defibrillator	Implant	Implantable defibrillator
Intra-aortic balloon pump	Instrument	Increases myocardial oxygen perfusion and cardiac output
Contractility modulation pulse generator	Implant	Increases cardiac contraction by improving function of cardiomyocytes
Biventricular pacemaker	Implant	Controls abnormal heart rhythm. Can pace both septal and lateral walls of left ventricle
Permanent pacemaker	Implant	Controls abnormal heart rhythm
Prosthetic heart valves (e.g. Freedom Solo, Carpentier-Edwards)	Prosthesis	Aortic valve replacement procedure
Sorin Bicarbon bileaflet	Prosthesis	Valvuloplasty
MitraClip	Implant	Percutaneous mitral valve repair device
Kalangos ring, De Vega semicircular rings	Implant	Annuloplasty
Annuloplasty ring, semi-rigid ring, rigid ring	Implant	Valve repair in management of mitral regurgitation
Coapsys device	Implant	Decreases chronic ischaemic mitral regurgitation by geometrically reshaping mitral valve
Mitral contour system (Carillon system)	Implant	Implanted into coronary venous system to enable tension of mitral ring in order to improve coaptation of leaflets
Mobile respiratory spirometric device	Appliance	Monitors respiratory capability
Embolic protection system	Consumable	Angioplasty procedure
Blood gas analyser	Instrument	Monitors ventilation and acidosis
Aortic cross-clamp	Instrument	Clamps aorta and separates systemic circulation from outflow of heart
Electrocautery	Instrument	Cuts and cauterizes tissue and blood vessels
Snare	Instrument	Assists marking of mucosa at tumour
Oral gastric tube	Instrument	Nasogastric decompression during surgery
Cyanoacrylate glue	Consumable	Prevents postoperative sternal wound infections
Radiation-absorbing drape	Consumable	Shield for protection

Continues…

Device[a]	Description	Function
Suture	Consumable	Surgery
Ligature	Consumable	Surgery
Gauze	Consumable	Surgery
Clip	Consumable	Surgery

CT, computed tomography; INR: international normalized ratio; IVD: in vitro diagnostic; MRI: magnetic resonance imaging.

[a] Proprietary marks have been included where this information was readily identified through source material.

[b] May be implantable or extracorporeal.

Ischaemic heart disease and cerebrovascular disease are commonly caused by stenosis of a coronary or cerebral artery due to atherosclerosis. These diseases are diagnosed by testing cardiovascular functionality and morphology. Electrocardiography, Holter monitor, echocardiography, X-ray, sonography, computed tomography (CT) and positron-emission tomography (PET) are the main diagnostic apparatus identified. In addition, several in vitro biomarker tests have been used for differential diagnoses. Bypass grafting procedures and vascular reconstruction procedures are the main surgical strategies for management. Implantable cardiac devices such as implantable defibrillator and cardiac resynchronization therapy devices may be used to assist ventricular function and to prevent sudden cardiac death. Numerous devices were identified for the treatment of cerebrovascular conditions, including catheters and guide-wires for endovascular delivery of embolic coil and stents, and devices for removing blood clots. Stents, such as drug-eluting stents, may be used to resolve vascular stenosis. Numerous other assisting devices and consumables are involved in providing these services and treatment options.

Hypertensive heart disease may be idiopathic or secondary to another disease, commonly cardiovascular or renal in origin. Associated cardiac diseases include atherosclerotic diseases and cardiac functional insufficiencies that could result from malignant hypertension, such as cardiac valve pathologies, cardiomyopathies, aneurysms, cardiomegaly and cardiac hypertrophy.

In addition to the modalities identified in the diagnosis of atherosclerotic diseases, the literature search identified the use of magnetic resonance imaging (MRI), nuclear cardiac imaging and electro-anatomical mapping in the diagnosis of hypertensive heart diseases. Manometers such as the sphygmomanometer are commonly used to monitor blood pressure. Valve pathology is corrected by valve reconstruction or prosthetic valve implantation. Numerous rings and mechanical or biological valves are used. Support devices are implanted for the prevention of cardiac and vascular ruptures. Devices to prevent heart failure and improve health outcomes include a broad range of implantable devices such as valves, stents and pacemakers.

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4. Malignant neoplasms

4.1 INTRODUCTION

Malignant neoplasms are generally the product of a mutation in a cell's DNA that disrupts the cell's lifecycle. Malignant neoplasms, or cancers, may be the result of a single mutation or a greater number of mutations that have accumulated over time. Physiologically, cancerous cells are characterized by unchecked proliferation. Damage to the DNA of a cell may arise as a result of environmental factors, or the mutation may be inherited. Cancerous cells may invade local tissue and metastasize via the circulatory or lymphatic system to distant sites; metastases are the major cause of death due to cancer *(1)*.

The incidence of cancer rises with age, and ageing is a non-modifiable risk factor for the development of many cancers; this could be due to the accumulation of environmental risk factors as well as the underlying biological processes involved in ageing. In the Western Pacific Region, 22% of all estimated deaths in 2012 were due to cancer *(2)*. Cancer of the lung, stomach, liver, colorectum and breast are the five leading causes of death due to cancer. The Western Pacific Region accounts for a large proportion (more than 50%) of the world's liver and stomach cancers and for the majority of world mortality due to these cancers. The incidences of various malignant neoplasms worldwide and in the Western Pacific Region are summarized in Table 10. The mortality associated with various malignant neoplasms worldwide and in the Western Pacific Region is summarized in Table 11. All data were obtained from the online Globocan database and are based on estimates from 2012 *(3)*.

Table 10 Incidence of cancer, worldwide and Western Pacific Region *(3)*

Type of cancer	Number of cases		Worldwide cases reported in Western Pacific Region (%)
	Worldwide	Western Pacific Region	
All cancers, excluding non-melanoma skin cancer	14 067 894	4 543 359	32
Breast	1 671 149	329 762	20
Lung	1 824 701	838 978	46
Prostate	1 094 916	153 167	14
Colorectum	1 360 602	459 958	34
Stomach	951 594	571 139	60
Liver	782 451	500 506	64
Oesophagus	455 784	254 572	56
Bladder	429 793	91 294	21
Non-Hodgkin's lymphoma	385 741	84 401	22
Leukaemia	351 965	95 087	27
Lip, oral cavity	300 373	47 524	16
Kidney	337 860	98 473	29
Pancreas	337 872	113 015	33
Larynx	156 877	29 647	19
Brain, nervous system	256 213	82 184	32
Other pharynx	142 387	19 241	14

Type of cancer	Number of cases		Worldwide cases reported in Western Pacific Region (%)
Melanoma of skin	232 130	27 772	12
Gallbladder	178 101	81 549	46
Nasopharynx	86 691	45 726	53
Multiple myeloma	114 251	20 932	18
Testis	55 266	5 819	11
Thyroid	298 102	101 489	34
Hodgkin's lymphoma	65 950	5 066	8

Table 11 Mortality due to cancer, worldwide and Western Pacific Region *(3)*

Type of cancer	Number of deaths		Worldwide deaths reported in Western Pacific Region (%)
	Worldwide	Western Pacific Region	
All cancers, excluding non-melanoma skin cancer	8 201 575	2 978 084	36
Lung	1 589 925	747 920	47
Stomach	723 073	409 897	57
Liver	745 533	476 692	64
Colorectal	693 933	224 808	32
Breast	521 907	85 837	16
Oesophagus	400 169	219 296	55
Cervix uteri	265 672	43 220	16
Pancreas	330 391	108 444	33
Prostate	307 481	45 977	15
Leukaemia	265 471	76 977	29
Non-Hodgkin's lymphoma	199 670	47 335	24
Brain, nervous system	189 382	59 984	32
Bladder	165 084	39 606	24
Ovary	151 917	26 163	17
Lip, oral cavity	145 353	22 068	15
Kidney	143 406	38 951	27
Gallbladder	142 823	68 486	48
Other pharynx	96 105	12 048	13
Larynx	83 376	15 778	19
Corpus uteri	76 160	22 776	30
Multiple myeloma	80 019	15 689	20
Nasopharynx	50 831	26 763	53
Melanoma of skin	55 488	9 802	18
Thyroid	39 771	10 469	26
Hodgkin's lymphoma	25 469	1 801	7
Testis	10 351	1 264	12

4.2 CANCER OF THE MOUTH AND OROPHARYNX

Introduction

Oropharyngeal cancer is cancer arising from any region of the oropharynx: the base of the tongue, soft palate, uvula, tonsillar pillar, tonsil or lateral or posterior pharyngeal wall. Mouth cancer is cancer arising from any region of the oral cavity: the lip, gum/gingiva, hard palate, retromolar trigone or tongue *(4)*. Mouth and oropharyngeal cancers are distinct neoplastic entities. The major risk factors for cancer of the mouth and oropharynx are tobacco and alcohol consumption. Chewing betel nut is also a risk factor. Infection with the human papilloma virus has been implicated in the aetiology of oropharyngeal tumours, which is commonly reported in younger patients (aged 40–60 years) *(5)*.

The incidence of oral cancer is higher in men than women and is more common in developing countries than developed countries *(6)*. The age-standardized worldwide rate of cancer in 2012 was 0.9 per 100 000 for cancers of the lip or oral cavity and 0.5 per 100 000 for cancers of the other pharynx *(3)*. The incidence of oral cavity and oropharyngeal cancer varies substantially between countries, with particularly high incidence rates in south-central Asia and India. Preventive strategies may be focused on reducing smoking and alcohol consumption. WHO has established a Global Oral Health Programme to assess risk factors and assist in the planning of intervention programmes *(6)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of mouth and oropharyngeal cancer. The following filters were applied to the search results: English language and published within the past five years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	mouth neoplasm (MeSH terms)
#3	mouth AND neoplasm*
#4	mouth AND tumor*
#5	mouth AND tumour*
#6	mouth AND cancer*
#7	oropharynx neoplasms (MeSH)
#8	oropharyn* and neoplasm*
#9	oropharyn* AND tumour*
#10	oropharyn* AND tumor*
#11	oropharyn* AND cancer*
#12	#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11
#13	#12 AND #1

The results of the search were supplemented with clinical practice guidelines *(7)*.

Results

The strategy yielded 183 results. On the title and abstract screen, 86 studies were identified that reported the use of a device for the prevention, diagnosis or treatment of mouth and oropharyngeal cancer. The details of the key studies retrieved for full text review are summarized in Table 12. A broader list of identified devices was obtained through title and abstract review of all included studies (Table 13).

A review of the literature identified a focus on screening and diagnostic machines and procedures, as well as therapeutic procedures. Laser ablation

of precancerous conditions such as oral leukoplakia may be considered to be a preventive procedure *(8)*. Broader preventive strategies were aimed at the control of risk factors such as smoking and high levels of alcohol consumption. Human papilloma virus has been implicated in the aetiology of oropharyngeal cancers, and future preventive strategies may focus on this risk factor.

The search strategy identified a number of devices used to visualize lesions in screening examinations performed by a dentist or physician (Table 13). Cancers of the mouth and oropharynx are rare, however, and a large proportion of patients present with advanced or metastatic disease. Histological analysis of biopsy samples is the definitive diagnosis of mouth and oropharyngeal cancer, and the search identified several biopsy devices.

The main therapeutic interventions identified included radiotherapy, brachytherapy, surgical excision and chemotherapy. Clinical advice indicates that specific tools such as oropharyngeal retraction systems and transoral carbon dioxide lasers are used to access the primary tumour during surgery (G Rees, Queen Elizabeth Hospital, Adelaide, Australia, personal communication, 29 January 2013). Transoral robotic resection is currently used in clinical practice in some countries where the device is available. A large range of devices used in reconstruction following resection and treatment of radiotherapy-induced complications was identified, including speaking valves (Table 13).

The search identified one study indicating that high epidermal growth factor receptor expression and other molecular markers in tumour samples may assist in identifying patients who would benefit from accelerated radiotherapy *(9)*; this novel test has been identified as a horizon-scanning technology.

Table 12 Oropharyngeal and mouth cancer – key studies

Study	Level of evidence	Primary focus[a]	Secondary focus
Arden et al 1999 *(10)*	IV	Three-dimensional bendable mandibular reconstruction plates	Solid screws Drill Skin graft Radiotherapy: external beam Brachytherapy Hyperfractionation radiotherapy
Balevi et al 2007 *(11)*	NA	VELscope®	None
Deo et al 2005 *(12)*	II	Harmonic scalpel (ultrasonic dissection)	Electrocautery Silk ligatures Coagulation shears Skin staplers Sponges Drains
Herberer et al 2011 *(13)*	IV	Dental implants	Ablative therapy
Mucke et al 2010 *(14)*	IV	Surgery	CT imaging MRI Skeletal scintigraphic surveys Sonography Gastroscopy Bronchoscopy X-ray

Continues…

Study	Level of evidence	Primary focus[a]	Secondary focus
Sweeny et al 2011 *(15)*	IV	Handheld detection device (combination autofluorescence and tissue reflectance)	White-light visualization Biopsy Tissue reflectance (handheld) Fibre-optic spectrometers Depth-sensitive oral spectroscopy

CT: computed tomography; MRI: magnetic resonance imaging; NA: not applicable.

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 13 Oropharyngeal and mouth cancer – devices identified for prevention, diagnosis and treatment

Device[a]	Description	Function
Prevention		
Er:YAG laser	Appliance	Ablates lesions (oral leukoplakia)
CO_2 laser	Appliance	Ablates lesions (oral leukoplakia)
Diagnosis		
White-light imaging unit	Instrument	Improves visualization in screening and detection of squamous cell carcinomas
Narrow-band imaging unit	Instrument	Oral cancer screening/detection of squamous cell carcinomas
Handheld autofluorescence unit	Instrument	Oral cancer screening
Biopsy needle	Instrument	Takes tissue samples for screening and diagnosis
Handheld tissue reflectance unit	Instrument	Oral cancer screening
Fibre-optic spectrometer	Instrument	Oral cancer screening
Depth-sensitive oral spectroscope	Instrument	Oral cancer screening
Forceps	Instrument	Biopsy procedures
Ultrasound	Appliance	Guides biopsy procedures
CT system	Appliance	Medical imaging modality using computer-processed X-rays to generate cross-sectional images of body. May involve intravenously injected contrast agents. Provides images of areas of body to assist in diagnosis and staging
MRI scanner	Appliance	Medical imaging modality using magnetic fields and radiowaves to visualize anatomy, in particular soft tissue, organs and muscle. Provides images of areas of body to assist in diagnosis and staging
Gastroscope	Instrument	Helps to visualize oral cavity
Bronchoscope	Instrument	Helps to visualize oral cavity
X-ray machine	Appliance	Uses penetrating electromagnetic radiation to visualize anatomical structures for diagnosis and staging of cancer
PET system	Appliance	Nuclear medicine imaging modality using positron-emitting radionuclide tracers to generate three-dimensional images of metabolic processes within body. Provides images of areas of body to assist in diagnosis and staging (nuclear imaging technique)
Treatment		
Medical linear accelerator	Appliance	Generates radiation in radiotherapy procedures, including hyperfractionation and external beam radiotherapy
Collimator	Appliance	Delivers radiotherapy in intensity-modulated radiotherapy
Catheter	Consumable	Delivers brachytherapy
Interstitial radioactive seed	Material	Required to deliver brachytherapy
Robotic surgical system (da Vinci Surgical System®)	Appliance	Robotic surgery for treatment of malignant head and neck lesions

Device[a]	Description	Function
CO_2 laser	Appliance	Treatment of radiation-induced mucositis Surgical resection procedures
Retractor	Instrument	Surgical resection procedures
Three-dimensional bendable mandibular reconstruction plate	Implant	Reconstruction in oral cavity/oropharyngeal carcinoma
Solid screw	Consumable	Reconstruction in oral cavity/oropharyngeal carcinoma
Drill	Appliance	Reconstruction in oral cavity/oropharyngeal carcinoma
Obturator	Implant	Reconstruction in oral cavity/oropharyngeal carcinoma
Intubating laryngeal mask airway tracheal tube	Instrument	Intubation in patients scheduled for oral surgery
Endonasal endoscope	Instrument	Minimally invasive treatment of pituitary adenomas
Therabite mechanical jaw mobilization system	Appliance	Improves mandibular mobility after composite resection
LigaSure™ vessel sealing system	Instrument	Seals vessels in lobectomy of parotid gland
Harmonic scalpel system	Instrument	Ultrasonic dissection
Electrocautery unit	Instrument	Cautery dissection
Silk ligature	Consumable	Surgical procedures
Coagulation shears	Instrument	Surgical procedures
Sponge	Consumable	Surgical procedures
Skin stapler	Instrument	Surgical procedures
Drain	Instrument	Surgical procedures
Dental implant	Implant	Reconstruction in head/neck cancer
Face pad	Consumable	Application of pressure to face after parotid surgery
Bipolar diathermy system	Appliance	Homeostasis in surgical procedures
Syringe	Consumable	Administers anaesthesia
Patient-controlled analgesia unit	Appliance	Delivers pain-relieving medicine following surgery
Intubation tube	Consumable	Intubation in patients scheduled for oral surgery
Gelclair®	Material	Pain relief of oral mucositis
Nasal cannula	Instrument	Treatment of radiation-induced xerostomia
Bedside humidifier	Appliance	Treatment of radiation-induced xerostomia
Indwelling tracheo-oesophageal speaking valve	Implant	Voice restoration following total laryngectomy
Gastrostomy tube	Consumable	Nutritional delivery device postoperatively

CT: computed tomography; Er:YAG: erbium-doped yttrium aluminium garnet; MRI: magnetic resonance imaging; PET, positron-emission tomography.

[a] Proprietary marks have been included where this information was readily identified through source material.

4.3 OESOPHAGEAL CANCER

Introduction

Cancer of the oesophagus is associated with a wide range of conditions and risk factors, including gastro-oesophageal reflux disease, human papilloma virus infection, Plummer–Vinson syndrome, tylosis, Howel-Evans syndrome, coeliac disease and family history of cancer. Environmental factors such as tobacco use, heavy consumption of alcohol, consumption of hot drinks, exposure to certain chemicals (such as nitrosamines, acetaldehyde, mycotoxins and polycyclic aromatic hydrocarbons), nutritional deficiencies, poor oral health, achalasia and low socioeconomic status are also risk factors *(16)*.

Oesophageal cancer is the ninth most common cancer worldwide and the seventh most common cause of cancer-related deaths. The incidence varies between countries, for example from 3.5 per 100 000 in Australia to 12.5 in China *(3)*. Squamous cell carcinoma and adenocarcinoma are the major histological types of the disease. Squamous cell carcinoma represents approximately 90% of total oesophageal cancer incidence worldwide. Nearly half of the cases of squamous cell carcinoma are reported from China *(17)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of stomach cancer. The following filters were applied to the search results: English language and published within the past five years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	esophageal neoplasms [MeSH terms]
#3	esophag* AND neoplasm*
#4	oesophagi* AND neoplasm*
#5	esophag* AND tumor*
#6	oesophag* AND tumor*
#7	esophag* AND tumour*
#8	oesophag* AND tumour*
#9	esophag* AND cancer*
#10	oesophag* AND cancer*
#11	#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10
#12	#1 AND #11
#13	#1 AND #11

Results

The strategy yielded 45 results. On the title and abstract screen, 15 studies were identified that reported the use of a device for the prevention, diagnosis or treatment of oesophageal cancer. The details of the key studies retrieved for full text review are summarized in Table 14. A broader list of identified devices was obtained through title and abstract review of all included studies (Table 15).

The search identified devices related to the diagnosis and treatment of oesophageal cancer. No preventive modalities or in vitro diagnostic tests were identified; however, the literature suggested that screening for *H. pylori* may be helpful in identifying patients prone to the disease.

Oesophagogastroduodenoscopy is the most commonly used diagnosis procedure for oesophageal cancer. A variety of endoscope designs were identified, including those for chromoendoscopy and videoendoscopy *(18)*. A number of imaging devices may assist with disease staging and differential diagnosis; for example, PET/CT scanning is recommended for all types of oesophageal cancer diagnosis *(19)*. The search did not identify MRI and optical coherence tomography, although supplemental investigation identified that these tests may have a role in diagnosis *(20,21)*.

Early stages of the cancer are managed by endoscopic mucosal resection and ablation techniques *(22)*, including radiofrequency ablation for Barrett's oesophagus. Advanced oesophageal cancer is treated with radical oesophagectomy and oesophagogastrostomy *(25)*, together with chemotherapy and various types of radiotherapy *(24)*. Complications of advanced disease may be managed using stents, and enteral feeding may be required for severe dysphagia or reflux *(25)*.

Table 14 Oesophageal cancer – key studies

Study	Level of evidence	Primary focus[a]	Secondary focus
Kranzfelder et al 2009 *(26)*	I	Diagnosis of tumour staging and potential systemic diseases, including F-deoxyglucose PET, PET/CT scan, endoscope (oesophagoscopy, panendoscopy, bronchoscopy, laparoscopy), endoscopic ultrasound, CT, echocardiography, electrocardiography, sonography, endosonography, X-ray	Gastric tube, stapler, needles Procedures: Ivor Lewis procedure, transhiatal oesophagectomy
Shen et al 2012 *(27)*	II	Imaging, including PET/CT, PET/CT/X-ray (e.g. GE Discovery® LS4 PET/CT), ring detectors (attachment to PET)	Procedure: hand/video-assisted thoracoscopic oesophagectomy, Ivor Lewis oesophagectomy, double-lumen endotracheal intubation
Muto et al 2010 *(18)*	II	Endoscopic imaging Narrow-band imaging White light imaging	Lugol chromoendoscopy, narrow-band imaging filters, endoscope (e.g. GIF-Q240Z), video-endoscope system (e.g. EVIS Lucera®) Procedures: endoscopic mucosal resection
Bergman et al 2011 *(28)*	II	Endoscopic radiofrequency ablation Electrode, balloon (e.g. HALO^{90} and HALO^{360}) Catheters, catheter balloon	White-light endoscopy, chemoendoscopy, Lugol's chromoendoscopy, CT endoscope (e.g. Olympus GIF-H260), endoscopes (Lucera™ systems), mechanical radial ultrasonic gastrovideoscope (e.g. Olympus GF-UM2000), biopsy forceps Procedure: fundoplication
Blomberg et al 2010 *(29)*	II	Stents/SEMS: anti-reflux stent, anti-reflux valve/sleeve; conventional SEMS (e.g. Ultraflex®, Wallstent®)	X-ray (fluoroscopic monitoring), guide-wire (e.g. Savary-Gilliard wire), endoscope, balloon dilator

CT: computed tomography; PET, positron-emission tomography; SEMS: self-expandable metallic stent.

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 15 Oesophageal cancer – devices identified for diagnosis and treatment

Device[a]	Description	Function
Diagnosis		
Endoscope Conventional white-light imaging Video-assisted thoracoscope	Instrument	Examination of oesophagus for screening and diagnosis
Narrow-band imaging endoscope	Instrument	Endoscopic diagnostic imaging technique using light of specific blue and green wavelengths to enhance detail of certain aspects of surface mucosa
Ultrasound (endoscopic ultrasound)	Appliance	Guides fine-needle aspiration and biopsy in cancer diagnosis
PET system	Appliance	Nuclear medicine imaging modality using positron-emitting radionuclide tracers to generate three-dimensional images of metabolic processes within body
CT system	Appliance	Medical imaging modality using computer-processed X-rays to generate cross-sectional images of body. May involve intravenously injected contrast agents
PET/CT system	Appliance	Medical imaging modality combining metabolic activity with anatomical location
Treatment		
Endoscope	Instrument	Visualizes endoscopic submucosal dissection
Radiofrequency ablator	Appliance	Focal ablation of areas of Barrett's oesophagus
Laser and photodynamic therapy machine	Appliance	Provides very high-intensity light to allow ablation and scarring
Multipolar electrocoagulator machine	Appliance	Endoscopic ablation of oesophageal mucosa

Continues…

Device[a]	Description	Function
Argon plasma coagulation machine	Appliance	Controls bleeding from certain lesions in gastrointestinal tract
Cryoablation machine	Appliance	Low temperature used to treat/ablate dysfunctional tissue
Radiofrequency machine	Appliance	Ablates dysfunctional tissue
Stents: self-expandable metallic stent (e.g. Ultraflex®, Wallstent®); anti-reflux stent (Z-Stent®); double-layered; Niti-S stent	Implant	Management of anastomotic leakage after oesophagectomy to manage dysphagia
Anti-reflux valve	Implant	Prevents gastro-oesophageal reflux following stent insertion
Electrocautery	Instrument	Marking/cutting of mucosa at tumour
Guide-wire	Consumable	Part of catheter used to deploy stents
Snare	Consumable	Marking of mucosa at tumour
Nasogastric tube	Consumable	Assistance to surgery and nasogastric decompression
Stapler	Instrument	Oesophagogastric anastomosis after oesophageal cancer resection
Heat and moisture exchanger (e.g. Provox HME®)	Instrument	Prevents drying of respiratory mucosa during mechanically ventilation
Gauze	Consumable	Surgical procedures
Suture	Consumable	Surgical procedures
Clip	Consumable	Surgical procedures
Ligature	Consumable	Surgical procedures

CT: computed tomography; PET: positron-emission tomography.

[a] Proprietary marks have been included where this information was readily identified through source material.

4.4 CANCER OF THE LUNG, TRACHEA AND BRONCHUS

Introduction

Cancers of the lung, trachea and bronchus are the most common cancers worldwide. Lung cancer is categorized as either small cell lung cancer or non-small cell lung cancer. Small cell lung cancer is the more aggressive, having a higher propensity to metastasize *(30)*. The predominant causal factor for lung cancer is tobacco smoking. Environmental risk factors for the development of lung cancer include exposure to radon gas, and industrial or chemical carcinogens such as asbestos and air pollution. A family history of lung cancer and pre-existing diseases of the lung such as tuberculosis and pneumonia are also associated with an increased risk. Lung cancer incidence rates among males are reported to have peaked in North America, Australia, New Zealand and many countries in north-western Europe during the 1980s, and have subsequently declined. In contrast, incidence rates have been increasing or have begun to plateau in many southern and eastern European countries, Japan and China. Overall the percentage of new lung cancers diagnosed in developing countries as a proportion of lung cancers worldwide rose from 31% in 1980 to approximately 50% in 2002 *(30)*.

By 2008 there were an estimated 1.61 million new cases of lung cancer and lung cancer was the most common cause of cancer mortality. The age-standardized rate of lung cancer worldwide for people aged 60 years or over is estimated to be 148 per 100 000, with men affected more frequently than women *(3)*. The epidemiology of lung cancer reflects trends in smoking prevalence throughout the world: high rates are observed in central, eastern and southern Europe, North America and eastern Asia, while very low rates are estimated in middle and western Africa *(31)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of lung, trachea and bronchus cancer. The following filters were applied to the search results: English language and published within the past five years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	neoplasm, tracheal [MeSH terms]
#3	trachea* AND tumor*
#4	trachea* AND neoplasm*
#5	trachea* AND tumour*
#6	trachea* AND cancer*
#7	#2 OR #3 OR #4 OR #5 OR #6
#8	bronchial neoplasms [MeSH terms]
#9	bronchia* AND neoplasm*
#10	bronchia* AND tumor*
#11	bronchia* AND tumour*
#12	bronchia* AND cancer*
#13	#8 OR #9 OR #10 OR #11 OR #12
#14	lung neoplasms [MeSH terms]
#15	lung AND neoplasm*
#16	lung AND tumor*
#17	lung AND tumour*
#18	lung AND cancer*
#19	#14 OR #15 OR #16 OR #17 OR #18
#20	#7 OR #13 OR #19
#21	#20 AND #1

Results

The strategy yielded 181 results. On the title and abstract screen, 52 studies were identified that reported the use of a device for the prevention, diagnosis or treatment of lung, trachea or bronchus cancer. The details of the key studies retrieved for full text review are summarized in Table 16. These studies were then used to inform the list of devices presented in Table 17.

A review of the included studies identified a focus on diagnosis and treatment. The search did not identify any devices for the prevention of lung cancer. Screening using X-ray and sputum cytology in the general population or with scanning in high-risk patients does not appear to be supported *(31–33)*.

The search identified a range of devices used in the diagnosis and staging of lung cancer, including imaging devices and devices to obtain a tissue sample for pathology (Table 17). Treatment options include surgical resection (lobectomy), chemotherapy and radiotherapy. Ablative technologies and video-assisted thorascopic surgery were identified as emerging therapies for lung cancer.

The search also identified a range of sealant materials and devices for the reduction of alveolar air leak following pulmonary resection.

4.5 STOMACH CANCER

Introduction

Gastric cancer is the second most common cancer of the gastrointestinal system and the fourth most prevalent cancer worldwide. Although there is no definitive cause, *H. pylori* infection, smoking, age over 50 years, unbalanced diet and excessive salt intake (more than 10 g/day) are risk factors. Family history of stomach cancer, including familial adenomatous polyposis and hereditary non-polyposis colorectal cancer, also predisposes to the disease *(41)*.

Table 16 Lung, trachea and bronchus cancer – key studies

Study	Level of evidence	Primary focus[a]	Secondary focus
Brunelli et al 2010 *(5)*	II	Air leak and intrapleural pressure monitoring device	X-ray Chest drain Staplers
Carrafiello et al 2012 *(35)*	II	Radiofrequency ablation Microwave ablation	Biopsy needle CT Thoracic multidetector row CT CT fluoroscopy
Cerfolio et al 2008 *(36)*	II	Heimlich valve	Water seal device Pulmonary function CT PET Epidural equipment Needles Forceps Chest retractor
Grand et al 2011 *(37)*	II	Electromagnetic needle system	Chest radiograph CT fluoroscopy Single-detector row scanner High-speed CT Coaxial lung biopsy needle
Han et al 2010 *(38)*	II	Abdominal compression	Four-dimensional CT simulation with vacuum cushion Respiratory cycle signal monitoring system Stereotactic body radiation therapy Vacuum cushion alone or within stereotactic body frame
Hetzel et al 2012 *(39)*	II	Cryoprobe Flexible bronchoscope Rigid tube	Forceps
Miyamoto et al 2010 *(40)*	II	Integran®: sheet type absorbable topical collagen haemostat	TachoComb: bioabsorbable polyglycolic acid mesh sheet Fibrin glue Stapler

CT: computed tomography; PET: positron-emission tomography.

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 17 Lung, trachea and bronchus cancer – devices identified for diagnosis and treatment

Device[a]	Description	Function
Diagnosis		
Helical CT system	Appliance	Medical imaging modality using computer-processed X-rays to generate cross-sectional images of body. May involve intravenously injected contrast agents. Used for screening and diagnosis
Biopsy needle	Instrument	Takes tissue sample for pathology
Flexible fibre-optic bronchoscope	Instrument	Visualizes lung structures
Coaxial lung biopsy needle	Instrument	Biopsy of lung mass
Electromagnetic needle system (including computer workstation, electromagnetic field generator, fiducial markers and electromagnetic tracking needle)	Appliance	Guides biopsy for correct positioning and maximum diagnostic yield

Device[a]	Description	Function
Forceps	Instrument	Takes tissue sample for pathology
Brush	Instrument	Takes tissue sample for pathology
Biopsy needles: Tru-cut-type; modified Menghini-type needle	Instrument	Takes tissue sample for pathology
Cryoprobe	Instrument	Takes tissue sample for pathology (cryobiopsy)
Endobronchial ultrasound system	Appliance	Assists in navigation in biopsy
Mediastinoscope	Instrument	Collects tissue or fluid from lungs
PET system	Appliance	Nuclear medicine imaging modality using positron-emitting radionuclide tracers to generate three-dimensional images of metabolic processes within body. Provides guidance in lung biopsy
Spirometer	Instrument	Measures flow and volume of exhaled air
Radial ultrasonic probe	Instrument	Assists accurate insertion of bronchoscope
Suction catheter	Instrument	Bronchoscopic tissue sampling
X-ray machine	Appliance	Uses penetrating electromagnetic radiation to visualize anatomical structures. Used for distinguishing pathological tissue from normal tissue; diagnosis of lung cancer; pretreatment, intraoperative monitoring, follow-up and screening
MRI system	Appliance	Medical imaging modality using magnetic fields and radiowaves to visualize anatomy, in particular soft tissue, organs and muscle. Provides images of lung tissues
Electrocardiogram machine	Appliance	Electrocardiographic assessment of patients.
Treatment		
Sealants: BioGlue®; Vivostat®; TachoSil®; TachoComb®; bioabsorbable polyglycolic acid mesh sheet; fibrin glue; Integran® (sheet type absorbable topical collagen haemostat)	Consumable	Reduces alveolar air leak after pulmonary resection
Microelectronic mechanical system sensor	Appliance	Reduces alveolar air leak after pulmonary resection
Digital continuous recording system	Appliance	Monitors air leak
Radiofrequency ablation system (including probe, radiofrequency generator and temperature-monitoring probe)	Appliance	Ablates lung tumours
Microwave ablation system (including microwave generator, microwave antennae and saline perfusion system)	Appliance	Ablates lung tumours
Transcutaneous electrical nerve-stimulation unit	Appliance	Treats pain after thoracotomy
Radiotherapy machine (medical linear accelerator)	Appliance	Generates radiation for radiotherapy treatments
Immobilization system	Instrument	Immobilizes patient during stereotactic body radiation therapy
Ventilator	Appliance	Supports postoperative lung function and during thoracoabdominal oesophagectomy
Chest retractor	Instrument	Pulmonary resection
Stapler	Instrument	Surgical procedures
Stents: silicone; metal; covered; uncovered	Implant	Treats obstruction in thyroid cancer that has invaded larynx or trachea
Syringe	Consumable	Administers pharmacological agents
Intercostal drain	Instrument	Drains lungs following interventional procedure

CT: computed tomography; MRI: magnetic resonance imaging; PET, positron-emission tomography.

[a] Proprietary marks have been included where this information was readily identified through source material.

Approximately 1 million new cases of gastric cancer were estimated in 2012, amounting 7% of the total cancer incidence. More than 70% of cases occur in developing countries. The risk of stomach cancer is nearly twice as high in men than women. Overall the 5-year survival of stomach cancer is only 15–20% because it is mostly diagnosed at an advanced stage. The highest estimated mortality rates are in eastern Asia: 24.0 per 100 000 men and 9.8 per 100 000 women *(3)*.

Prevention of gastric cancer can be broadly divided into primary and secondary prevention. Primary prevention is essentially behavioural modification, which seeks to control aetiological determinants. Secondary prevention relies on early detection, which can be achieved through regular cancer screenings.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of stomach cancer. The following filters were applied to the search results: English language and published within the past five years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	stomach neoplasms [MeSH terms]
#3	stomach AND neoplasm*
#4	stomach AND tumor*
#5	stomach AND tumour*
#6	stomach AND cancer*
#7	gastr* AND neoplasm*
#8	gastr* AND tumor*
#9	gastr* AND tumour*
#10	gastr* AND cancer*
#11	#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10
#12	#1 AND #11
#13	#1 AND #11 Filters: randomized controlled trails, systematic reviews, published in the past five years, English

Results

The strategy yielded 70 results. On the title and abstract screen, 18 studies were identified that reported the use of a device for the prevention, diagnosis or treatment of colorectal cancer. The details of the key studies retrieved for full text review are summarized in Table 18. A broader list of identified devices was obtained through title and abstract review of all included studies (Table 19).

The search identified devices related to the prevention, diagnosis and treatment of gastric cancer. Endoscopes were identified as screening strategies for precancerous infections such as *H. pylori (42)*. Serological testing of pepsinogens and gastrin-17 markers appears to be emerging in in vitro diagnostics in early identification of patients at high risk of gastric cancer *(43)*. The search identified several diagnostic procedures, including imaging, histopathology and in vitro tests.

The main therapeutic procedures were undertaken through open laparotomy, laparoscopically or endoscopically. Gastrojejunostomy and stent placement are commonly used treatments for malignant gastric outlet obstruction. Chemotherapy and radiotherapy are also used in the management.

Table 18 Stomach cancer – key studies

Study	Level of evidence	Primary focus[a]	Secondary focus[a]
Wilhelm et al 2011 *(44)*	II	Dissection techniques Ultrasonic dissector (e.g. Harmonic Wave®)	Sutures Ligatures Gauzes Clips Electrocautery
Kim et al 2010 *(45)*	II	Stents Covered self-expanding metallic stents Uncovered self-expanding metallic stents	Endoscope (e.g. Olympus® GIF-H260, GIF-2T240) X-ray for fluoroscopy Guide-wire
Tatsumi et al 2012 *(42)*	II	Dissection techniques Water-jet videoendoscope Conventional videoendoscope	Knives (insulated tipped knife, needle knife) Disposable attachment (e.g. Olympus® D-201–11804) Forceps, coagrasper (e.g. Olympus® FD-410LR) Coagulation systems (e.g. Intelligent™ Cut and Coagulation 200) Diathermy devices Mechanical pump (e.g. Olympus® OFP-2), J-scope (e.g. EVIS™ GIF-Q260J)
Kiyotoki et al 2010 *(46)*	II	Imaging Narrow-band imaging Indigocarmine chromoendoscopy	Light source (e.g. CV-260SL) Forceps Knifes Electrocautery with tip of high-frequency snare (e.g. SD-5L-1s) Light microscopy (e.g. BX41) Imaging tools such as DP2-BSW software

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 19 Stomach cancer – devices identified for prevention, diagnosis and treatment

Device[a]	Description	Function
Prevention		
Endoscope	Instrument	Endoscopic biopsy for H. pylori diagnosis
pH monitoring systems (e.g. BRAVO™ catheterless)	Instrument	Assists diagnosis of gastro-oesophageal reflux disease and regulation of gastric acid
Diagnosis		
Endoscopes: 2-way and 4-way angulation endoscopes; magnifying endoscopy with narrow-band imaging; indigocarmine chromoendoscopy	Instrument	Screening and diagnosis of gastric cancer. Imaging and contrast material assists viewing of lesions
Ultrasound (endoscopic ultrasound)	Appliance	Guides fine-needle aspiration and biopsy in cancer diagnosis
CT system	Appliance	Medical imaging modality using computer-processed X-rays to generate cross-sectional images of body. May involve intravenously injected contrast agents
PET system	Appliance	Nuclear medicine imaging modality using positron-emitting radionuclide tracers to generate three-dimensional images of metabolic processes within human body
Treatment		
Endoscope Water-jet videoendoscope Small-calibre endoscope	Instrument	Assists surgical procedures such as endoscopic submucosal dissection, insertion and deployment of stents etc.
Ultrasonic dissector[b] (Harmonic Wave®)	Instrument	Marks and cuts mucosa at tumour

Continues…

Device[a]	Description	Function
Stents: covered and uncovered SEMS; anti-reflux stent	Implant	Management of anastomotic leakage after gastrectomy and malignant gastric outlet obstruction
Guide-wire	Consumable	Guides insertion of stents in management of bowel obstruction
Coil (interlock detachable coil)	Consumable	Embolizes gastroduodenal artery
Catheters: Soft-VU® catheter; angled guiding catheter	Consumable	Provides assistance for surgical procedures
Clips (e.g. NiTi Hand CAC™ 30)	Consumable	Anastomotic clips and compression devices
Vascular plugs (e.g. Amplatz™ vascular plug)	Instrument	Transcatheter vessel occlusion in prevention of radiation-induced peptic ulceration following radiotherapy
Nasogastric tube	Instrument	Nasogastric decompression during surgery
Oral gastric tube	Instrument	Nasogastric decompression during surgery
Laryngeal masks (e.g. LMAProSeal™ mask)	Instrument	Assists surgery and anaesthesia
Electrocautery	Instrument	Marks and cuts mucosa at tumour
Vessel-sealing systems (e.g. LigaSure™)	Instrument	Ligates and seals vessels
Stapler	Instrument	Oesophagogastric anastomosis after gastric cancer resection
Snare	Instrument	Marks mucosa at tumour
Knife (insulated tipped knife)	Instrument	Assists endoscopic submucosal dissection
Suture	Consumable	Surgical procedures
Ligature	Consumable	Surgical procedures
Gauze	Consumable	Surgical procedures

CT: computed tomography; PET, positron-emission tomography; SEMS: self-expandable metallic stent.

[a] Proprietary marks have been included where this information was readily identified through source material.

[b] The device consists of a generator and shear-like instrument connected via a plug-in linking cable and is activated by hand.

4.6 LIVER CANCER

Introduction

Liver cancer, or hepatocellular carcinoma, most commonly occurs in patients with chronic liver disease and cirrhosis of the liver. Viral hepatitis B and C are causes of chronic liver disease associated with hepatocellular carcinoma. Cirrhosis of the liver as a result of alcoholic and non-alcoholic fatty liver disease is also associated with hepatocellular carcinoma. Less commonly, hepatocellular adenoma, a benign tumour of the liver, may become malignant. In less than 10% of cases, hepatocellular carcinoma occurs in a normal liver *(47)*.

The International Agency for Research on Cancer reports that hepatocellular carcinoma is the fifth most common cancer in men and the seventh most common cancer in women worldwide. The incidence of hepatocellular carcinoma varies greatly: in western countries the incidence has been reported as three cases per 100 000 people, but in some parts of the world the incidence is as high as 15 cases per 100 000 people *(47)*. Approximately 85% of hepatocellular carcinoma cases occur in developing countries, including eastern and south-eastern Asia, middle and western Africa, Melanesia, Micronesia and Polynesia *(3)*. Overall, hepatocellular carcinoma occurs more commonly in men than women. The incidence increases with age, although age-specific patterns of incidence vary according to region and distribution of risk factors within the population. In high-risk areas the major risk factors are chronic hepatitis B infection and consumption of foodstuffs contaminated with aflatoxin B_1 *(48)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify

devices that could be used in the prevention, diagnosis or treatment of liver cancer. The following filters were applied to the search results: English language and published within the past 10 years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	liver neoplasms [MeSH terms]
#3	liver AND neoplasm*
#4	liver AND tumor*
#5	liver AND tumour*
#6	liver AND cancer*
#7	hepatic AND neoplasm*
#8	hepatic AND tumor*
#9	hepatic AND tumour*
#10	hepatic AND cancer*
#11	#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10
#12	#11 AND #1

Following a search of PubMed, supplementary resources were consulted to inform the broader clinical context of screening, diagnosis and treatment of liver cancer. Resources consulted included, but were not limited to, the Best Practice database of the BMJ Evidence Centre *(49)* and clinical practice guidelines *(47)*.

Results

The strategy yielded 187 results. On the title and abstract screen, 109 studies were identified that reported the use of a device for the prevention, diagnosis or treatment of liver cancer. The details of the key studies retrieved for full text review are summarized in Table 20. A broader list of identified devices was obtained through title and abstract review of all included studies (Table 20).

The search identified several devices for the diagnosis and treatment of liver cancer. The search did not identify any devices for the prevention of liver cancer. Broader review indicated that control of risk factors, primarily chronic liver disease, is the key focus for preventive strategies.

Preventive strategies focus on the association between chronic liver disease and hepatocellular carcinoma; strategies include vaccination against hepatitis B and programmes to stop transmission of hepatitis B and C *(47)*. Clinical signs of hepatocellular carcinoma include abdominal pain, jaundice, abdominal distension, leg oedema and weight loss; many patients are asymptomatic, however, and are diagnosed during a screening ultrasound *(49)*.

Surveillance screening may be indicated in patients with cirrhosis and consists of abdominal ultrasound and serum alpha-fetoprotein. Screening for and treatment of underlying viral infections that lead to cirrhosis may also be appropriate. The search also identified a study indicating the G/G polymorphism in the *EGF* gene as a predictive factor in the risk for hepatocellular carcinoma in patients with chronic hepatitis C. The clinical utility of this biomarker and a test for it are unknown.

Treatment strategies for liver cancer are based on the stage of disease, the number and size of lesions, and the patient's comorbidities and liver function. Treatments identified include liver transplantation, surgical resection, radiotherapy, systemic therapy, ablative therapies and minimally invasive therapies. A large number of devices used in hepatic resection, transarterial chemoembolization and percutaneous embolizing procedures were identified (Table 21). These devices appear to encompass established instruments, machines and materials for treatment, as well as more emerging alternative devices.

The search identified radiofrequency ablation and microwave ablation devices for the treatment of hepatocellular carcinoma. The literature indicated that radiofrequency ablation is a novel, but radical, alternative to surgery *(47)*. Microwave ablation is a less established ablative therapy and is considered to be a procedure that is on the horizon of being introduced or newly emerging.

Palliative treatments in patients with locally advanced or metastatic disease include percutaneous interventions, radiotherapy and systemic therapy. The search also identified stents as implantable devices relative to palliation in selected patients (Table 21).

Table 20 Liver cancer – key studies

Study	Level of evidence	Primary focus[a]	Secondary focus
Campagnacci et al 2007 *(50)*	II	LigaSure™ electrothermal bipolar vessel device	Ultrasonic shears Ultrasonic dissectors Dissecting sealers Intraoperative ultrasound CT MRI Fluid drains Electrocautical instruments Clamps
Liu et al 2010 *(51)*	II	Ultrasound-guided microwave ablation	Ultrasound Contrast-enhanced ultrasound Contrast-enhanced CT Gadolinium-enhanced MRI Thermal monitoring system Thermal monitoring needles Electrocautical equipment
Shibata et al 2009 *(52)*	II	Radiofrequency ablation system	Ultrasound guidance CT Thermocouple device Peristaltic pump Arterial portography Catheter Coeliac angiography Gelatin sponge particles Dynamic controlled CT Abdominal ultrasound Biopsy needle
Smyrniotis et al 2005 *(53)*	II	Scalpel	Clamps Argon-beam coagulation CT MRI Computed portography Intraoperative ultrasonography
Hendlisz et al 2010 *(54)*	II	Y-resin microspheres	Coils Lung shunts PET SPEC Catheters

Study	Level of evidence	Primary focus[a]	Secondary focus
Torzilli et al 2008 *(55)*	II	Monopolar floating ball (TissueLink™)	Intraoperative ultrasound Contrast-enhanced intraoperative ultrasonography Fibrin glue Electrocautery equipment Suction drains
Fisher et al 2011 *(56)*	II	TachoSil® adhesive	Argon-beam coagulation Vascular clips Ligatures Sutures
Malagari et al 2010 *(57)*	II	Drug-eluting beads	Angiography Catheters
Dudeck et al 2011 *(58)*	II	Standard pushable coils	Fibered interlock detachable coils Micro-catheters Introducer sheaths
Sofue et al 2011 *(59)*	II	Multi-detector row helical CT	CT with arterial portography CT with hepatic arteriography

CT: computed tomography; MRI: magnetic resonance imaging; PET: positron-emission tomography; SPECT, single photon-emission computed tomography.

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 21 Liver cancer – devices identified for diagnosis and treatment

Device[a]	Description	Function
Diagnosis		
Viral hepatitis panel[b]	IVD	Determines viral cause of chronic liver disease
Full blood count[b]	IVD	Checks for microcytic anaemia and/or thrombocytopenia
Liver function test[b]	IVD	Measures severity of disease; assesses suitability for liver resection
Prothrombin time, INR[b]	IVD	Measures function of liver; assesses candidacy for liver resection
Alpha-fetoprotein test[b]	IVD	Ordered following abnormal liver ultrasound
EGF genotype G/G assay	IVD	Assesses risk for hepatocellular carcinoma
Ultrasound	Appliance	May be contrast-enhanced. Guides biopsy and resection procedures
MRI system	Appliance	Medical imaging modality using magnetic fields and radiowaves to visualize anatomy, in particular soft tissue, organs and muscle. Distinguishes pathological and normal tissues for preoperative imaging and confirmation of diagnosis
CT system	Appliance	Medical imaging modality using computer-processed X-rays to generate cross-sectional images of body. May involve intravenously injected contrast agents. Preoperative imaging and diagnosis of patients; evaluates, detects, diagnoses and sizes hepatic lesions
Automatic power injector	Instrument	Administration of contrast material
Computed portography unit	Appliance	Establishes patency of vein; diagnosis of liver cancer
Arterial portography unit	Appliance	Establishes patency of the vein.
Catheter	Consumable	Computed portography and arterial portography procedures
Biopsy needle	Instrument	Biopsy procedures
Treatment		
LigaSure™ electrothermal bipolar vessel sealer	Instrument	Hepatic resection for division of parenchyma
Ultrasonic shears	Instrument	Hepatic resection for division of parenchyma

Continues…

Device[a]	Description	Function
Hydrodissection hydrojet	Instrument	Hepatic resection for division of parenchyma
Ultrasonic dissector	Instrument	Hepatic resection for division of parenchyma
TissueLink™ dissecting sealer	Instrument	Hepatic resection for division of parenchyma
Bifocal forceps	Instrument	Surgery for liver transaction
Electrocautery unit	Instrument	Incision of Glisson capsule of liver
Clamps: various	Instrument	Hepatic resection for crushing of liver parenchyma and control of liver inflow
Scalpel	Instrument	Hepatic resection
Vascular stapler	Instrument	Hepatic resection
TachoSil®	Consumable	Applied to resection surfaces to achieve haemostasis (absorbable surgical patch coated with human fibrinogen and human thrombin)
Fibrin glue	Consumable	Achieves haemostasis as liver surface sealant
Argon-beam coagulator	Appliance	Hepatic resection for control of residual capillary bleeding
Suture	Consumable	Ligation of vessels
Suction drain	Instrument	Controls bilirubin levels
Rubber tape	Consumable	Clamps portal triad using tourniquet technique
Microwave ablation probe	Appliance	Ablates hepatic lesions
Ultrasound	Appliance	Guides ablative procedures.
Cool-shaft antennae	Instrument	Controls temperature in ablative procedures
Thermocouple thermal monitoring probe	Instrument	Controls temperature in ablative procedures
Thermal monitoring needle	Instrument	Controls temperature in ablative procedures
Cool-tip radiofrequency ablation system	Appliance	Radiofrequency ablation of hepatic metastases
Peristaltic pump	Appliance	Maintains tip temperature of 20–25°C in ablative procedures
Beads/microspheres: Y-resin microspheres; drug-eluting beads	Materials	Delivers local high-dose radiation or chemotherapy
Multi-hole needle	Instrument	Injection of sterile ethanol in embolizing procedures
PVA particles: 250–355 µm; 355–500 µm; 500–710 µm	Materials	Embolization agents
Medical linear accelerator	Appliance	Generates radiation in radiotherapy procedures
Collimators (intensity-modulated radiotherapy machine)	Appliance	Delivers radiotherapy in intensity-modulated radiotherapy
CT system	Appliance	Obtains images for treatment simulations with three-dimensional conformal radiotherapy
Stents: metal; plastic; covered/uncovered	Implant	Palliative treatment for malignant biliary obstruction
Delivery system	Instrument	Stent placement
Duodenoscope	Instrument	Endoscopic retrograde cholangiopancreatography – endoscopic drainage
Catheters: reverse catheters; micro-catheters	Consumable	Deliver embolization materials and tracers to achieve access to portal vein and facilitate angiography
Coil	Consumable	Embolization procedures
Lung shunt	Instrument	Occlusion of hepatic circulation during embolization
Guide-wires	Consumable	Percutaneous embolization procedures
Introducer system	Instrument	Introduces guide-wire
Angiography sheath	Instrument	Establishes access to portal vein

Device[a]	Description	Function
Gelatin sponge	Consumable	Controls flow of target artery during embolization procedure
Vascular plug	Instrument	Transcatheter embolization procedures
Mechanically detachable long micro-coil	Consumable	Occlusion of gastroduodenal artery before selective internal radiotherapy
Pushable coil	Consumable	Occlusion of gastroduodenal artery before selective internal radiotherapy or for other occlusive procedures

CT, computed tomography; INR: international normalized ratio; IVD: in vitro diagnostic; MRI, magnetic resonance imaging.

[a] Proprietary marks have been included where this information was readily identified through source material.

[b] Identified by supplementary searches.

4.7 LYMPHOMA

Introduction

Lymphoma is a term that includes lympho-proliferative malignant diseases originating from T- and B-cells in the lymphatic system. It is usually considered to be Hodgkin's lymphoma or non-Hodgkin's lymphoma *(60)*. Non-Hodgkin's lymphoma encompasses a heterogeneous group of malignancies. The heterogeneity of lymphomas is due to the various lymphocyte types present in the body *(61)*. Classification of non-Hodgkin's lymphoma is carried out according to the cell lineage of the lymphocyte (T- or B-cell); B-cell lymphoma is the most common type. Hodgkin's lymphoma is a histopathologically distinct lymphoma characterized by the presence of Hodgkin or Reed–Sternberg cells; this form of lymphoma is rare and manifests predominantly in young adulthood and advanced age *(60)*.

The aetiology of Hodgkin's and non-Hodgkin's lymphoma is complex and not fully understood. Non-Hodgkin's lymphoma is linked to viruses, bacteria and autoimmune disorders. In Hodgkin's lymphoma, immune deficiency and infection with the Epstein–Barr virus are established risk factors. The following have been associated with an increased risk of both Hodgkin's and non-Hodgkin's lymphoma:

- immunosuppression therapy
- human immunodeficiency virus (HIV) infection
- congenital immunodeficiency
- autoimmune diseases.

Infective organisms, including *H. pylori*, human T-lymphotrophic virus type I and human herpesvirus 8, have also been identified as risk factors for the development of lymphoma *(60)*.

The estimated global incidence in 2012 was 5.0 per 100 000 people (age-standardized rate) for non-Hodgkin's lymphoma and 0.9 per 100 000 for Hodgkin's lymphoma. The Western Pacific Region accounted for 22% of new cases of non-Hodgkin's lymphoma and 8% of new cases of Hodgkin's lymphoma in 2012 *(3)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of lymphoma. The following filters were applied to the search results: English language and published within the past 10 years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))

#2	lymphoma [MeSH terms]
#3	hodgkin AND lymphoma*
#4	non-hodgkin AND lymphoma*
#5	#1 OR #2 OR #3 OR #4 OR #5
#6	#5 AND #1

Relevant clinical practice guidelines regarding lymphoma were also consulted *(60)*.

Results

The strategy yielded 131 results. On the title and abstract screen, 88 studies were identified that reported the use of a device for the prevention, diagnosis or treatment of lymphoma. The details of the key studies retrieved for full text review are summarized in Table 22. A broader list of identified devices was obtained through title and abstract review of all included studies (Table 23).

The search identified a limited number of devices for the diagnosis and treatment of lymphoma. No preventive devices or strategies were identified. Diagnosis is a complex process based on history, physical examination, laboratory testing, imaging studies, tissue biopsy and cell markers obtained from immunohistochemical, flow-cytometric and cytogenetic testing. Accurate diagnosis is important for treatment because the treatment protocol is based on the histological subtype of lymphoma.

Pathological evaluation of tissue samples is the definitive method for diagnosis, and several devices for obtaining a biopsy sample were identified (Table 23). Several biomarkers with prognostic value in the diagnosis of lymphoma were also identified. These can be investigated using several techniques such as immunohistochemistry, flow cytometry and genetic assays. Broader review also indicated that the diagnosis and characterization of lymphoma are challenging and may require the involvement of expert haematopathologists *(61)*.

A range of imaging devices used in the evaluation and staging of lymphoma was also identified (Table 23). Treatment for lymphoma consists of a range of treatment protocols, which include chemotherapy, radiotherapy, bone marrow transplant and autologous stem cell transplant. Adjunct treatments include the administration of growth factors, central nervous system prophylaxis and antimicrobial factors. Isolated lesions may be resected surgically. Treatments for concomitant infections may also be relevant.

Table 22 Lymphoma – key studies

Study	Level of evidence	Primary focus[a]	Secondary focus
Ott et al 2010 *(62)*	II	Immunohistochemistry: expression levels of markers, including CD5, CD10, BCL2, BCL6	CHOP chemotherapy therapy with or without rituximab
Liang et al 2007 *(63)*	II	Ultrasound-guided percutaneous spleen biopsy, 18-gauge and 21-gauge needles Magnum® automated biopsy gun Fine-needle biopsy	Immunohistochemistry Sonographic examination CT Surgical pathology
Anselmo et al 2004 *(64)*	II	Chemotherapy Radiotherapy	Physical examination Blood analysis Chest X-ray Chest, abdominal and pelvic CT Ultrasound examination of liver and spleen Bilateral bone marrow biopsy Electrocardiogram evaluation

Study	Level of evidence	Primary focus[a]	Secondary focus
Faber et al 2006 *(65)*	II	Stem cell transplant COBE® Spectra blood separators Ice-Cube 1810 appliance Temperature-controlled tanks Immunofluorescence flow cytometry assay	Central venous lines Chemotherapy Graft reinfusion
Garcia Vicente et al 2012 *(66)*	IV	PET/CT with F-deoxyglucose	PET/CT
van Heeckeren et al 2006 *(67)*	II	High-dose chemotherapy CliniMACS® device	Baseline: blood count, lymphocyte subset analysis including CD4+ and CD8+ T-lymphocytes (CD3+ cells), B-lymphocytes (CD19+ cells) and NK cells (CD16/CD56+ CD3) Immunofluorescent flow cytometry: FACSCalibur™ flow cytometer

CHOP: cyclophosphamide, hydroxydaunorubicin, oncovin, prednisone; CT: computed tomography; PET: positron-emission tomography.

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 23 Lymphoma – devices identified for diagnosis and treatment

Device[a]	Description	Function
Diagnosis		
PET system	Appliance	Nuclear medicine imaging modality using positron-emitting radionuclide tracers to generate three-dimensional images of metabolic processes within human body. Detects recurrence of lymphoma and used in staging of lymphoma. Techniques include F-deoxyglucose PET
MRI system	Appliance	Medical imaging modality using magnetic fields and radiowaves to visualize anatomy, in particular soft tissue, organs and muscle. Detects recurrence of lymphoma and stages lymphoma
X-ray machine	Appliance	Uses penetrating electromagnetic radiation to visualize anatomical structures. Detects recurrence of lymphoma and stages lymphoma
CT system	Appliance	Medical imaging modality using computer-processed X-rays to generate cross-sectional images of body. May involve intravenously injected contrast agents. Detects recurrence of lymphoma and stages lymphoma
Ultrasound	Appliance	Diagnosis of lymphoma
Electrocardiogram machine	Appliance	Cardiological assessment of patient suitability for chemotherapy/ radiotherapy
Biopsy needle	Instrument	Biopsy procedures
Biopsy gun	Instrument	Biopsy procedures
FACSCalibur™ (flow cytometer)	Appliance	Analyses immunofluorescent flow cytometry sample
Tests: full blood count; blood smear; basic metabolic; liver function; lactate dehydrogenase; erythrocyte sedimentation rate[b]	IVD	Assesses organ function in diagnosis and treatment planning
BCL6 gene assay	IVD	Clarifies relationship between primary mediastinal B-cell lymphoma and other non-thymic diffuse large-cell lymphomas
Immunohistochemical expression test	IVD	Tests for cell surface markers, e.g. CD5, CD10, BCL2, BCL6, HLA-DR for use in prognostic assessment
FISH assay	IVD	Tests for bcl-2 protein, a potential biological prognostic marker in intermediate and high-grade non-Hodgkin's lymphoma
Treatment		
Catheters: Hickman catheter; peritoneal catheter; Portacath	Consumable	Deliver chemotherapy

Continues…

Device[a]	Description	Function
COBE® Spectra blood separator	Appliance	Autologous peripheral stem cell transplant
Medical freezer	Appliance	Autologous peripheral stem cell transplant
Temperature-controlled tank	Appliance	Autologous peripheral stem cell transplant (cryopreservation)
Flow cytometer	Appliance	Autologous peripheral stem cell transplant
Medical linear accelerator	Appliance	Generates radiation in radiotherapy procedures
Collimator	Appliance	Delivers radiotherapy in intensity-modulated radiotherapy
Low-energy helium–neon laser	Appliance	Treatment of radiation-induced oral mucositis
Mouthwash	Consumable	Treatment of oral mucositis after radiotherapy
CliniMACS® CD34 cell-separation system	Appliance	Separates cells

CT: computed tomography; FISH: fluorescence in situ hybridization; HLA: human leukocyte antigen; IVD: in vitro diagnostic; MRI: magnetic resonance imaging; PET: positron-emission tomography.

[a] Proprietary marks have been included where this information was readily identified through source material.

[b] Identified via supplementary searches.

4.8 BREAST CANCER

Introduction

Breast cancer is a malignancy that originates in the breast *(68)*. Diagnosis of breast cancer may be defined as follows:

- Breast carcinoma in situ is confined to the ducts and lobules of the breast (ductal carcinoma in situ and lobular carcinoma in situ) *(69)*.
- Primary invasive breast cancer is cancer that has spread to surrounding breast tissues *(70)*.
- Metastatic breast cancer is cancer that has spread beyond the breast and ipsilateral lymph nodes *(71)*.

Many genetic factors have been associated with primary invasive breast cancers, including *BRCA* gene mutations (in either of the genes *BRCA1* and *BRCA2*), which confer an elevated lifetime risk of breast and ovarian cancer. Oestrogen has also been implicated in the aetiology of breast tumours, with evidence suggesting that increased levels of endogenous sex hormones are correlated with an elevated risk of breast cancer. The risk of developing breast cancer increases with advancing age, and the majority of new diagnoses are in women aged 50 years or over *(72)*. Preventive strategies in women identified to be at a high risk of developing breast cancer include treatment with selective oestrogen receptor modulators and prophylactic mastectomy or oophorectomy *(3)*. Male breast cancer is rare, accounting for less than 1% of all breast cancers.

Globally, breast cancer is a common neoplastic disease in both the developed and developing world. It is the most frequent cancer among women and the most frequent cause of death from cancer among women worldwide. The International Agency for Research on Cancer estimates that 1.6 million new breast cancers were diagnosed in 2012 *(3)*. In more developed countries the reported incidence of breast cancer is high (more than 80 per 100 000 women), while in developing countries the reported incidence is lower (less than 40 per 100 000 women); this is likely to be due to reduced access to mammography and other screening devices in developing countries. Variation in mortality due to breast cancer between countries is less pronounced due to more favourable survival outcomes for women in more developed countries compared with developed countries *(3)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of breast cancer. The following filters were applied to the search results:

English language and published within the past five years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	breast neoplasms [MeSH terms]
#3	breast AND neoplasm*
#4	breast AND tumor*
#5	breast AND tumour*
#6	breast AND cancer*
#7	#2 OR #3 OR #4 OR #5 OR #6
#8	#7 AND #1

Results

The strategy yielded 251 results. On the title and abstract screen, 167 studies were identified that reported the use of a device for the prevention, diagnosis or treatment of breast cancer. The details of the key studies retrieved for full text review are summarized in Table 24. A broader list of identified devices was obtained through title and abstract review of all included studies (Table 25).

The search strategy identified several devices for the prevention, diagnosis and treatment of breast cancer. Preventive strategies vary according to an individual's risk of developing breast cancer. Genetic tests for *BRAC1* and *BRAC2* mutations have a role in determining the level of risk to a patient. For patients at high risk of developing breast cancer, various preventive strategies, including chemoprevention, prophylactic mastectomy and prophylactic oophorectomy, may be employed. In women over 70 years of age, genetic screening for *BRCA1* and *BRCA2* is less appropriate (P Walsh, Queen Elizabeth Hospital, Adelaide, Australia, personal communication, 3 January 2013).

The search identified several devices involved in screening for breast cancer. Clinical advice indicates that X-ray mammography units are the main screening devices in women of advanced age (over 70 years) (P Walsh, Queen Elizabeth Hospital, Adelaide, Australia, personal communication, 3 January 2013). Patients undergoing mammography may have plain or contrast-enhanced mammography. Three-dimensional tomosynthesis mammography may also be available; this technique appears to be investigational *(73)*. Ultrasound and MRI were identified as being important in the diagnosis of women under the age of 50 years, as these technologies are more effective in detecting cancers in denser breast tissue, although the proportion of older women with dense breasts is unknown *(74)*.

Although screening initiatives may vary between countries, there is evidence to suggest that mammograms undertaken every 1–2 years in women aged 40–70 years may reduce breast cancer-related mortality *(75)*. The search identified a range of studies focused on initiatives to recruit women to screening programmes or to encourage adherence.

Definitive diagnosis is made by histological analysis of biopsy samples, and a number of devices used in biopsy procedures were identified in the search. Core biopsy, fine-needle aspiration and cytological puncture have different applications in the diagnosis of breast cancer, and a patient may require more than one kind of biopsy (Table 25). Several devices used in the preoperative assessment of sentinel node involvement for biopsy were also identified (Table 25).

Both MRI and CT are used in the staging of disease and planning of treatment. In the planning of treatment, testing for the hormone receptor status, human epidermal growth factor receptor 2 (*HER2*) gene status and genetic profile (Oncotype DX® assay) of the tumour may occur (Table 25) to assist in patient selection for chemotherapy.

Therapeutic devices identified for the treatment of breast cancer include those used in the treatment of the cancer and in postoperative care. Surgery, radiotherapy, chemotherapy and endocrine therapies are offered to patients with breast cancer. Treatment approach is based on the stage of the disease, comorbidities and tumour characteristics such as hormone receptor status. Several radiotherapy devices were identified in the search, including intensity-modulated radiotherapy, three-dimensional conformal radiotherapy, skin-sparing helical tomotherapy and targeted intraoperative radiotherapy; of these, the targeted intraoperative radiotherapy system was identified as an emerging therapeutic option (P Walsh, Queen Elizabeth Hospital, Adelaide, Australia, personal communication, 3 January 2013). This device is associated with shorter treatment times than traditional radiotherapy and may benefit patients who are not able to return for additional radiotherapy after the initial surgery.

Ablative devices identified by the search are not currently established for the treatment of breast cancer. Discussion with a clinical expert indicated that the role of ablative devices in the management of breast cancer is most likely to be used in a palliative manner to control cancer in patients with advanced disease (P Walsh, Queen Elizabeth Hospital, Adelaide, Australia, personal communication, 3 January 2013).

Surgery for breast cancer may include dissection of lymph nodes, which can result in postoperative lymphoedema. The search identified several devices for the treatment of lymphoedema. Additionally, devices for guidance in resection were also identified (Table 25). Other devices identified were prostheses for breast reconstruction, procedures and related devices for the treatment of malignant pleural effusion (in advanced metastatic disease), and tissue glues to avoid postoperative seroma.

Table 24 Breast cancer – key studies

Study	Level of evidence	Primary focus[a]	Secondary focus
Berg et al 2011 *(76)*	ND	Positron-emission mammography (PEM) MRI PEM and MRI	Mammography and ultrasonography
Canavese et al 2009 *(77)*	II	Lymphoscintigraphy Lymphatic dye mapping Gamma-ray detecting probe	Mammography
Godoy et al 2012 *(78)*	IV	Facilitating apparatus (arm movement)	Compression sleeve Compression bandage Compression garment Active exercise Lymphoscintigraphy
Iovino et al 2012 *(79)*	II	Harmonic scalpel (generator delivering electrical energy, hand piece, blade)	Conventional scalpel Suction drain Fibrin sealant Electrocautery equipment Scissors Ligations
Kerrou et al 2011 *(80)*	ND	Hand-held gamma-ray detection camera	Lymphoscintigraphy Dual detection using radioactive colloids and blue dye

Study	Level of evidence	Primary focus[a]	Secondary focus
Klimberg et al 2011 *(81)*	II	Laser ablation: interstitial laser photocoagulation at time of lumpectomy Radiofrequency ablation Ultrasound guidance Percutaneous biopsy	Ultrasound guidance Stereotactic biopsy MRI
Krekel et al 2011 *(82)*	II	Ultrasound guidance Palpation guidance	Wire localization Radio-occult localization
Medved et al 2011 *(83)*	ND	High-spectral and spatial resolution MRI with or without contrast X-ray mammography	None
Nelson et al 2009 *(84)*	IV	MammoSite® breast brachytherapy catheter	Whole-breast irradiation

MRI: magnetic resonance imaging; ND: not able to be determined.

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 25 Breast cancer – devices identified for diagnosis and treatment

Device[a]	Description	Function
Prevention		
Genetic testing for *BRCA* mutation	IVD	Establishes risk of developing breast cancer
Diagnosis		
Oncotype DX® assay	IVD	Informs patient selection for breast cancer treatments
Hormone receptor assay	IVD	Guides treatment in known breast cancer
HER2 status assay	IVD	Guides treatment in known breast cancer
X-ray mammography system	Appliance	Screens for breast cancer, mammographic detection of breast cancer. Also used with contrast materials to produce mammograms
Three-dimensional Tomosynthesis mammography system	Appliance	Screens for breast cancer. Mammogram produced displays tissue as three-dimensional image
MRI system	Appliance	Medical imaging modality using magnetic fields and radiowaves to visualize anatomy, in particular soft tissue, organs and muscle. Used to distinguish pathological tissue from normal tissue
PET system	Appliance	Nuclear medicine imaging modality using positron-emitting radionuclide tracers to generate three-dimensional images of metabolic processes within human body. Used to distinguish pathological tissue from normal tissue (PET). Also used in positron-emission mammography
Suction tube[b]	Instrument	Collects fluid in ductal lavage or nipple-aspiration procedure
Catheter[b]	Consumable	Collects fluid in ductal lavage or nipple-aspiration procedure from nipple: screening for breast cancer
Computer-aided detection software system	Software	Used with mammography machines to interpret results
Syringe	Consumable	Used to collect milk duct cells for analysis in fine-needle aspiration
Biopsy needles: various gauges	Instruments	Collect cells under image guidance during biopsy
Ultrasound machine	Appliance	Guides biopsy procedures including fine-needle aspiration and cytological puncture. Produces sonogram that assists in differentiating pathological tissue from normal tissue. Guides sentinel node biopsy with injection of dye
CT system	Appliance	Medical imaging modality using computer-processed X-rays to generate cross-sectional images of body. May involve intravenously injected contrast agents. Used to obtain cross-sectional pictures

Continues…

Device[a]	Description	Function
X-ray machine	Appliance	Uses penetrating electromagnetic radiation to visualize anatomical structures. Guides stereotactic breast biopsy. Distinguishes pathological tissue from normal tissue
Near-infrared laser breast imaging system	Appliance	CT laser mammography procedures
Treatment		
Medical linear accelerator	Appliance	Generates radiation in radiotherapy procedures
Collimator	Appliance	Delivers radiotherapy in intensity-modulated radiotherapy and intraoperative radiotherapy
Applicator system	Appliance	Delivers intraoperative radiotherapy
Patient-immobilization device	Instrument	Moulded device assisting in maintaining patient's positioning in radiotherapy treatment
Shielding devices	Instrument	Protect healthy tissues from radiation
Helical tomotherapy system	Appliance	Delivers helical tomotherapy
CT scanner	Appliance	Obtains images for treatment simulations with three-dimensional conformal radiotherapy
MammoSite® Radiation Therapy System	Instrument	Delivers temporary radiation seed to site of lumpectomy
Laser	Appliance	Photocoagulation technique used to obtain surgical margins
Radiofrequency energy delivery probe	Appliance	Delivers radiofrequency energy to lesions, causing tissue necrosis
Radiofrequency generator	Appliance	Generates radiofrequency energy for use in ablative procedures
Ultrasound: MarginProbe®	Appliance	Guides ablative procedures and surgical procedures. Assesses margins in surgical procedures
Temperature-monitoring probe	Instrument	Monitors tissue temperatures during ablative procedures
Gamma probe	Instrument	Detects sentinel lymph nodes intraoperatively
Continuous-infusion pump system	Appliance	Delivers pain-relieving medication postoperatively
Intravenous patient-controlled analgesia device	Appliance	Delivers pain-relieving medication postoperatively
Harmonic scalpel (consisting of hand piece, electrical generator and blade)	Instrument	Cavitation, coaptation and cutting in axillary dissection surgery
Scalpel	Instrument	Surgical procedures (axillary dissection)
Suction drain	Implement	Surgical procedures
Fibrin sealant	Consumable	Surgery for breast cancer to prevent seroma formation
Electrocautery device	Instrument	Surgical dissection and haemostasis
Scissors	Instrument	Surgical procedures
Ligature	Consumable	Surgical procedures
Clip	Consumable	Surgical procedures
Short stretch bandage	Consumable	Compression treatment of lymphoedema
Compression sleeve	Consumable	Compression treatment of lymphoedema
Compression garment	Consumable	Compression treatment of lymphoedema
Hoist	Apparatus	Facilitate limb movement postoperatively
Ga-As laser	Appliance	Low-level laser therapy to treat post-mastectomy lymphoedema
Cellu-M50 LPG System	Appliance	Delivers mechanical massage for tissue mobilization
Hydrogel dressing	Consumable	Treats radiotherapy-induced moist skin desquamation
Meplix® Lite dressings	Consumable	Treats erythema in women who have received radiation therapy

Device[a]	Description	Function
Topical purified honey ointment	Consumable	Treats radiation burn
Long-pulsed dye laser	Appliance	Treats radiodermatitis
Intense-pulsed light laser	Appliance	Treats radiodermatitis
Hand-held gamma-camera	Instrument	Preoperative imaging in sentinel node biopsy
Syringe	Consumable	Delivers dye for lymphoscintography procedures and sentinel node biopsy procedures. Dyes may include blue dye and radioactive colloid
Breast implant	Implants	Breast reconstruction
Plastic cup	Instrument	Breast volume and shape
Plastic cast	Instrument	Assess breast volume and shape
Three-dimensional laser scanner	Appliance	Assess breast volume and shape
Ultrasound system	Appliance	Guides resection of breast cancer. Guides injection of radiopharmaceuticals (radio-guided occult lesion localization)
X-ray system	Appliance	Guides biopsy (wire localization technique). Guides injection of radiopharmaceuticals (radio-guided occult lesion localization)
Needle	Instrument	Administers wire in wire localization of breast biopsy or resection procedures
Wire	Consumable	Guides breast biopsy or resection (wire-localization technique), placed via needle under X-ray guidance
Syringe	Consumable	Delivers radiopharmaceuticals (radio-guided occult lesion localization)
Thoracostomy tube	Instrument	Delivers agents for pleurodesis in palliative care of patients with malignant pleural effusion (metastatic breast cancer)
Fotona Fidelis Plus II (Er:YAG laser)	Appliance	Laser surgery and biostimulation as treatment for osteonecrosis of the jaw (women receiving bisphosphonates)
Transcutaneous electrical nerve stimulation unit	Appliance	During mastectomy
Antimicrobial-coated sutures	Consumable	Wound closure
Needle	Consumable	Delivers local anaesthetic instellate ganglion block, performed under ultrasound, CT or fluoroscopic guidance

CT: computed tomography; Er:YAG: erbium-doped yttrium aluminium garnet; IVD: in vitro diagnostic; MRI, magnetic resonance imaging; PET, positron-emission tomography.

[a] Proprietary marks have been included where this information was readily identified through source material.

4.9 COLON AND RECTUM CANCER

Introduction

Colorectal cancer, also known as large bowel cancer, is the third most common cancer in the world. Approximately 60% of cases occur in the industrial countries. The lowest incidences are reported from Africa (except southern Africa) and south-central Asia and are intermediate in Latin America. The disease is more common in men than women.

Bowel cancer is the fifth most common cause of deaths related to cancer *(3)*. The highest estimated mortality rates are in central and eastern Europe (20.3 per 100 000 males, 11.7 per 100 000 females), and the lower rates are in middle Africa (3.8 per 100 000 males, 3.9 per 100 000 females). The 5-year survival rate after diagnosis of colorectal cancer is about 45%, and 50–60% of patients eventually develop metastases *(85,86)*.

Although there is no definitive cause for the disease, approximately 20% of patients diagnosed with colorectal cancer have a familial association. Genetic abnormalities such as Lynch syndrome, hereditary non-polyposis colorectal cancer, familial adenomatous polyposis syndromes and *MYH*-associated polyposis can lead to familial colorectal

malignancy *(87)*. The disease is also associated with risk factors such as previous colonic polyps, diabetes mellitus, unbalanced diet (e.g. red meat, high-fat diet, inadequate fibre intake), obesity, sedentary lifestyle, smoking and excessive consumption of alcohol *(88)*. Colorectal cancer is more common in patients with ulcerative colitis or Crohn's disease *(89–91)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of colorectal cancer. The following filters were applied to the search results: English language and published within the past five years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	colonic neoplasms [MeSH terms]
#3	colon* AND neoplasm*
#4	colon* AND tumor*
#5	colon* AND tumour*
#6	colon* AND cancer*
#7	#2 OR #3 OR #4 OR #5 OR #6
#8	neoplasm, rectum [MeSH terms]
#9	rect* AND neoplasm*
#10	rect* AND tumor*
#11	rect* AND tumour*
#12	rect* AND cancer*
#13	#8 OR #9 OR #10 OR #11 OR #12
#14	#7 OR #13
#15	#1 AND #14
#16	#1 AND #14 Filters: randomized controlled trails, systematic reviews, published in the past five years, English

Results

The strategy yielded 191 results. On the title and abstract screen, 34 studies were identified that reported the use of a device for the prevention, diagnosis or treatment of colorectal cancer. The details of the key studies retrieved for full text review are summarized in Table 26. A broader list of identified devices was obtained through title and abstract review of all included studies (Table 27).

The search identified devices related to screening, diagnosis and treatment of colorectal cancer.

A population-based screening programme for colorectal cancer is under way in many advanced economies. For instance, the faecal occult blood test for men and women aged 50–74 years has been recommended by the European Union for this purpose *(92)*. The search identified two faecal occult blood tests – Guaiac and immunochemical. Biomarker testing such as the M2-PK test appeared to be useful in the screening, but the search did not produce studies that specifically highlighted this assay. Endoscopic screening methods are also increasingly being used.

In vitro tests are used in diagnosis and disease staging. A full blood count confirms the diagnosis of anaemia, which may be associated with bleeding from cancerous tissue. Carcinoembryonic antigen test reconfirms the diagnosis of cancer *(93)*. A liver function test identifies metastases to the liver, as identified through supplementary searches.

Severity of the disease is addressed according to the tumour–node–metastasis (TNM) staging. The cancer is confirmed by biopsy examination. X-ray following barium enema, CT of the chest, abdomen and pelvis, endorectal ultrasound, narrow-band imaging and autofluorescence imaging may be used to confirm the diagnosis and identify metastases. Two- and three-dimensional

CT colonography and cone-beam CT are used in patients where endoscopy is contraindicated or cannot be completed. Magnetic resonance volumetry and colonography are helpful in monitoring disease progression. PET was not identified by the literature search, but it may be used in the diagnosis *(94)*.

The management of the condition depends on the stage of disease and the underlying comorbidities. Surgical management includes resection of the cancerous bowel and reanastomosis. The resection can be performed as an open laparotomy or through laparoscopy. Ideally the resection is carried out as a single stage and is curative. Alternatively, the surgery may be performed in two or more stages due to underlying comorbidities. Colostomy is the initial stage of the resection to clear the obstruction; intestinal waste is collected in a colostomy bag.

Numerous devices are implanted to prevent complications of colorectal cancer and to assist with surgery. Colonic stents, specifically self-expanding metallic stents, are used in the prevention and management of obstruction. The search identified covered and uncovered types of self-expanding metallic stent. Park and colleagues implanted a sodium hyaluronate-based bioresorbable membrane with similar intentions *(95)*. Additionally, Serra-Aracil and colleagues used a mesh in the prevention of parastomal hernia following colostomy *(96)*.

In anal sphincter preservation following surgery, ultrasonically activated scalpels and monopolar electrocautery shovels have been used *(97)*. Stapling devices such as the Ethicon Proximate ILS and Autosuture Premium Plus CEEA are used specifically to prevent anastomotic leaks. Supplementary searches using clinical practice guidelines identified implant radiotherapy and brachytherapy as additional techniques used in management that were not identified through the results of the systematic literature review *(98)*.

Table 26 Colorectal cancer – key studies

Study	Level of evidence	Primary focus[a]	Secondary focus
Kuiper et al 2011 *(99)*	II	Endoscopy: endoscopic trimodal imaging (e.g. Olympus® Evis Lucera) – high-resolution endoscopy; autofluorescence imaging; narrow-band imaging; standard resolution video colonoscopy	Light source, red–green–blue filters, charge-coupled devices
Adler et al 2009 *(100)*	II	Endoscopy: narrow-band imaging by wide-angle colonoscope	High-definition television, snare, forceps
Tribonias et al 2010 *(101)*	II	Endoscopy: chromoendoscopy; narrow-band imaging; high-definition imaging	Forceps, gold probe, snare, polypectomy snare, video processor, high-definition screen
Park et al 2010 *(102)*	II	Stents: covered and uncovered self-expanding metallic stents	Polytetrafluoroethylene membrane, CT, X-ray (fluoroscopy), guide-wire, endoscope, stent-delivery catheter, balloon dilator
Zhou et al 2008 *(97)*	II	Instruments: electrocautery shovel; scalpel (ultrasonically activated scalpel)	Electrocautery, knife
Lee et al 2009 *(103)*	II	Imaging: CT; MRI; ultrasound machine Staplers: curved cutter stapler (e.g. contour); lineal stapler (e.g. DST series® TA®); disposable staple cartridge	Knife, clamps, scalpel, suture, electrocautery

CT: computed tomography; MRI: magnetic resonance imaging.

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 27 Colorectal cancer – devices identified for prevention, diagnosis and treatment

Device[a]	Description	Function
Prevention		
Faecal occult blood test	IVD	Screens for colorectal cancer
Guaiac-based faecal occult blood test	IVD	Screens for colorectal cancer
Immunochemical faecal occult blood test	IVD	Screens for colorectal cancer
Diagnosis		
Flexible endoscopes: white-light high-definition television endoscope; high-resolution endoscope; high-definition wide-angle endoscope; double-balloon endoscope; Third Eye® Retroscope®; narrow-band imaging; autofluorescence imaging endoscope	Instrument	Diagnosis of colorectal cancer by examination of bowel lumen and by biopsies collected during procedure
Extensions to endoscope (e.g. cap, hood, three-dimensional navigation, i-scan)	Instrument	Enhances imaging capability of endoscopes and endoscopic techniques
MRI	Appliance	Provides additional retrograde view to detect polyps behind folds
CT colonography system	Appliance	Medical imaging modality using computer-processed X-rays to generate cross-sectional images of body. May involve intravenously injected contrast agents. Used in patients in whom colonoscopy is contraindicated or cannot be completed, in detection and differentiation of colorectal lesions
Cone-beam CT system	Appliance	Measures interfractional changes in rectal movement and dimensions, and rectal and bladder volume
MRI system: diffusion-weighted imaging	Appliance	Medical imaging modality using magnetic fields and radiowaves to visualize anatomy, in particular soft tissue, organs and muscle. Predicts treatment outcomes of locally advanced rectal cancers with preoperative chemoradiotherapy
Magnetic resonance volumetry	Appliance	Predicts treatment outcomes of locally advanced rectal cancers with preoperative chemoradiotherapy
Magnetic resonance colonography	Appliance	Detects colorectal lesions
Treatment		
Stent: e.g. covered and uncovered SEMS	Implant	Manages bowel obstruction
Bioresorbable membranes	Implant	Reduces adhesive intestinal obstruction after colorectal cancer surgery (e.g. sodium hyaluronate-based bioresorbable membrane)
Transanal tube	Instrument	Prevents and reduces anastomotic leakage
Staplers: e.g. linear stapler, curved cutter stapler	Instrument	Secures distal rectum during low anterior resection in mid to low rectal cancers
Scalpel	Instrument	Provides assistance to anal sphincter-preservation procedures in rectal cancer
Shovel	Instrument	Provides assistance to anal sphincter-preservation procedures in rectal cancer
Mesh	Implant	Prevents parastomal hernia after colostomy

CT: computed tomography; IVD: in vitro diagnostic; MRI: magnetic resonance imaging; SEMS: self-expandable metallic stent.

[a] Proprietary marks have been included where this information was readily identified through source material.

4.10 PROSTATE CANCER

Introduction

Prostate cancer is defined as a malignant tumour of glandular origin situated in the prostate. The aetiology of prostate cancer is unknown. A high-fat diet and a family history of prostate cancer are associated with an increase in the relative risk of developing prostate cancer *(104)*. Prostate cancer is the second most frequently diagnosed cancer in men, with 1.1 million new cases registered worldwide in 2012 *(3)*. The disease predominantly

affects older men, with the age-standardized rate of prostate cancer increasing from 67.0 per 100 000 in men aged 55-59 years to 136.4 per 100 000 in men aged 60-64 years; beyond 64 years, the age-standardized rate continues to increase to 386.9 per 100 000 in men aged 75 years or older *(3)*.

The majority of cases of prostate cancer are reported in developed countries, where the practice of early detection is more prevalent than in developing countries. Although the incidence of prostate cancer varies widely according to geography, there is less variation in the mortality rates, with similar numbers of deaths reported from prostate cancer in developed and developing countries *(3)*. Most prostate cancer is slow-growing, and there is evidence to suggest that 60–70% of older men have histological prostate cancer; however, prostate cancer is diagnosed in only 15–20% of men during their lifetime *(105)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of prostate cancer. The following filters were applied to the search results: English language and published within the past five years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	prostate neoplasms [MeSH terms]
#3	prostate AND neoplasm*
#4	prostate AND tumor*
#5	prostate AND tumour*
#6	prostate AND cancer*
#7	#2 OR #3 OR #4 OR #5 OR #6
#8	#7 AND #1

Results

The search strategy yielded 245 results. On the title and abstract screen, 133 studies were identified that reported the use of a device for the prevention, diagnosis or treatment of prostate cancer. The details of the key studies retrieved for full text review are summarized in Table 28. A broader list of identified devices was obtained through title and abstract review of all included studies (Table 29).

The search did not identify any devices for the prevention of prostate cancer. Devices for the screening, diagnosis and treatment of prostate cancer were identified. A review of the literature identified a focus on early detection in men at high risk of developing prostate cancer as opposed to broad-spectrum screening programmes. Large screening studies have suggested that population-based screening is not appropriate because the risk of overdiagnosis is high and reductions in mortality appear modest, particularly in the short term (less than 6 years of follow-up) *(105)*. The optimal age and screening interval for early detection are yet to be established.

Established screening methods for prostate cancer include a prostate-specific antigen test and a digital rectal examination; the results of these are used to evaluate the need for biopsy. A panel of kallikrein markers (total prostate-specific antigen, free prostate-specific antigen, intact prostate-specific antigen, kallikrein-related peptidase 2) has been proposed as a supplementary test to determine the necessity of biopsy *(106)*. Definitive diagnosis of prostate cancer is based on histopathological analysis of biopsy samples. The search identified transrectal ultrasound as the primary guidance method for biopsy, and clinical input indicated that samples should be obtained from the entire gland. Broader searches identified an epigenetic assay

for detecting prostate cancer in false-negative biopsy samples *(107)*. This assay appears to be investigational. The search also identified MRI as being under investigation for use in the diagnosis of prostate cancer.

The results also identified several imaging devices and tests that can be used in the staging of prostate cancer, including CT, MRI, PET and nuclear scanning. Each imaging device may be used for several purposes and, depending on the suspected progression of the disease, multiple devices may be used. Several in vitro diagnostic tests may also be used in the assessment of patient suitability for different treatment options or to indicate locally advanced disease (Table 29). Endoscopy and cystoscopy were identified as devices that may be used if specific indications are present, such as urethral stricture.

The main therapeutic strategies identified for the treatment of prostate cancer are radical prostatectomy, radiotherapy and brachytherapy. Radical prostatectomy is performed as an open, laparoscopic or robot-assisted procedure; each of these is associated with different patterns of morbidity following surgery. The da Vinci Surgical System is one robotic device identified within the search results. Devices for the administration of anaesthesia and drainage following the procedure were also identified. Several devices of unknown state of establishment were identified, including the robotic camera holder and Cavemap device (Table 29).

Radiotherapy, including three-dimensional conformal radiotherapy, intensity-modulated radiotherapy and external-beam radiotherapy, is delivered with or without concomitant androgen deprivation. Devices involved include radiotherapy machines and immobilization devices. Devices associated with brachytherapy included delivery systems, imaging devices (ultrasound, CT, MRI) and radioactive seeds.

In some cases of aggressive, high-risk disease, multimodal treatment may be used. This includes a combination of radical prostatectomy, adjuvant radiotherapy and neoadjuvant hormone therapy. Ablative devices including cryotherapy and high-energy focused ultrasound were identified as devices that are not yet established.

The search also identified several devices for the treatment of complications following prostatectomy, including incontinence and erectile dysfunction (Table 29). For the treatment of incontinence, artificial sphincters, slings and bulking agents appear to be the most established therapies. For erectile dysfunction, treatment includes vacuum devices, penile implants and pharmacological therapies.

Table 28 Prostate cancer – key studies

Study	Level of evidence	Primary focus[a]	Secondary focus
Catto et al 2011 *(108)*	IV	Focal ablative therapies High-intensity frequency ultrasound Cryotherapy	Brachytherapy Focused radiotherapy
Chin et al 2012 *(109)*	II	Cryoablation	Radiotherapy equipment
Davis et al 2009 *(110)*	II	Vacuum erection device	None
Giberti et al 2009 *(111)*	IV	Suburethral sling positioning (synthetic or biological or mixed slings)	Electrical stimulation Extracorporeal magnetic innervation Implantable devices, injection of bulking agents Periurethral balloons, flexible urethral cystoscopy

Study	Level of evidence	Primary focus[a]	Secondary focus
Kollmeier and Zelefsky 2011 *(112)*	NA	Brachytherapy: permanent interstitial radioactive seed or temporary interstitial iridium-192 Afterloading catheters	Intraoperative imaging guidance in brachytherapy Transrectal ultrasound guidance Intraoperative CT and MRI Immobilization ramps
Lebeau et al 2011 *(113)*	IV	Robotic-assisted laparoscopic prostatectomy (da Vinci® Surgical System)	None
Sciarra et al 2011 *(114)*	NA (non-systematic literature review)	Multiparametric MRI	Anatomic T2-weighted imaging Magnetic resonance spectroscopic imaging Dynamic contrast-enhanced MRI Diffusion-weighted imaging

CT: computed tomography; MRI: magnetic resonance imaging; NA: not applicable.

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 29 Prostate cancer – devices identified for diagnosis and treatment

Device[a]	Description	Function
Diagnosis		
PSA level test	IVD	Screens men aged > 50 years. Used in combination with digital rectal examination
Four-K kallikrein panel[b]	IVD	Reduces unnecessary biopsy in men with elevated total PSA
Epigenetic assay[b]	IVD	Detects malignant disease in patients with false-negative biopsies (determines methylation status of GSTP1, APC and RASSF1)
Renal function tests[b]	IVD	Abnormal renal function is indicative of more locally advanced disease
Testosterone level test[b]	IVD	Considered in men for androgen deprivation
Liver function test[b]	IVD	Baseline in patients considering androgen-deprivation therapy
Full blood count[b]	IVD	Tests for symptomatic anaemia
Ultrasound	Appliance	Guides biopsy procedures
Biopsy needles	Instrument	Biopsy of prostate gland
MRI system (computer workstation, software, separate control room)	Appliance	Medical imaging modality using magnetic fields and radiowaves to visualize anatomy, in particular soft tissue, organs and muscle. Various MRI techniques are used, including: multiparametric, dynamic contrast enhancement, anatomic T2-weighted, diffusion-weighted and spectroscopic imaging
PET system	Appliance	Nuclear medicine imaging modality using positron-emitting radionuclide tracers to generate three-dimensional images of metabolic processes within human body. Detects focal lesions
CT system	Appliance	Medical imaging modality using computer-processed X-rays to generate cross-sectional images of body. May involve intravenously injected contrast agents. Evaluates prostate size and assesses regional lymph nodes
X-ray machine	Appliance	Uses penetrating electromagnetic radiation to visualize anatomical structures. Checks for osseous metastasis
Nuclear scanner	Appliance	Scans for bone metastases in patients with intermediate- and high-risk prostate cancer
Endoscope	Instrument	Used in planning of treatment approach
Flexible urethral cytoscope	Instrument	Excludes possible urethral stricture or bladder neck contracture
Treatment		
Medical linear accelerator	Appliance	Generates radiation in radiotherapy procedures
Collimator	Appliance	Delivers radiotherapy in intensity-modulated radiotherapy
Interstitial radioactive seed	Material	Delivers brachytherapy

Continues…

Device[a]	Description	Function
Afterloading catheter	Consumable	Delivers radioactive materials as part of brachytherapy
Immobilization ramp	Instrument	Minimizes lower-extremity movement during treatment
Hyaluronic acid	Material	Increases distance between prostate and anterior rectal wall (decreases toxicity from radiation)
Da Vinci Surgical System®	Appliance	Robot-assisted prostatectomy
High-intensity focused ultrasound probe	Instrument	Treatment of prostate cancer
Burdizzo clamp	Instrument	Androgen-deprivation therapy, clamp ablation of testes
Cryoablation system (consisting of cryoprobes, ultrasound machine and thermocouple monitoring probes)	Appliance	Treatment of prostate cancer
Needle	Instrument	Delivers anaesthesia
Drain	Instrument	Drainage in laparoscopic prostatectomy procedures
Robotic camera holder	Instrument	Endoscopic prostatectomy
TachoSil®	Consumable	Prevents lymphocele development after extraperitoneal radical retropubic prostatectomy with pelvic lymphadenectomy
Barbed polyglyconate sutures	Consumable	Anastomosis in robot-assisted prostatectomy to reduce urine leak
Artificial sphincter	Implant	Treatment of incontinence following prostatectomy
Electrical stimulation unit	Appliance	Treatment of incontinence following prostatectomy
Bulking agent	Materials	Treatment of incontinence following prostatectomy
Periurethral balloon	Instrument	Treatment of incontinence following prostatectomy
Suburethral slings: synthetic; biological; mixed	Material	Treatment of incontinence following prostatectomy
Bone screw	Consumable	Treatment of incontinence following prostatectomy (suburethral sling positioning)
Bone-anchoring system	Instrument	Treatment of incontinence following prostatectomy (suburethral sling positioning)
Surgical mesh	Implant	Treatment of incontinence following prostatectomy(suburethral sling positioning)
Vacuum erection system	Implant	Treatment of incontinence following prostatectomy(suburethral sling positioning)
Penile implant	Implant	Treatment of erectile dysfunction following prostatectomy

CT: computed tomography; IVD: in vitro diagnostic; MRI: magnetic resonance imaging; PET: positron-emission tomography; PSA: prostate-specific antigen.

[a] Proprietary marks have been included where this information was readily identified through source material.

[b] Information obtained via supplementary searches.

4.11 CONCLUSION

Nine neoplastic diseases were investigated in this project. Independent searches were conducted on each disease to inform the results of the review. A range of devices that are used commonly in the prevention, diagnosis or treatment of neoplastic diseases was identified.

Overall, devices for the prevention of neoplastic diseases were not identified. Preventive strategies tended to be focused on modifiable lifestyle factors that may increase an individual's risk of developing cancer, such as smoking. Preventive strategies may be context-specific; for example, because liver cancer is associated with chronic liver disease, vaccinations may be considered preventive measures in countries where the prevalence of viral hepatitis is high. Similarly, early identification of *H. pylori* infection and irradiation may control this risk factor for gastric cancer.

Screening for cancer involves looking for early signs of a particular disease in asymptomatic people. The aim is to identify cancer or abnormalities that may lead to cancer as early as possible in order to allow early treatment. Screening tools identified include in vitro diagnostic tests, physical examinations and imaging devices such

as mammograms. Overall, the search indicated that large-scale screening programmes were not supported for neoplastic disease of most sites; notable exceptions included screening for breast cancer, prostate cancer and colorectal cancer. Conflicting arguments regarding screening for lung cancer were identified. The searches also revealed a research focus on web- and print-based media aimed at increasing awareness of and participation in screening programmes for breast and prostate cancer.

The diagnosis of neoplastic disease is a sequential process, and a large number of diagnostic devices were identified. Biopsy samples may be taken either before or after imaging studies; however, histological analysis of a biopsy specimen is the definitive method of diagnosis for all cancers investigated. Devices used to obtain a biopsy specimen are many and varied. The choice of biopsy instruments and method is dependent on the site of suspected cancer and the accessibility of the lesion. Multiple biopsy specimens and hence methods may be required in a single patient. No information was identified regarding the specific pathology equipment required for cancer diagnosis.

The searches identified that imaging technologies are central to patient management in oncology. The literature indicates that multiple imaging devices are required for patient diagnosis and treatment planning. Most imaging devices identified consist of equipment, computer workstations and computer software. Interpretation of the results requires skill and training.

The approach to treating neoplastic disease is based on a combination of histological analysis of biopsy specimens, imaging studies and in some cases in vitro diagnostic tests. Decision-making is also guided by the patient's presentation, preferences and comorbidities. Surgical resection or dissection, with or without chemotherapy and/or radiotherapy, were the main therapeutic options identified.

Devices used in surgery include ultrasound dissection devices, robotic systems and other surgical equipment such as scalpels. Surgery requires an operating theatre equipped with procedure- and anaesthesia-related devices. Numerous disposables and chemicals are used in sterilization and disinfection.

The searches identified a large number of radiotherapy techniques for the treatment of cancers. As with most interventions associated with diagnosis and management of neoplastic disease, the type of radiotherapy used is determined by the site and stage of cancer and the patient's comorbidities and choice. Variations and improvements in standard radiotherapy machines appear to focus on the targeted delivery of radiation to precisely located lesions. Imaging devices are important for treatment planning, and computer programs and software are necessary for calculating dose delivery.

Minimally invasive therapies appeared to be an area of research focus, and ablative devices identified were considered to be emerging. Minimally invasive therapies, including ablative devices, were generally not considered curative treatments but were occasionally indicated in control of metastatic disease and palliation or in the management of early stages of oesophageal cancer.

The choice of medical device used in the diagnosis and treatment of the cancers investigated will depend on the patient's presentation, the clinician's preference and experience, and the comparative safety and effectiveness of each device. It is also clear that the choice of device will be informed by its suitability as described by the crucial "4 As" of availability, accessibility, appropriateness and affordability, issues that vary substantially both across and within jurisdictions *(115)*. There will be differences in the accessibility of medical devices between urban and rural settings and between facilities in similar areas. The relative availability of medical devices within a jurisdiction will have downstream effects on the overall approach to neoplastic disease; in settings with low access to

diagnostic tools or screening devices, patients may enter treatment at later stages in the disease and thus have a poorer prognosis. Additionally, many of the medical devices identified require trained experts to operate them or to interpret the results, as well as appropriate infrastructure, financial support and materials to run and service them.

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5. Respiratory diseases

5.1 INTRODUCTION

Chronic respiratory diseases are chronic diseases of the airways and other structures of the lung. Some of the most common are COPD, asthma, occupational lung diseases and pulmonary hypertension. Common risk factors include tobacco use, poor nutrition, frequent lower respiratory infections during childhood, and environmental air pollution (indoor, outdoor, occupational) *(1)*.

In 2012, a total of 4.0 million deaths worldwide were attributed to respiratory diseases, with 3.1 million of these attributed to COPD. Specifically in the Western Pacific Region for people aged 60 years and older, a total of 1.2 million deaths were attributed to respiratory diseases, of which 1.0 million deaths were from COPD *(2)*.

5.2 CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Introduction

Chronic obstructive pulmonary disease is a lung disease resulting in reduced lung function and poor quality of life *(3)*. It is characterized by an airflow limitation that is not fully reversible, chronic and worsening dyspnoea, cough and sputum production *(4)*. The COPD diagnosis now includes chronic bronchitis and emphysema, with these terms no longer being used to describe specific conditions *(1)*. The disease presents with chronic inflammation, increased numbers of specific inflammatory cell types in different parts of the lung, and structural changes resulting from repeated injury and repair *(4)*. In general, the inflammatory and structural changes in the airways become worse with disease severity and continue even when causative factors have been removed.

Chronic obstructive pulmonary disease affects 6% of the general population and is a leading cause of death globally *(5)*. In 2012, more than 3 million people worldwide died of COPD *(1)*. The disease is the fourth leading cause of chronic morbidity and mortality in the United States of America. It is predicted that COPD will rank fifth in burden of disease worldwide by 2020 *(4)*.

The disease is preventable, with the primary cause being tobacco smoking *(1)*. The more tobacco consumed and years spent smoking, the higher the risk of developing COPD. The disease is progressive and is related to an abnormal inflammatory response of the lung to noxious particles or gases *(4)*. Other causes of COPD include occupational exposures to toxins or irritants, air pollution, genetic factors, age and autoimmune disease.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of COPD. The following filters were applied: English language and published within the past five years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	chronic obstructive respiratory disease
#3	chronic obstructive airway disease
#4	chronic obstructive lung disease
#5	chronic obstructive pulmonary disease
#6	pulmonary disease, chronic obstructive [MeSH terms]
#7	(#2 OR #3 OR #4 OR #5 OR #6)
#8	(#1 AND #7)

Results

The strategy yielded 179 studies, comprised largely of randomized controlled trial evidence and systematic reviews. On the title and abstract screen, 75 studies were identified to report the use of a device for the diagnosis, screening or treatment of COPD; however, the search did not find any mention of devices for the prevention of COPD.

Key studies were retrieved for full text review, the details of which are summarized in Table 30. A broader list of identified devices, obtained through title and abstract review of all included studies, is available in Table 31.

A review of the literature identified a focus on therapeutic equipment and aids, therapeutic surgical interventions and diagnostic tests.

Established screening methods identified for COPD included pulmonary function tests and arterial blood gas analysis. Diagnostic devices included pulse oximeters, body plethysmographs, CT scanners, electrocardiograms and spirometers. Although initial screening for COPD primarily involves the use of a spirometer, definitive diagnosis may be made with chest X-ray, blood tests, echocardiogram, peak flow test, or phlegm or sputum sample.

A number of studies indicated that the spirometer is now available to use through telemedicine. Online spirometry involves connecting a specialized form of spirometer to a computer or mobile phone, blowing into the device, and electronically forwarding the test results to a health care professional for assessment. The use of this new technology with established devices such as the spirometer facilitates ongoing clinical evaluation by enabling patients to be monitored at home. This technology may also allow for remote diagnosis or access to expert opinion online. This has implications for a number of similar diagnostic devices that may be adjusted for use in telemedicine.

Conventional therapeutic devices included oxygen systems, inhalers and ventilators. Some less conventional devices were also identified, together with clinical applications of non-medical devices. For example, acupuncture, exercise machines, mobile phones, pedometers and harmonicas were all identified in the search as alternative approaches to treatment. Most of these devices have in common the focus of facilitating physical exercise and exercising the lungs, with the aim of improving lung function or slowing disease progression.

The results identified three main therapeutic surgical interventions for late-stage disease: bullectomy, lung volume-reduction surgery and lung transplantation. No devices related specifically to these procedures were found in the search, apart from devices that would normally be required in surgery of the thorax.

Table 30 Chronic obstructive pulmonary disease – key studies

Study	Level of evidence	Primary focus[a]	Secondary focus[a]
Ambrosino et al 2009 *(6)*	I	Evaluation of end-stage COPD	Non-invasive positive-pressure ventilation, invasive ventilation, bullectomy, lung volume-reduction surgery, lung transplantation, nasal mask, facemask, controlled oxygen therapy, mechanical ventilation, endotracheal intubation, pulmonary rehabilitation, neuromuscular transcutaneous electrical stimulation, biological lung volume reduction, nebulizer, tracheotomy
Filosso et al 2010 *(7)*	II	Evaluation of digital air-leak monitoring after lobectomy for primary lung cancer in patients with moderate COPD	Chest tube, drainage system, lobectomy, fissureless surgery, pleural tents, glues, lung sealants, one-way valve (Heimlich valve), compact drainage device, traditional chest-drainage system (Argyle Thora-Seal III), digital continuous air-leak recording system (Drentech® Simple Plus), medical electric equipment (PALM), chest X-ray, posterolateral fifth intercostal space thoracotomy, staplers, sealants (TachoSil™), systematic lymphadenectomy, chest drainages, chest roentgenogram, radiogram

Study	Level of evidence	Primary focus[a]	Secondary focus[a]
Storre et al 2009 *(8)*	IV	Non-invasive ventilation	Pressure-limited non-invasive positive ventilation, volume-limited non-invasive positive-pressure ventilation, ventilatory circuit, pneumotachograph (Ventrak-Respiratory Monitoring System), ventilator, PV 403 ventilator, oronasal mask (Mirage™ Full Face Mask), short tube, T-connector, Combi-Stopper (Braun), lung-function parameters (Masterlab-Compact), blood gas analyser (AVL OMNI), hand-held portable pulse oximeter (NPB-40)
Lareau and Hodder 2012 *(3)*	I	Inhalers	Pulmonary rehabilitation, lung volume-reduction surgery, lung transplantation, compressor-driven nebulizer, handheld inhalers, pressured-metered dose inhalers, dry-powder inhalers, soft-mist inhalers
Masa et al 2011 *(9)*	II	Spirometer (VMax 20)	Conventional spirometer, online spirometer, hand-held spirometer, reference spirometer, computer with spirometer software (VMax™ SensorMedic), second computer and software (VNC® Free Edition), webcam (Logitech Quickcam USB), webcam software (Microsoft Netmeeting), bacterial filter
Strickland et al 2009 *(10)*	IV	Long-term oxygen therapy: Helios, HomeFill, FreeStyle and compressed oxygen cylinder systems	Home concentrator, portable concentrator, compressed oxygen, liquid oxygen, oxygen concentrator, continuous-flow oxygen, compressed oxygen cylinder, liquid oxygen canister, liquid oxygen system (Helios), compressed oxygen cylinder system filled from home concentrator (HomeFill), portable battery-powered concentrator (FreeStyle™)

COPD: chronic obstructive pulmonary disease; RCT: randomized controlled trial.

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 31 Chronic obstructive pulmonary disease – devices identified for diagnosis and treatment

Device[a]	Description	Function
Diagnosis		
Pulse oximeter	Appliance	Monitors saturation of haemoglobin
X-ray machine	Appliance	Provides images to assist with diagnosis of COPD
Plethysmograph	Appliance	Measures changes in lung volume
Blood gas analyser	Appliance	Measures PaO_2, $PaCO_2$ and acidity (pH). SaO_2 can also be determined
Electrocardiogram	Appliance	Records heart's electrical activity
Spirometer	Instrument	Measures volume of air inspired and expired by lungs. Pocket version is also available
Treatment		
Cylinder concentrator	Apparatus	Oxygen therapy
Oxygen systems: Helios, Homefill, Freestyle™, compressed oxygen cylinder system, standard home oxygen system	Apparatus	Oxygen therapy
Continuous-flow oxygen system	Apparatus	Supplies oxygen constantly, irrespective of whether patient is inhaling or exhaling
Accu02	Apparatus	Conserves oxygen
Liquid oxygen portable device	Apparatus	Provides liquid oxygen therapy in portable form
Portable oxygen concentrator	Apparatus	Provides oxygen therapy at substantially higher concentrations of oxygen than levels of ambient air, in portable form
Oxygen tank	Apparatus	Stores oxygen for provision of oxygen therapy
Oxygen mask and helmet	Apparatus	Transfers oxygen from storage tank to lungs
Oxygen flow regulator	Apparatus	Automatically continuously regulates delivery of oxygen quantity to patient while constantly acquiring saturation value

Continues…

Device[a]	Description	Function
Inhalers: dry-powder inhaler (Breezehaler®, Handihaler®, Diskus®, Novoliser®, Genuair®, Turbuhaler®); handheld inhaler devices; Respimat soft-mist inhaler; metered-dose inhaler	Apparatus	Delivers medication to lungs
Ventilators: non-invasive positive-pressure ventilation (using facemask); invasive positive-pressure ventilation (intubation)	Appliance	Mechanically moves breathable air into and out of lungs
Nebulizer	Appliance	Administers medication in form of mist inhaled into lungs
Thorax support vest	Apparatus	Prevents sternum instability after cardiac surgery
Chest tube	Instrument	Removes air, fluid or pus from intrathoracic space
High-frequency chest-wall oscillation: vest therapy	Apparatus	Clears airway
Humidifier	Appliance	Increases humidity in room or larger area
Negative-pressure ventilator (iron lung)	Appliance	Enables patient to breathe if normal muscle control has been lost or work of breathing exceeds patient's ability
Chest-drainage system	Apparatus	Treats pneumothorax, haemothorax, empyema and other collections within pleural cavities
Transdermal tulobuterol patch	Apparatus	Administers bronchodilator

COPD: chronic obstructive pulmonary disease; $PaCO_2$: carbon dioxide tension; PaO_2: arterial oxygen tension; SaO_2: arterial oxyhaemoglobin saturation.

[a] Proprietary marks have been included where this information was readily identified through source material.

5.3 CONCLUSION

It is estimated that chronic respiratory disease were responsible for 10% of all deaths in the Western Pacific Region in 2012, COPD accounted for more than 8% of all deaths in the region, and asthma and other respiratory diseases accounted for less than 2% of all deaths in the region *(2)*. The project therefore focused on COPD, and the search identified devices used in the diagnosis and treatment of this disease.

Tobacco smoking increases the risk of developing COPD. Preventive measures may include cessation of smoking and avoiding exposure to environmental toxins or pollutants. The literature reviewed identified a focus on therapeutic equipment and aids, therapeutic surgical interventions and diagnostic tests. The main screening device is a spirometer. Devices used in the diagnosis of COPD include X-ray machines, plethysmographs, blood gas analysers and pulse oximeters. Therapeutic interventions identified were oxygen therapy and ventilation, and more invasive interventions for respiratory failure such as bullectomy, lung volume-reduction surgery and lung transplantation. These aggressive interventions are generally used in end-stage disease following failure of previous treatment.

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6. Sense organ diseases

6.1 INTRODUCTION

Sense organ disease is a broad term that encompasses diseases of the sensory system, a part of the nervous system responsible for processing sensory information. Age-related ophthalmic and otic diseases were identified for investigation.

Ophthalmic diseases are specific to the eye. These include glaucoma, cataracts, macular degeneration and refractive errors. The underlying aetiologies of these eye diseases are varied and may include damage to the optic nerve, degradation of the optical quality of the crystalline lens, growth of abnormal blood vessels under the macula and into the subretinal space, deterioration of the light-sensitive cells in the macula and age-related changes to the eye. Other factors may also contribute to eye disease, including genetic predisposition, gender, race, systemic factors, physical and age-related changes to the eye, smoking, obesity, diabetes mellitus, long-term use of corticosteroids, previous intraocular surgery and environmental factors.

Eye diseases occur throughout the world, but there is greater prevalence of blindness in developing countries than developed countries due to inadequate ophthalmic services in developing countries and differences in social surroundings, climate and nutrition *(1)*. Global causes of visual impairment are shown in Figure 1. From this figure, it is clear that refractive errors and cataracts are the leading causes of visual impairment worldwide, with other eye diseases, such as glaucoma and macular degeneration, being less contributory. A large proportion of causes (18%) are undetermined.

Otic diseases encompass a range of disorders of the external, middle and inner ear commonly manifesting as earache, hearing loss, otorrhoea, tinnitus and vertigo. Hearing loss is a common presentation of otic diseases, and adult-onset hearing loss affects a significant proportion of people over the age of 65 years, in some instances leading to severe hearing loss or deafness. The aetiology of hearing loss is varied, as anything deleteriously affecting the transduction of sound or auditory signals through the ear to the brain may decrease hearing quality.

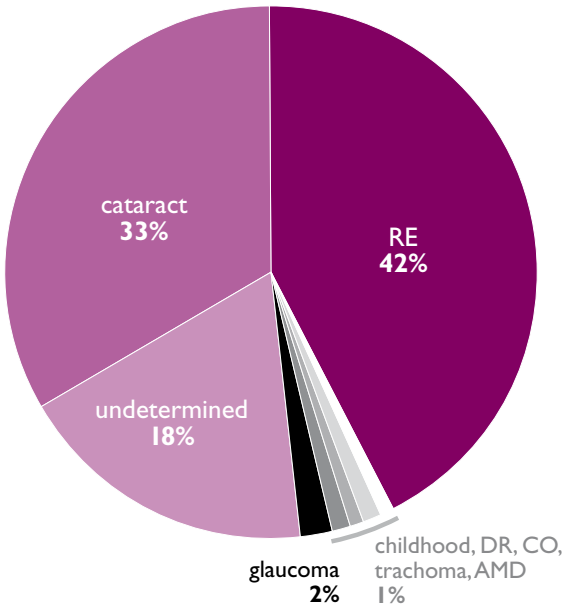
6.2 OPHTHALMIC DISEASES

6.2.1 Glaucoma

Introduction

Glaucoma is a chronic progressive eye disease and is one of the leading causes of severe visual impairment and blindness worldwide *(2)*. The optic nerve is damaged in such a way that blindness in the affected eye may result if left untreated. The disease is traditionally considered an optic nerve head disease, associated with a progressive loss of vision and increased intraocular pressure *(3)*. There are two main types of glaucoma: primary open-angle glaucoma and angle-closure glaucoma. Primary open-angle glaucoma is characterized by a slow and insidious onset, whereas angle-closure glaucoma tends to appear suddenly and is more

Figure 1 Global causes of visual impairment



DR: diabetic retinopathy; CO: corneal opacities; AMD: age-related macular degeneration; RE: refractive errors.

Source: Global Data on Visual Impairments 2010. Geneva: World Health Organization, 2012 (WHO/NMP/PBD/12.01).

acute. Most forms of glaucoma progress without clinical symptoms and often advance to a severe stage before the patient is aware of the disease *(2)*. Treatment aims to prevent further loss of vision: usually vision lost in glaucoma cannot be restored.

Risk factors for glaucoma include those that are limited to the onset of the disease and those that are associated with progressive worsening in the already established disease. Notably, age, genetic predisposition, gender, race and systemic reasons are risk factors for the disease *(4)*.

Glaucoma is found in approximately 2% of the population aged 40 years and above. It is estimated that more than 70 million people worldwide are affected by the disease *(3)*. More specifically, in people of European descent over 40 years of age, the prevalence of primary open-angle glaucoma is approximately 1.5–3% *(5)* and the prevalence of angle-closure glaucoma is reported to be 0.4% *(6)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of glaucoma. The following filters were applied: English language and published within the past 10 years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	glaucoma [MeSH terms]
#3	glaucoma
#4	(#2 OR #3)
#5	(#4 AND #1)

Results

The strategy yielded 220 studies that comprised a range of evidence, including systematic reviews, randomized controlled trials, non-randomized comparative evidence, case series and non-systematic clinical reviews. On the title and abstract screen, 128 studies were identified to report the use of a device for the prevention, diagnosis or treatment of glaucoma. The full text of seven key studies (Table 32) and a review of clinical practice guidelines were retrieved and used to inform the list of needed devices and to provide additional clinical context (Table 33).

A review of the literature identified medical devices and procedures for the diagnosis and treatment of glaucoma; no devices were identified for the prevention of glaucoma.

Angle-closure glaucoma is a leading cause of blindness worldwide and is potentially preventable *(7)*. There was a suggestion in the literature that everyone aged 40 years or older undergoing an eye examination, either routinely or for a specific reason, should be screened for angle-closure glaucoma to prevent unnecessary blindness *(8)*.

Definitive diagnosis of glaucoma may be made using a number of tests. Ophthalmoscopy is used as a primary test for glaucoma *(9)*. Other tests include visual field testing and gonioscopy *(9)*.

Table 32 Glaucoma – key studies

Study	Level of evidence	Primary focus	Secondary focus
Bollinger et al 2011 *(10)*	IV	Fluocinolone acetonide implant	Glaucoma-drainage device Vitrectomy 8–0 polypropylene suture Snellen chart
D'Eliseo et al 2003 *(11)*	II	Deep sclerectomy with implant Combined deep sclerectomy phacoemulsification	Trabeculectomy phacoemulsification Stegmann's viscocanalostomy Best corrected visual acuity test Biomicroscopy Gonioscopy Goldman applanation tonometer 6–0 prolene superior rectus bridle suture Step diamond knife Dumont forceps Vannas scissors Triangular drainage device Nylon 10–0 throws Tenon nylon 10–0 suture
Ivandic et al 2009 *(12)*	IV	Low-intensity laser irradiation	Ophthalmoscope Biomicroscope and slit lamp
Pablo et al 2010 *(13)*	II	Heidelberg Retina Tomograph Scanning laser polarimetry (GDx)	Photographic evaluation of optic nerve head Retinal nerve fibre layer photography Optical coherence tomography Fundoscopy Red-free fundus photography Biomicroscope Slit lamp Intraocular pressure measurement Central corneal ultrasonic pachymetry Standard automated perimetry Short-wavelength automated perimetry
Staffieri et al 2011 *(14)*	IV	Telemedicine	Kerameter Autorefractor Tonopen XL Pachmate DGH 55 Visual acuity standard log MAR Bailey-Lovie visual acuity chart Computerized visual field testing Humphrey 24–2 SITA (Zeiss) visual field analyser Intraocular pressure measurement Central corneal thickness measurement Stereoscopic optic disc photographs Nidek 3-Dx stereodisc camera

Study	Level of evidence	Primary focus	Secondary focus
Toth et al 2007 *(2)*	IV	Scanning laser polarimetry (GDx-VCC) Matrix Frequency Doubling Technology	Optic nerve head photography Scanning laser tomography Scanning laser polarimetry Frequency-doubling technology Variable corneal compensator Goldmann applanation tonometer Slit lamp Goniolens Humphrey visual field analyser Standard visual acuity testing 90-dioptre non-contact aspheric lens Diurnal intraocular pressure curve Central corneal thickness measurement Optic nerve head evaluation Standard automated visual field testing
Vizzeri et al 2009 *(15)*	IV	Heidelberg Retina Tomograph	78-dioptre lens Confocal scanning laser ophthalmoscopy

NA: not applicable.

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 33 Glaucoma – devices identified for prevention, diagnosis and treatment

Device	Description	Function
Prevention		
Bailey-Lovie chart	Chart	Measures visual acuity
Autorefractor/keratometer	Appliance	Assesses refractive status
Pachymeter	Appliance	Measures central corneal thickness
Stereoscopic camera	Appliance	Visualization of optic disc
Visual field analyser: Humphrey analyser; matrix frequency-doubling instrument	Appliance	Measures visual field
Diagnosis		
Snellen eye chart	Chart	Measures visual acuity
Tonometer: Goldmann application; Pascal dynamic contour; Reichart Ocular Response Analyser	Appliance	Assesses intraocular pressure
Biometer	Appliance	Measures axial length and corneal curvature
Pachymeter	Appliance	Measures central corneal thickness
Scanning laser polarimetry (GDx)	Appliance	Measures thickness of retinal nerve fibre layer
Heidelberg Retina Tomograph	Appliance	Visualization of optic nerve head
Pentacam	Apparatus	Visualization of anterior chamber depth
Slit-lamp biomicroscope	Appliance	Examination of eye
Fundus camera	Apparatus	Viewing of eye, including fundus
Goniolens	Apparatus	Identification of angle closure
Tomograph	Appliance	Examination of retina, measures retina thickness and identifies lesions
Treatment		
Lasers: argon laser; Nd:YAG laser	Appliance	Reduces intraocular pressure through laser trabeculoplasty and laser iridotomy
Glaucoma-draining implant	Implant	Reduces intraocular pressure

ND:YAG: neodymium-doped yttrium aluminium garnet.

6.2.2 Cataracts

Introduction

Cataracts are defined as the degradation of the optical quality of the crystalline lens, resulting in progressive opacification of the eye, which can lead to loss of vision *(16)*. Cataracts are the leading cause of blindness worldwide, with an estimated 51% of all cases of blindness (approximately 20 million people) in 2010 being attributed to cataracts *(17)*. Left untreated, patients with cataracts may experience a steady decline in visual and physical function. Surgery is typically highly successful, leading to the restoration of vision and resumption of regular activities of daily living *(16)*.

The most common risk factors linked with the development of cataracts are smoking, diabetes mellitus, long-term use of corticosteroids and previous intraocular surgery *(16)*.

There are regional variations in disease aetiology. In developing countries, there is a higher prevalence of cataracts due to environmental factors. In these countries, the disease begins at an earlier age and affects a greater number of people, many of whom do not have access to treatment *(17)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of cataracts. The following filters were applied: English language and published within the past five years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	cataract [MeSH terms]
#3	cataract
#4	#2 OR #3
#5	#1 AND #4

Results

The strategy yielded 217 studies, comprised largely of randomized controlled trial evidence. On the title and abstract screen, 130 studies were identified to report the use of a device for the diagnosis or treatment of cataracts. The details of the key studies retrieved for full text review are summarized in Table 34. A broader list of identified devices was obtained through title and abstract review of all included studies (Table 35). Supplementary clinical practice guidelines were also consulted to identify additional devices relevant to cataracts *(18)*.

The search did not yield any preventive devices, but a number of medical devices and procedures for the diagnosis and treatment of cataracts were identified.

Definitive diagnosis of cataracts may be made using a number of eye tests. A direct physical examination is conducted to look for cloudy areas on the lens. This may involve a dilated fundus examination, measurement of intraocular pressure, glare-vision test or slit-lamp examination.

Surgery is the only effective treatment for cataracts *(19)*. The procedure involves removing the clouded eye lens and replacing it with a plastic lens implant.

Table 34 Cataracts – key studies

Study	Level of evidence	Primary focus	Secondary focus
Barsam et al 2008 *(20)*	II	Phacoemulsification devices	Ophthalmic viscosurgical device Slit-lamp examination Dilated fundoscopy Visual acuity Optical coherence tomography
Coelho et al 2009 *(21)*	II	Nd:YAG laser	Visual acuity testing Slit-lamp examination Applanation tonometry Keratometry Axial length measurements Anterior chamber depth measurements Slit-lamp biomicroscopy 2.75 mm knife Phacoemulsification Fundus examination
Dell et al 2011 *(22)*	II	Ocular hydrogel bandages Collagen corneal shield	Intraocular lenses
Fernandez de Castro et al 2008 *(23)*	II	Phacoemulsification devices, including handheld attachment	Snellen chart Intraocular pressure measurement Slit-lamp examination Dilated fundus examination
Ferreira and Almeida 2012 *(24)*	II	Refraction	Snellen chart Slit-lamp examination Goldmann applanation tonometer Dilated fundoscopy Partial coherence interferometer Pentacam Mendez degree gauge and axis marker Phacoemulsification Injector/inserter Viscosurgical device Wavefront abberometer systems Intraocular lenses
Gangwani et al 2011 *(25)*	II	Intraocular lens	Partial coherence interferometry Intraocular lenses Ophthalmic viscosurgical devices Phacoemulsification Slit-lamp evaluation Snellen chart Autorefraction measures Anterior chamber depth measures Intraocular pressure measures Retinal examination Nd:YAG laser
Martinez Palmer et al 2008 *(26)*	II	Intraocular lenses	Diamond knife Phacoemulsification Intraocular lens delivery systems Refractor Intraocular pressure measurement Slit-lamp examination Fundus examination Partial coherence tomography

Continues…

Study	Level of evidence	Primary focus	Secondary focus
Swamy et al 2009 (27)	IV	Early treatment diabetic retinopathy study chart CSV-1000E Chart 1 Humphrey automated visual field unit Perkins applanation tonometer Slit-lamp biomicroscopy Direct ophthalmoscopy	Spectacles Refractor

Nd:YAG – Neodymium-doped yttrium aluminium garnet.

Table 35 Cataracts – devices identified for diagnosis and treatment

Device	Description	
Diagnosis		
Charts: early treatment diabetic retinopathy study chart; CSV-1000E Chart 1	Chart	Measures monocular and binocular visual acuity, and contrast sensitivity
Visual field analyser	Appliance	Assesses visual field
Tonometer	Instrument	Assesses intraocular pressure
Scopes: slit-lamp biomicroscope; direct ophthalmoscope	Instrument	Examines eye
Refractor	Instrument	Measures refractive error
Fundus camera	Apparatus	Examination of eye, including fundus
Pentacam	Apparatus	Obtains keratometry values
Optical coherence tomographer	Appliance	Measures retinal depth
Biometers: partial coherence interferometer; ultrasound	Appliance	Measures axial length, anterior chamber depth and surface curvature
Snellen eye chart	Chart	Measures visual acuity
Keratometer/ophthalmometer	Instrument	Measures curvature of anterior surface of cornea to assess extent of astigmatism
Wavefront abberometer system	Instrument	Identification of corneal and internal aberrations when combined with autorefractometer and topographer
Treatment		
Spectacles	Aid	Improves visual acuity
Intraocular lens	Implant	Restores vision
Intraocular lens delivery systems	Instrument	Assists in lens implantation
2.75 mm diamond knife	Instrument	Delivers corneal incision
Phacoemulsification and associated attachments	Instrument	Removal of lens material using ultrasonic, fluidic and vacuum power. Attachments include sonic oscillations to increase efficiency of cataract removal
Lasers: Nd:YAG	Appliance	Capsulotomy or to preoperatively open anterior capsule
Bandages/shields: ocular hydrogel bandages; collagen corneal shield	Consumable	Provides wound protection and pain relief postoperatively
Ophthalmic viscosurgical device	Material	Fills anterior chamber during lens implantation
Degree gauge and axis marker	Instrument	Marks implantation axis

Nd:YAG – Neodymium-doped yttrium aluminium garnet.

6.2.3 Refractive errors

Introduction

Refractive error is a condition of the eye that leads to inaccurate focusing of parallel light rays at the fovea. It is a common cause of impaired visual acuity. Refractive errors are classified as spherical and cylindrical errors. Myopia (near-sightedness) and hyperopia (far-sightedness) are spherical errors. In these circumstances, parallel rays of light focus anteriorly (myopia) or posteriorly (hyperopia) to the fovea, resulting in blurry vision. Astigmatism and presbyopia are cylindrical errors. Astigmatism is caused by the irregular shape of the cornea and/or lens. Presbyopia is age-related vision impairment where the eye shows a progressively diminished ability to focus on near objects. In addition, different refractory errors and magnifications between the two eyes lead to anisometropia and aniseikonia *(28)*.

In the Western Pacific Region, WHO estimates that less than 1% of all DALYs in 2012 were due to refractive errors *(29)*. It is estimated that vision impairment resulting from uncorrected refractive errors affected 1–4% of the world's population in 2012. The prevalence of uncorrected refractive errors is greatest in people over 50 years of age *(30)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of refractive errors. The following filters were applied to the search results: English language and published within the past five years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	error, refractive [MeSH terms] OR refractive error* OR myopia OR hyperopia OR astigmatism OR presbyopia OR aniseikonia OR anisometropia
#3	#1 AND #2
#4	#1 AND #2

Results

The strategy yielded 142 results. On the title and abstract screen, 35 studies were identified that reported the use of a device for diagnosis or management of refractive errors. The details of the key studies retrieved for full text review are summarized in Table 36. A broader list of identified devices was obtained through title and abstract review of all included studies (Table 37).

None of the devices was related to screening or prevention of refractive errors in elderly people.

People with blurred vision, double vision, eye strain or eye discomfort are examined to identify potential causes for symptoms. Spectacles and contact lenses provide sufficient aid for many people. Contact lenses can be for long-term or short-term use. Disposable contact lenses, which have been designed for short-term use, have the additional benefit of increased cleanliness and sterility compared with reusable contact lenses. To minimize the risk of eye infections, extraocular contact lenses are cleaned with special cleaning solutions. Supplementary searches using clinical practice guidelines identified phoropters, trial lenses and trial frames for the correction of

refractive errors, which were not identified through the results of the systematic literature review *(31)*.

Severe refractive errors may be managed by refractive surgery. The refractive errors are corrected by either changing the shape of the cornea using corneal incision, surface or flap procedures, or by implanting an intraocular lens to effectively change the power of the natural lens. Several types of intraocular lenses were identified (Table 36). Remodelling of the cornea can be performed with the help of ablation techniques.

Table 36 Refractive errors – key studies

Study	Level of evidence	Primary focus[a]	Secondary focus[a]
OHTAS 2009 *(32)*	I	Intraocular lenses: phakic intraocular lens (e.g. Collamer® Implantable); iris-fixated lenses; posterior chamber lenses	Laser systems: VISX CustomVue™ and Alcon CustomCornea® Claw Snellen chart Spectacles Contact lenses Corneal pachymetry Corneal topography Specular photomicroscopy Biometry
Choi et al 2009 *(33)*	II	Intraocular lenses: spherical aberration-free intraocular lenses (e.g. Akreos AO™, Akreos Adapt™); aspheric intraocular lenses (e.g. Acrysof® IQ)	Visual capacity analyser Wavefront analysis (WaveScan WaveFront™) Diamond knife irrigation/aspiration system Lens insertion system (e.g. Sofport® System Inserter) Snellen visual acuity chart Luminometer Pupillometer (Colvard®) Software (e.g. SPSS version 13.0)
Chan et al 2008 *(34)*	II	Femtosecond lasers (e.g. IntraLase™, Star S4 IR™)	Pachymetry Excimer laser reticle Aberrometer Mechanical keratome (Hansatome) Software (SPSS version 11.0)
Barisic et al 2010 *(35)*	II	Intraocular lens (e.g. Tecnis® Multifocal)	Spectacles Special multifocal lenses (bifocal and progressive) PHACO machines (e.g. Infiniti®, Alcon®, Signature®)
Ivarsen and Hjortdal 2012 *(36)*	II	Imaging: TMS-1 corneal topography; ultrasound; pachymetry	Knife Excimer laser photoablation Schwind Supratome Cutting heads Bandage contact lens Optical analysis software (e.g. Zemax™ EE) Wavefront aberrations spectacles Keratometry

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 37 Refractive errors – devices identified for diagnosis and treatment

Device[a]	Description	Function
Diagnosis		
Refractor	Instrument	Measures refractive error
Disparity vectographic apparatus: vectographic Titmus; random dot stereotests; Howard–Dolman	Appliance	Measures stereoacuity
Vision contrast test system (e.g. Vistech® VCTS 6500)	Appliance	Tests vision contrast
Tonometers: applanation tonometer; Perkins applanation tonometer; Goldmann applanation tonometer; Pascal dynamic contour tonometer; applanation resonance tonometer	Appliance	Assesses intraocular pressure measurements or direct transcorneal measurement of intraocular pressure
Ultrasound	Appliance	Measures various dimensions of eye and its components and their interrelationships
Ultrasound pachymeter	Instrument	Measures thickness of cornea in glaucoma, in suspected hypertension or before refractive surgery
Stray-light meter	Instrument	Measures stray light
Optical coherence tomograph	Appliance	Analyses anterior segment and its thickness
Visual field analyser	Appliance	Assesses visual field
Ocular response analyser	Appliance	Assesses biomechanical properties of corneal tissue
Functional vision analyser	Appliance	Tests vision
Aberrometer (ANIDEK® OPD)	Instrument	Measures refractive aberrations
Ophthalmoscope	Instrument	Examination of eye
Cameras: fundus camera; Scheimpflug photography (Pentacam)	Apparatus	Views and photographs eye
Partial coherence interferometer	Appliance	Measures various dimensions of eye and its components and their interrelationships
iVIS® Suite	Software	Assesses pupil, anterior segment elevations, true shapes, asphericity and critical surgical dimensions
iTrace®	Software	Management/education software for patients with unsatisfactory vision
Poco®	Software	Quantifies results from retroillumination photographs
CustomVue®	Software	Used in laser ablation system
Treatment		
Spectacles	Aid	Improves visual acuity
Contact lenses: silicone hydrogel lens; disposable contact lens	Aid	Improves visual acuity
Intraocular lenses: monofocal and multifocal lenses; aspheric and spherical lenses; phakic lens	Implant	Surgical correction of refractive errors
Hessburg-Barron suction trephine	Instrument	Aids keratotomy and keratoplasty procedures
Laser	Appliance	Ablative reconstruction of curvature of cornea
Femtosecond laser	Appliance	Creates flap during bladeless LASIK
Perspex ring	Implant	Physical alteration of shape of cornea
Bandage	Consumable	Provides wound protection and pain relief postoperatively

LASIK: laser-assisted in situ Keratomileusis.

[a] Proprietary marks have been included where this information was readily identified through source material.

6.2.4 Macular degeneration

Introduction

Age-related macular degeneration is characterized by central vision loss. There are two forms of age-related macular degeneration. The dry form results from the deterioration of the light-sensitive cells in the macula, leading to a gradual blur in the central vision of the affected eye. The more insidious wet form occurs when abnormal blood vessels grow under the macula and into the subretinal space, leading to rapid damage to the macula and resulting in further visual deterioration, which may lead to complete visual loss *(37)*.

A variety of genetic and environmental factors have been implicated in causing age-related macular degeneration. Modifiable risk factors include cigarette smoking and obesity *(37)*.

In the elderly population of industrialized countries, age-related macular degeneration is the leading cause of central blindness or low vision, with prevalence increasing substantially with the ageing of the population *(37,38)*. Globally, more than 82% of all blind people are aged over 50 years. Studies conducted in countries of the Western Pacific Region have estimated age-related macular degeneration to be responsible for between 3% and 50% of all blindness *(39)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of age-related macular degeneration. The following filters were applied: English language and published within the past 10 years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	age related macular degeneration [MeSH terms]
#3	age related macular degeneration
#4	#2 OR #3
#5	#1 AND #4

Results

The strategy yielded 110 studies comprising a range of evidence, including systematic reviews, randomized controlled trials, non-randomized comparative evidence, case series and non-systematic reviews. On the title and abstract screen, 45 studies were identified to report the use of a device for the prevention, diagnosis or treatment of age-related macular degeneration. The details of the key studies retrieved for full text review are summarized in Table 38. A broader list of identified devices was obtained through title and abstract review of all included studies (Table 39).

The search strategy identified several devices for the prevention, diagnosis and treatment of macular degeneration. Proven preventive strategies include smoking cessation and nutritional supplements such as the Age-Related Eye Disease Study formula *(40)*. Regular dilated eye examinations are recommended every 2–4 years for people aged 40–64 years and every 1–2 years for people aged 65 years and older *(41)*. A number of charts may be used in the screening of macular degeneration (Table 39). Blue or yellow automated perimetry is also used in the screening of macular degeneration.

A definitive diagnosis of macular degeneration may be made using a number of tests. Optical coherence tomography is used to confirm the presence of subretinal and intraretinal fluid. Two types of angiography are also used to diagnose macular degeneration: fluorescein angiography and indocyanine angiography. Angiography involves injection of dye into the vein and the use of X-ray

Table 38 Macular degeneration – key studies

Study	Level of evidence	Primary focus	Secondary focus
Brown et al 2011 *(44)*	IV	Implantable miniature telescope	None
Christoforidis et al 2011 *(37)*	NA	Diagnostic and therapeutic options	None
Culham et al 2004 *(45)*	IV	Electronic head-mounted low-vision devices	Early treatment diabetic retinopathy study chart Bailey-Lovie near word and word charts Pelli-Robson chart
Karnon et al 2008 *(46)*	I	Screening programme	Amsler grid Slit-lamp Argon laser Transpapillary thermo-therapy Laser photocoagulation Fluorescein angiography
Koss et al 2009 *(47)*	II	Rheopheresis treatment system	Early treatment diabetic retinopathy study chart
Neelam et al 2009 *(48)*	IV	Slit-lamp biomicroscopy Fundus photography	None
Nowak et al 2012 *(38)*	IV	Photodynamic therapy Transpapillary thermo-therapy	Snellen chart Intraocular pressure measurement Slit-lamp examination Fundoscopy Fluorescein angiography Optical coherence tomography
Parodi et al 2004 *(49)*	II	Prismatic correction spectacles	Early treatment diabetic retinopathy study chart
Schmitz-Valckenberg et al 2008 *(50)*	IV	Fundus camera Confocal scanning laser ophthalmoscope	None

NA: not applicable.

Table 39 Macular degeneration – devices identified for prevention, diagnosis and treatment

Device	Description	Function
Prevention		
Amsler grid	Chart	Monitors central visual field
Perimeter	Appliance	Detects early changes in age-related macular degeneration
Diagnosis		
Charts: Snellen chart; early treatment diabetic retinopathy study chart; Bailey-Lovie near word/word chart; Pelli-Robson chart	Chart	Measures visual acuity and contrast sensitivity
Tonometer	Instrument	Assesses intraocular pressure
Slit-lamp biomicroscope	Instrument	Examination of eye

Continues…

Device	Description	Function
Confocal scanning laser ophthalmoscope	Instrument	Examination of eye
Fundus camera	Apparatus	Views eye, including fundus
Optical coherence tomographer	Appliance	Examination of retina, measures retina thickness and identifies lesions
Angiograph	Appliance	Determination of lesion morphology. Helps decipher best treatment option
Angiogram	Appliance	Images blood vessels. Used in fluorescein angiography and indocyanine angiography
Treatment		
Visual aids: magnifying glass; telescope; electronic head-mountable device	Aid	Improves visual function by decreasing viewing distance of target
Electronic visual aid (including closed-circuit television and adaptive computer hardware/software)	Aid	Projects magnified image on video monitor, television screen or computer monitor
Prismatic correction spectacles	Aid	Stabilizes oculomotor function to promote better function of preferred retinal loci
Low-vision filter	Aid	Reduces short-wavelength light and reduces glare. Identifies light preferred by patient. May protect from further ultraviolet damage
Implantable miniature telescope	Implant	Improves vision
Laser	Appliance	Destroys or seals off new blood vessels to prevent leakage
Rheopheresis treatment system	Appliance	Filters out rheologically relevant plasma proteins

based imaging techniques. Fluorescein angiography allows for the identification and localization of abnormal vascular processes, while indocyanine angiography provides a detailed representation of choroidal circulation.

Treatment for macular degeneration is dependent on the category of disease at presentation. It is aimed at reducing the rate of progression of immediate macular degeneration to advanced disease, and preserving sight *(42)*. Laser treatment was identified in the search as a primary treatment, with the aim of controlling blood vessel growth in the macula. Double-filtration plasmapheresis to filter the blood and reduce its viscosity was identified through the search as an experimental treatment for dry macular degeneration. High-dose antioxidant and mineral supplementation, intravitreal injection with vascular endothelial growth factor inhibitors, thermal laser photocoagulation and photodynamic therapy plus verteporfin were not identified through the literature search but were identified through clinical practice guidelines *(43)*.

6.3 OTIC DISEASES

6.3.1 Adult-onset hearing loss

Introduction

Hearing loss becomes increasingly common with age. It is estimated that 25–60% of the population aged over 65 years has hearing impairment *(51,52)*. This prevalence increases to more than 80% in people aged over 80 years *(53)*. Hearing loss is strongly associated with functional decline and depression *(54)*.

The aetiology of hearing loss is varied, as anything that interferes with the movement of sound from the external ear to the middle ear to the inner ear and then to the brain can affect hearing quality. Sensorineural hearing loss is the most common type of hearing loss and occurs where there is damage to the hair cells of the cochlea (sensory) or to the nerve pathway from the inner ear to the brain (neural). This may be congenital or acquired and is generally permanent. As there is no way of repairing this type of damage, sensorineural hearing loss is normally treated through the

amplification of sound through various means. Conductive hearing loss is a condition where sound is not conducted properly through the external auditory canal, the tympanic membrane (eardrum) or the ossicular chain (bones of the ear) to the oval window of the cochlea. Impacted cerumen (earwax) within the external ear canal is the most common cause of conductive hearing loss and can affect up to one in three older adults *(55)*. As the causes of conductive hearing loss are generally mechanical in nature, treatment is often surgical. Mixed hearing loss occurs when there are impediments to both conductive and sensorineural pathways.

Age-related hearing loss (presbycusis) is generally bilateral, gradual and progressive *(53)*. It is normally sensorineural in nature as a result of damage to cochlea hair cells. Many factors may contribute to presbycusis, including genetic factors, exposure to loud noise or ototoxic agents, a history of inner ear infections, and systemic diseases such as diabetes *(53)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of hearing loss. The following filters were applied to the search results: English language and published within the past 10 years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	presbycusis [MeSH terms]
#3	presbycusis
#4	adult onset hearing loss
#5	hearing loss [MeSH terms]
#6	#2 OR #3 OR # 4 OR #5
#7	#1 AND #6

Results

The strategy yielded 151 results. The majority of studies were randomized clinical trials, although a number of systematic reviews were also retrieved. On the title and abstract screen, 135 studies were identified to report the use of a device for the prevention, diagnosis or treatment of hearing loss. The details of the key studies retrieved for full text review are summarized in Table 40. A broader list of identified devices was obtained through title and abstract review of all included studies (Table 41).

A broad range of procedures, interventions and devices was identified to prevent, diagnose, aid and treat various forms of hearing loss. The literature search also identified the use of hearing-protection devices as workplace safety equipment to reduce damage to the ear, together with educational programmes to promote their use and improve compliance.

Due to the slow and progressive nature of presbycusis, many older people may not be aware that they have a hearing problem. Consequently, screening of elderly people may provide a useful tool in identifying hearing loss in this population *(52,53,56,57)*. The literature search identified a wide range of screening strategies. Two common approaches include the AudioScope (a handheld combined audiometric device and otoscope) and Hearing Handicap Inventory for the Elderly – Screening version (a self-administered questionnaire). Further audiology tests identified included the Bench–Kowal–Bamford sentence scores for sentence perception, the Speech Perception in Noise tests and the Glasgow Hearing Aid Benefit Profile to measure the subjective benefit of hearing aids.

Questionnaires and programmes were identified that aimed to improve the fitting and continued successful use of external hearing aids. These educational initiatives included online programmes and forums and telephone consultations with an audiologist. Specific software was also identified that assisted the user in aspects of fitting and use of the hearing aid (Listening and Communication Enhancement programme), although it was not clear how this was provided.

Assistive listening devices may be offered to patients who may not benefit from or may not be able to afford the cost of hearing aids. Assistive listening devices can be used in association with household technologies such as telephones, doorbells, televisions and smoke detectors to improve a person's audiovisual stimuli in their own home.

Removal of impacted cerumen (earwax) can be accomplished by a clinician or may be done by the patient, for example using 70% alcohol from a squeezable bottle with a specially designed tip. Ear infections and fluid build-up are likely to be treated initially through systemic medication. A ventilation tube placed through the tympanic membrane can be used in the treatment of persistent otitis media with effusion. No specific devices were identified in the repair of the tympanic membrane. One

Table 40 Hearing loss – key studies

Study	Level of evidence	Primary focus[a]	Secondary focus
Balkany et al 2007 *(58)*	II	Cochlear implant (Nucleus Freedom™)	Hearing-in-noise test (HINT)-Q Audiometer and audiograms for pure-tone, word and sentence recognition Sound-treated booth Comparison with Nucleus Contour (CNC) word-recognition test
Chou et al 2011 *(53)*	I	Screening devices and tests	AudioScope (handheld combination audiometric and otoscope device) HHIE Hearing aid use Whispered voice, finger rub and watch-tick test Single-question screening and screening questionnaires
Yueh and Shekelle 2007 *(51)*	I	Screening, diagnosis and therapy	HHIE AudioScope Pure-tone audiometry Speech-reception threshold Hearing aids Assistive listening devices (e.g. amplifiers, headphones, visual telephones and door-knock systems) Cochlear implant

HHIE: Hearing Handicap Inventory for the Elderly.

[a] Proprietary marks have been included where this information was readily identified through source material.

Table 41 Hearing loss – devices identified for diagnosis and treatment

Device[a]	Description	Function
Diagnosis		
Otoscope	Instrument	Visualization of external auditory canal and tympanic membrane
Tone-emitting otoscope	Instrument	Combined otoscope and audiometer for identification of hearing loss

Device[a]	Description	Function
Audiometer	Instrument and associated software	Identification of hearing loss; an audiogram is the graphical representation of the results. Tests that can be undertaken include pure-tone audiometry, air–bone gap audiometry, azimuth audiometry (where sound source is angled), impedance audiometry (to determine status of tympanic membrane) and otoacoustic emission testing (detection of spontaneous or stimulated sounds produced from middle ear). Statistical algorithms (Fast Fourier Transform techniques with F-test and Fourier Linear Combiner) were identified to measure auditory steady-state response, an auditory evoked potential elicited with modulated tones to predict hearing sensitivity in patients of all ages
CT system	Appliance	Provides imaging information before implantation of devices such as cochlear implant, or provides additional information for diagnosis of conductive hearing loss
Treatment		
Linear analogue external hearing aid	Aid	Provides amplification for hearing loss
Digital hearing aids, e.g. Siemens Artis 2 SP behind-the-ear hearing aids, digital hearing aid with phase-preserving and non-phase-preserving amplification, binaural broadband digital hearing instruments	Aid	Provides amplification for hearing loss
Trainable hearing aid	Aid	Provides real-world preferred hearing aid gain
Automatic-volume-control hearing aid	Aid	Provides amplification for hearing loss
Wide-dynamic-range compression hearing aids	Aid	Compensates for loudness sensitivity
Open-mould behind-the-ear hearing aid	Aid	Improves ventilation
Hearing aid anti-cardioid directivity pattern	Aid/software	Improves speech recognition when originating behind the user (current options include omnidirectional and conventional adaptive directional aids)
Ventilation tube	Implant	Treatment of persistent otitis media with effusion
Modified Politzer device	Instrument	Naturally opens blocked eustachian tube with air
High-fidelity personal sound player with earphones	Other	Provides acoustic stimulus modified according to the patient's audiometric profile for reducing effects of tinnitus
RetroX®	Implant	Auditory implant of external ear for patients without occlusion of external auditory canal
Custom-made electrical stimulator	Instrument	Provides transcutaneous electrical stimulation for treatment of tinnitus (shown not to be effective)
Hyperbaric chamber	Appliance	Hyperbaric oxygen therapy for sudden sensorineural hearing loss
Squeezable bottle with specially designed tip	Instrument	Removal of cerumen (earwax) to reduce impaction, using 70% isopropyl alcohol
Needle and syringe	Consumable	Trans- or intra-tympanic steroid injections in treatment of sudden sensorineural hearing loss for patients who have failed to improve with initial systemic steroid treatments. Largely unproven *(58)*
Manual micro-perforator	Instrument	Stapedotomy: to create a hole in stapes footplate
Er:YAG laser	Appliance	Stapedotomy: to create a hole in stapes footplate
Piston prostheses, e.g. platinum wire prosthesis; heat-activated nitinol stapes piston prosthesis	Prosthesis	Stapedotomy: prostheses to allow movement in ossicular chain
Modified Lippy prosthesis	Prosthesis	Reconstruction of incus. For use in middle ear reconstruction
Middle ear prosthesis (titanium)	Prosthesis	Ossicular reconstruction
Cochlear implant (HiRes 120 with Harmony processor, HiRes90K, Clarion II, Nucleus Freedom, Advanced Bionics Corporation or Cochlear Corporation devices)	Implant and software	Treats severe to profound sensorineural hearing loss, usually in young people. Specific programming software includes Fitting to Outcomes eXpert (FOX)

Continues…

Device[a]	Description	Function
Cochlear implant electrode	Implant	Improves simulation of specific neural populations and reduces power consumption (no evidence). Electrodes can be dual- or single-electrode stimulation and can be inserted at different depths
Remote programming system with teleconference facilities	Appliance and software	Facilitates remote programming of cochlear implant
Auditory brainstem implant	Implant	Treats sensorineural hearing loss by directly stimulating brainstem
Bone-anchored hearing aid: BAHA® Cordelle	Implant	Treats bilateral permanent conductive hearing loss
Fully implantable middle-ear hearing devices (Carina™, Esteem™, Vibrant™ Soundbridge)	Implant	Treats mixed or conductive hearing loss, particularly in patients who are medically unable to wear, or have failed treatment with, conventional hearing aids. Stimulates round window membrane
Hybrid cochlear implant plus hearing aid in same ear Electric acoustic stimulation Med-El electric acoustic stimulation system	Implant and aid	Improves electrical (mid and high frequencies) and acoustic stimulation
Closed-loop cochlear implant	Implant	Alternative to current open-loop system

CT: computed tomography; Er:YAG: erbium-doped yttrium aluminium garnet.

[a] Proprietary marks have been included where this information was readily identified through source material.

method described a novel therapy involving the use of basic fibroblast growth factor, a gelatin sponge and fibrin glue to assist in the regeneration of the tympanic membrane without the need for conventional surgery (type I tympanoplasty or myringoplasty).

A range of implantable devices is available for hearing loss, including cochlear implants, bone-anchored hearing aids, middle ear implants and auditory brainstem implants. The choice of implant is dependent on the nature of the hearing loss. There are many procedures for the treatment of mechanical problems associated with hearing loss. Ossicular reconstruction can be undertaken in various manners. In stapedectomy, the stapes bone is removed and replaced with a micro-prosthesis. Due to the complications of surgery, stapedectomy surgery may be avoided in elderly people and hearing aids may be offered as an alternative (M Schultz, Memorial Hospital, Adelaide, South Australia, personal communication, 7 February 2013).

6.4 CONCLUSION

Five sense organ diseases were investigated as part of this project. Independent searches were conducted on each disease and a range of devices were identified as being used commonly in the prevention, diagnosis or treatment of sense organ diseases.

For ophthalmic diseases, preventive strategies were focused on early detection through the use of eye charts and the use of handheld diagnostic devices. Preventive eyewear such as lenses and spectacles may be used to prevent the progression of symptoms of some eye diseases and to stop ultraviolet radiation from aggravating the condition. Healthy diet and avoidance of smoking were also important preventive strategies. Preventive strategies may be location-specific. Limited ophthalmic resources and staff, variations in climate, insect vectors, social surroundings and nutrition profoundly affect the pattern of eye disease in developing countries, and consequently the number of people with eye disease is higher in those countries.

For otic diseases, no specific preventive medical devices were identified; as with ophthalmic diseases, however, there was a focus on preventive strategies. A large number of devices have been developed to aid or repair the physical problems (both mechanical and sensorineural) that have led

to deafness. These devices vary widely in cost and complexity and in many cases require specialist surgical skills. For the ageing population, bilateral sensorineural hearing loss is commonly assisted by conventional external hearing aids; many associated paper- and computer-based tools are available to assist in the proper use of these aids.

Generally, the devices used in the prevention, diagnosis and treatment of sense organ conditions will be dependent on the patient's presentation, the clinician's preference and experience, and the accessibility of devices. In particular, the accessibility and availability of devices varies substantially between developed and developing countries, and between facilities in similar areas. The relative availability of medical devices will have downstream effects on the overall approach to sense organ disease. In settings with low access to diagnostic tools, for example, patients may enter treatment at later stages in the disease and thus have poor prognosis. Additionally, many of the devices identified require trained experts to operate them or to interpret the results, as well as appropriate infrastructure and materials to run and service them.

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7. Neuropsychiatric conditions

7.1 INTRODUCTION

Dementia is defined as a clinical syndrome characterized by progressive deteriorations in multiple cognitive domains that are severe enough to interfere with a person's daily functioning *(1)*. Dementia affects memory, thinking, orientation, comprehension, calculation, learning capacity, language and judgement. Worldwide, 35.6 million people have dementia and there are 7.7 million new cases every year *(2)*. The total number of people with dementia is projected to almost double every 20 years, to 65.7 million in 2030 and 115.4 million in 2050. Dementia is one of the major causes of disability and dependency among older people worldwide *(2)*.

7.2 ALZHEIMER'S DISEASE AND VASCULAR DEMENTIA

Introduction

Alzheimer's disease is the most common type of dementia, contributing to 60–70% of cases, followed by vascular dementia *(2)*. Symptoms of Alzheimer's disease include memory problems, progressive deterioration in the ability to perform basic activities of daily living, and behaviour changes (mainly apathy and social withdrawal, but also behavioural disturbances) *(3)*. Alzheimer's disease can be early or late in onset. The late-onset form is the most common and occurs after the age of 65 years, usually in the late 70s. This dementia is slowly progressive, with memory impairment as the principal feature *(4)*.

The cause of Alzheimer's disease is unknown. For late-onset Alzheimer's disease, several genes have been implicated as risk factors. These genes increase the probability of, but do not guarantee, the development of Alzheimer's disease *(5)*. Other risk factors that have been investigated include vascular and lifestyle factors. A recent review found good evidence supporting the control of vascular risk factors, especially hypertension, in preventing the development of Alzheimer's disease, but only weak or insufficient evidence for manipulation of lifestyle factors *(5)*.

Vascular dementia is the result of infarction of the brain as a consequence of vascular disease, including hypertensive cerebrovascular disease *(4)*. In comparison to Alzheimer' disease, people with vascular dementia more commonly have physical problems such as urinary incontinence, decreased mobility and balance problems *(3)*. Onset of vascular dementia is usually late in life *(4)*.

Methodology

An a priori search strategy was developed incorporating text and MeSH terms to identify devices that could be used in the prevention, diagnosis or treatment of Alzheimer's disease and vascular dementia. The following filters were applied to the search results: English language and published within the past five years and randomized controlled trials and systematic reviews.

#1	((aged [MeSH terms]) OR (health services for the aged [MeSH terms]) OR (aged) OR (senior) OR (elderly) OR (geriatric)) AND ((equipment and supplies [MeSH terms]) OR (assistive devices [MeSH terms]) OR (surgical instruments [MeSH terms]) OR (device*) OR (aid*) OR (equipment) OR (armamentarium) OR (appliance*) OR (instrument*) OR (apparatus) OR (good*) OR (implement*) OR (material*) OR (machine*)) AND ((diagnosis [MeSH terms]) OR (rehabilitation [MeSH terms]) OR (primary prevention [MeSH terms]) OR (secondary prevention [MeSH terms]) OR (after treatment [MeSH terms]) OR (therapeutics [MeSH terms]) OR (diagnos*) OR (therap*) OR (treatment*) OR (prevention) OR (monitoring) OR (screening) OR (rehabilitat*) OR (alleviat*))
#2	vascular dementia [MeSH terms]
#3	alzheimers disease, late onset [MeSH terms]
#4	senile dementia [MeSH terms]
#5	vascular dementia
#6	alzheimers and late onset
#7	senile dementia
#8	#2 OR #3 OR #4 OR #5 OR #6 OR #7
#9	#8 AND #1

Results

The strategy yielded 100 results. On the title and abstract screen, 53 studies were identified that reported the use of a device for the prevention, diagnosis or treatment of Alzheimer's disease or vascular dementia. In addition, following clinical expert opinion on the results of the initial search, clinical practice guidelines were used to supplement the literature results. During these searches it was noted that the American Academy of Neurology is in the process of updating its guidelines on diagnosis of dementia. The key studies retrieved (including clinical guidelines) for full text review are summarized in Table 42. All references were used to inform the list of devices presented in Table 43. In most instances the studies identified could not be designated a level of evidence due to the fact that they were clinical practice guidelines.

Of the 53 articles from the initial search, two were identified that reported on the use of treatments *(5,6)*.

The majority of studies identified in the initial search were on the use of cognitive, functional, global and neuropsychiatric scales used to (1) diagnose or screen for Alzheimer's disease or mild cognitive impairment, or (2) stage patients with dementia, or (3) assess outcomes in Alzheimer's clinical trials (Table 43). A very large number of tests are available, and there does not appear to be an endorsed gold standard, although two clinical guidelines state that the Mini-Mental State Examination appears to be one of the more widely used cognitive scales *(3,7)*.

In addition to scales for assessing cognitive function, functional decline and behavioural and psychological symptoms, a range of other tests are used to diagnose dementia. These include a clinical diagnosis (involving medical history and physical examinations), blood tests, neuroimaging tests, electroencephalography, cerebrospinal fluid examinations and genetic tests. No specific medical devices were identified in relation to clinical diagnosis, blood tests or genetic tests.

Cerebrospinal fluid biomarkers reportedly differentiate patients with Alzheimer's disease from patients with other dementias and from people without dementia *(3)*. Electroencephalography may help to differentiate between Alzheimer's disease, subjective complaints and psychiatric diagnoses *(7)*. One guideline reported that cerebrospinal fluid analysis and electroencephalography are not recommended as routine investigations *(3)*.

A limited number of devices were identified from the retrieved studies in relation to treatment for Alzheimer's disease and are listed in Table 43. Other therapies were also identified, including music, exercise, relaxation and cognitive stimulation; however, no specific medical devices were mentioned in relation to these therapies, and the effectiveness of these therapies was not ascertained.

Table 42 Alzheimer's disease – key studies

Study	Level of evidence	Primary focus	Secondary focus
Black et al 2009 *(8)*	NA	Scales used to measure outcomes of clinical trials for Alzheimer's disease	None
Chertkow et al 2008 *(6)*	NA	Guidance on diagnosis and treatment of MCI and cognitive impairment with no dementia	Physical exercise, cognitive activity
Lonie et al 2009 *(9)*	NA	MCI screening tests	None
Patterson et al 2008 *(5)*	NA	Guidance on risk assessment and primary prevention of Alzheimer's disease	Protective clothing and head protection

Rikkert et al 2011 *(10)*	NA	Scales used to stage dementia	None
Hort et al 2010 *(7)*	NA	Guidelines on diagnosis and management of dementia	None
SIGN 2006 *(3)*	NA	Guidelines on diagnosis and management of Alzheimer's disease	None

MCI: mild cognitive impairment, NA: not applicable.

Table 43 Alzheimer's disease – devices identified for diagnosis and treatment

Device	Description	Function
Diagnosis		
Functional MRI system	Appliance	Measures activity in different regions of brain by examining blood flow
Functional Spectroscope	Appliance	Assesses brain morphology and function
Tomography systems: SPECT; PET; F-deoxyglucose PET; CT	Appliance	Medical and nuclear imaging systems distinguishing between types of dementia, increasing diagnostic confidence in evaluation of dementia, distinguishing dementia from depression etc.
Needle	Consumable	Collects cerebrospinal fluid for biomarker testing
Electroencephalography machine	Appliance	Differential diagnosis of atypical clinical presentations of Alzheimer's disease
Treatment		
Repetitive high-frequency transcranial magnetic stimulation machine	Appliance	Improves cognitive function in people with mild to moderate Alzheimer's disease
Continuous positive airway pressure machine	Appliance	Improves cognitive function in people with Alzheimer's disease with obstructive sleep apnoea
Physical restraint	Other	Restrains people with dementia and behavioural problems
Bright-light therapy (phototherapy) machine	Appliance	Treats rest–activity (circadian) disruption in institutionalized people with Alzheimer's disease

CT: computed tomography; MRI: magnetic resonance imaging; PET: positron-emission tomography; SPECT: single photon-emission computed tomography.

7.3 CONCLUSION

Most of the retrieved studies were related to the diagnosis of dementia. Specifically the results identified a large number of cognitive, functional, global and neuropsychiatric scales used to assess people with mild cognitive impairment, dementia or specifically Alzheimer's disease. Many of the scales appear to assess similar factors, and there does not appear to be a single gold standard scale for diagnosis, although the Mini-Mental State Examination was reported by two guidelines to be one of the more common scales. Two scales were identified that discriminate between Alzheimer's disease and vascular dementia. Whether the identified scales are available in different languages could not be determined. Other diagnostic tools identified included neuroimaging devices, electroencephalography and cerebrospinal fluid analysis. The necessity of all these devices in the diagnosis of dementia is unclear. It is likely that the choice of tests may vary on a patient-by-patient basis and according to access to specific equipment. Many of the devices are used to rule out other medical conditions rather than specifically diagnose dementia or Alzheimer's disease.

A small number of devices were identified with respect to therapy for Alzheimer's disease. Physical exercise, relaxation therapy and cognitive therapy were reported in some studies and guidelines; no particular medical devices were mentioned in association with these therapies.

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8. Discussion

8.1 METHODS

For a truly comprehensive literature review it would be beneficial to search other relevant databases, such as Embase, Current Contents and the Cochrane Library. Given the broad focus of this research project, however, it was considered that the use of multiple sources would probably provide little added value for significant additional work. Additionally, highly detailed searches across a range of sources may add bias to the overall review by identifying studies of lower quality *(1)*. PubMed was chosen as it uses a number of reference databases and updates its indexing more regularly than some other sources.

Although the literature searches provided an a priori and unbiased methodology, there are certain limitations. Peer-reviewed literature is likely to be biased towards interventions and results that are of interest to journal editors and readership *(2)*. Well-established and conventional interventions and technologies may not be the focus of clinical trials and may not be reflected in peer-reviewed publications. During the course of this project, however, the identification of a broad range of literature, including clinical literature and systematic reviews, provided information on some of the more established devices and interventions, as well as the newer medical devices and techniques.

Using the results from a systematic literature review to identify devices focuses the information on devices commonly included in peer-reviewed published research. These devices will, therefore, have clinical safety and effectiveness evidence data, although the volume and quality of this information vary widely between each device. The literature identified in this way would also be relevant across a huge range of jurisdictions, although care would be needed in translating efficacy data from one practice to another. For example, randomized controlled trials are most frequently undertaken in large, well-equipped teaching hospitals, usually in developed countries with access to modern techniques and devices and with specialist skilled staff *(3,4)*. These trials commonly have very strict inclusion criteria for patient selection and may not be directly applicable to normal clinical practice, especially when applied to other countries or settings. A detailed report on the safety and efficacy of each identified medical device was beyond the scope of this report.

Other sources of information regarding needed medical devices may also be subject to bias. Clinical practice guidelines are invaluable in determining appropriate clinical management and in many cases are evidence-based and internationally recognized, but they are often country-specific and written within the context of the skills, resources and infrastructure applicable to that jurisdiction. These guidelines are also commonly produced by developed countries, where the access to and use of complex and expensive medical devices may be more common than in many developing countries. Individual clinicians also have varying degrees of bias in terms of their preferred clinical management and devices.

The methodology used in this review focused on the peer-reviewed literature; consequently, the results are a reflection of trends in research regarding medical devices for a range of health conditions. The research focus and description of device applications found in the literature may not necessarily be reflective of current or accepted clinical practice.

8.2 USE OF SUPPLEMENTARY RESOURCES

The majority of literature searches identified a broad range of devices that, when considered from a clinical management perspective, reflected most relevant procedures, interventions and devices. In some instances, it was clear when investigating the initial results from a clinical perspective that the systematic literature review may not have

identified all the key devices associated with the management of a specific condition. In these circumstances, clinical practice guidelines were used to establish the broader clinical management pathways and identify any missing interventions or devices. The primary example of this is the literature search for dementia and Alzheimer's disease, where the result was focused mainly on a wide range of cognitive, functional, global and neuropsychiatric scales used for testing and screening purposes. Reference to clinical practice guidelines identified further interventions related mainly to clinical diagnosis. These included blood tests, neuroimaging tests (nuclear and contrast), electroencephalography, cerebrospinal fluid examinations and genetic tests. It is likely that this experience with dementia and Alzheimer's disease is a result of a literature bias in the field, possibly associated with the fact that dementias are often diagnosed through the exclusion of other diseases and conditions rather than via a specific test leading to a definitive diagnosis.

8.3 OVERALL RESULTS OF INCLUDED MEDICAL DEVICES

Some topics were highly represented in the literature, for example topics related to the condition of cardiovascular diseases. In these cases, criteria (limiting to high-quality levels of evidence and more recent publications) were applied to increase the overall quality and relevance of the pool of literature. Other topics were clearly less highly represented in the identified literature, for example cancers of the mouth and oropharynx, and lymphoma. Due to the smaller total in the overall literature search results, these topics were not limited by study type. The variability between each of the 19 independent searches is representative of the research and publication focus of certain specialties.

The level of detail provided in terms of the composition and clinical utility of each identified medical device also varied across devices, studies and conditions. In this report the information regarding each device was provided in line with how it was reported in the original study, to avoid any misinterpretation of the results and misleading the reader.

Within each topic, some medical devices or groups of devices were commonly identified. Where relevant, this has been mentioned narratively in the results. For example, MRI and CT were common imaging devices across cancers and cerebrovascular conditions. Various forms of endoscope were used frequently for diagnostic and therapeutic purposes for a range of gastrointestinal cancers. Ultrasound was commonly used for diagnosis and in providing guidance for biopsy and surgical procedures.

In some circumstances, the nature or role of each device was not clear from the title and abstract searches, for example when the device was novel or the authors used trade names. In these cases, broader descriptors have been used to provide clarity to the report, with registered trade names listed as specific examples of devices that are marketed internationally (for example, various cochlear implants for hearing loss). In addition, similar devices, such as endoscopes, have been grouped together rather than reported independently. This work was undertaken to provide a level of clinical reasoning to what would otherwise be a crude list of medical devices. Where specifically identified, however, proprietary and marketing names were kept to avoid any potential misinterpretation of information from studies where the particular medical device may have been distinct from others.

Where there were many medical device options for a given intervention, it was difficult to assess what the more common techniques may be and the clinical benefits of each device. For example, a wide range of imaging devices may be used during diagnosis and staging for cancers. In these circumstances, the device used may be informed by its availability and may also be guided by clinical

preference. For example, initial diagnosis and TNM staging of specific cancers is initially accomplished with one or two imaging techniques (most commonly, CT or MRI); where available, however, a number of additional imaging tests may be undertaken to confirm initial results or to establish the presence or location of secondary neoplasms. These imaging devices, as with all other medical devices, are under continual improvement, with new versions offering improved image quality and specificity and with less risk to the patient, such as a lower dose of irradiation during the scanning procedure. The absolute and comparative clinical need of these additional tests was often unclear, and detailed studies of comparative safety and effectiveness would be needed to further inform on these issues.

Similarly, radiotherapy devices offer more accurate, image-guided delivery of higher doses of radiation, which has the potential benefit of offering an equivalent therapeutic dose of radiation with fewer sessions and fewer potential adverse events. This may be more acceptable to older patients and may also be of great convenience to patients living in rural or remote areas where regular access to larger hospitals in major metropolitan centres is difficult. The absolute or comparative clinical effectiveness or safety of these newer types of radiotherapy device was not clear from this preliminary research. Other benefits for people in remote areas include the use of remote programming technologies in cochlear implants and for monitoring cardiac resynchronization therapy implant function. These and other telemedicine facilities would depend on the availability of appropriate infrastructure for service delivery.

Clearly there is significant variability in the costs of the identified medical devices, with some basic items being very cheap, and larger, more complex devices being very expensive to purchase, use and maintain. The scope of this report did not allow a more detailed examination of the comparative or absolute cost–effectiveness of these devices, and this issue may benefit from further research.

Basic surgical equipment such as sutures, scalpels, surgical tables, other surgical instruments and equipment, medical gases, anaesthesia services and so on were not explicitly excluded from the search results. In the majority of cases, however, this level of detail was not seen in the identified literature. Overall the search did not identify a large number of these simple or conventional technologies as the use of these was often implicit but not described. This reflects the fact that medical devices reported in the peer-reviewed literature are generally tested, trialled and piloted in locations of medium- or high-resource settings. It is also reflective of the assumption that these basic devices are readily available and highly diffused across all jurisdictions. These basic medical devices would be considered to be standard equipment of any surgical operating theatre and may not be specific to any of the topics under investigation. An exception was found in some of the ophthalmology topics, where specific bandages and masks were identified.

It was also apparent from the results that the use of pathology equipment to test biopsy samples was infrequently reported and imprecisely described. This may reflect an assumption that pathology equipment or testing protocols are similar across jurisdictions and points to the limitations in transferability of results obtained in high-resource settings and their application in low-resource settings. For many of the in vitro diagnostic tests, the test was mentioned in the absence of any specific instrument or equipment. It is likely, however, that some form of medical device would have been involved for most, if not all, of these tests. In general, diagnostic tests were poorly represented in the identified literature.

8.4 PREVENTIVE DEVICES

The topics identified for research within this project cover a broad range of conditions, with various aetiologies. Some are idiopathic and others are secondary conditions associated with other disease states. The specific relationship of the ageing process to each of these topics is not well understood, as age is normally one of

a number of factors involved in the progression of these diseases. Relatively few preventive devices were identified, and all were associated with specific known risk factors. One preventive procedure that was identified was prophylactic mastectomy. In general, this would be considered only for women at very high risk of breast cancer, and the decision to progress with this radical therapy would include consideration of familial risk together with genetic tests. Oophorectomy may also be an option in a similar population. Screening of known risk factors (hepatitis for liver cancer, *H. pylori* screening for stomach cancer) or control and education of lifestyle choices (smoking for lung cancer, exercise and dietary education for cardiovascular conditions, hearing protection) are among the few other preventive interventions that were identified from the literature search.

For cancers, screening for early stages of the disease is possible for certain conditions. The removal of colorectal polyps may reduce the risk of colorectal cancer, and early detection and treatment of Barrett's oesophagus may reduce the risk of developing oesophageal cancer.

8.5 DEVICES ASSOCIATED WITH OLDER PEOPLE

A few examples were identified of devices with specific relevance to older people. Mammography may be advised for older patients, whereas younger women may benefit from ultrasound due to the increased density of the breast tissue. It may be that elderly people and patients with comorbidities may benefit from minimally invasive technologies that are becoming more common across a range of specialties. In hypertensive heart disease, valve insufficiencies may be treated with open or less invasive percutaneous surgery. The mid- and long-term effectiveness of percutaneous valve replacement procedures is unclear at the moment, but they may offer an option to older patients unable to undergo conventional valve replacement surgery.

Patients with chronic heart failure may be offered a range of implantable devices to protect or support heart function, the choice of which would be initially informed by the type and severity of the heart failure, but may also be informed through patient choice. A cardiac resynchronization therapy device provides continual pacing to improve ventricular function and has the aim of improving quality of life. These devices are available with or without a defibrillator function, which would have the added benefit of providing protection against sudden cardiac arrest and death. It may be that some older patients would choose not to be implanted with a defibrillator, due to the fact that the defibrillator may cause painful shocks with no associated clinical benefit.

Certain cancers can be treated with a variety of ablation techniques delivered percutaneously or through laparoscopy or laparotomy, in some instances aided by the use of a robot. It appears as if the gold standard, where possible, is surgical resection of the tumour, although ablative technologies may be an option to patients who have contraindications for conventional surgery, or may be used as a palliative measure. Therefore, although minimally invasive options are becoming more common and may, in certain instances, offer benefits compared with open surgery, their choice may depend on a range of factors, including comparative effectiveness with conventional surgical treatment, clinical presentation, risk and patient preference.

In the main, these examples were identified from a clinical consideration of the search results, and there were few examples of devices that were directly aimed at the elderly population in the literature. Exemptions to this were devices for hearing loss. Many trials and studies were focused on elderly populations, including for screening and diagnosis (questionnaires, audiometers), aids and treatments (external hearing aids, cochlear implants), and various programmes and methods to improve the effectiveness of or compliance with external or implantable hearing aids (including software, algorithms, educational programmes and online material).

Some experimental or novel interventions were identified that could be considered "horizon scanning" for the purposes of this project. Some examples include the use of plasma rheopheresis for filtering blood in the treatment of dry macular degeneration and the use of intraoperative radiation therapy in the treatment of breast cancer.

Many examples were identified of the continued evolution of medical devices. This included modifications to endoscopes to improve vision and function (such as the Third Eye Retroscope®), a variety of staplers used in surgical resection of cancers, and a wide variety of tests and devices used for ophthalmic and hearing problems. Hybrid imaging technologies are becoming increasingly common, such as the combination of mammography and MRI. These technological improvements may offer clinical benefits beyond the current conventional options; however, this preliminary review was not able to establish the clinical utility and cost–effectiveness of these devices.

Another relatively novel intervention associated with cancers of the prostate, breast and stomach was the use of genetic testing. This type of personalized medicine enables the genetic profile of a cancer to be understood and was usually used as a decision-aid to guide chemotherapy.

Medical devices with applications in palliative care or chronic diseases may be of particular importance in elderly populations, as older people often present with comorbidities or are unsuitable for surgical interventions. Newer medical devices may offer new or alternative treatment options, but even where these alternatives are available the final decision regarding the treatment may be informed by a range of personal choices and beliefs together with other societal and cultural considerations.

8.6 FUTURE RESEARCH AREAS

The methodology used in this project has provided broad information of clinical relevance on each of the 19 topics of interest. This information was not focused specifically on the Western Pacific Region and is broadly applicable to any country worldwide. The specific health problems in ageing populations within the Western Pacific Region, and the way in which they are treated, is highly varied as the region accounts for a large number of countries over a wide area. Clinical issues of safety and effectiveness are likely to be cross-jurisdictional and could be advised in an evidence-based manner through a comprehensive systematic review of peer-reviewed literature. The complete literature results from this project could be used to inform these searches. Cost–effectiveness issues for each device would be procedure-based where relevant and would likely vary from country to country. Although the basic elements of service delivery would remain similar, the availability and cost of different parts of the service could vary and be dependent on the skills available and infrastructure in each country. A systematic review or health technology assessment undertaken in one country may be adapted for application in another country *(5)*.

This project has highlighted that effective clinical management of any given health condition requires a consideration of all aspects of the management pathway. Preventive, diagnostic and therapeutic strategies, and the devices associated with each, are clearly linked to each other, and the true clinical effectiveness of any individual device or intervention can be established only within this framework. For instance, to be truly effective in the management of liver cancer, as well as establishing effective clinical treatments for treating the liver cancer and any secondary cancers, a jurisdiction also needs to establish screening programmes (such as for hepatitis), preventive measures for environmental risk factors, and appropriate diagnosis infrastructure, including imaging, biopsy and TNM staging. Without appropriate diagnosis, access to a range of needed therapeutic devices is negatively impacted.

8.7 CONCLUSIONS

This project has used systematic methodology to provide a robust list of devices relevant to 19 subconditions that are the cause of most

morbidity and mortality in elderly people in the Western Pacific Region. A final list of needed devices will likely benefit from a consideration of other methods, including those of economic evaluation and social impact, input regarding clinical, policy, organizational and infrastructure issues, and research contextualizing the results to each country in the Western Pacific Region.

It is intended that the output of this report will inform future research, with the ultimate aim to improve access of elderly people to needed devices.

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Annex 1

DESIGNATIONS OF LEVELS OF EVIDENCE ACCORDING TO TYPE OF RESEARCH QUESTION

Table A1.1 Designations of levels of evidence according to type of research question

Level	Intervention[a]	Diagnostic accuracy[b]	Prognosis	Aetiology[c]	Screening Intervention
I[d]	Systematic review of level II studies	Systematic review of level II studies	Systematic review of level II studies	Systematic review of level II studies	Systematic review of level II studies
II	Randomized controlled trial	Study of test accuracy with independent, blinded comparison with valid reference standard[e] among consecutive patients with defined clinical presentation[f]	Prospective cohort study[g]	Prospective cohort study	Randomized controlled trial
III-1	Pseudo-randomized controlled trial (alternate allocation or some other method)	Study of test accuracy with independent, blinded comparison with valid reference standard[e] among non-consecutive patients with defined clinical presentation *(6)*	All or none[h]	All or none[h]	Pseudo-randomized controlled trial (alternate allocation or some other method)
III-2	Comparative study with concurrent controls: non-randomized experimental trial;[i] cohort study; case–control study; interrupted time series with control group	Comparison with reference standard that does not meet criteria required for level II and III-1 evidence	Analysis of prognostic factors among patients in single arm of randomized controlled trial	Retrospective cohort study	Comparative study with concurrent controls: non-randomized experimental trial; cohort study; case–control study
III-3	Comparative study without concurrent controls: historical control study; two or more single-arm studies;[j] interrupted time series without parallel control group	Diagnostic case–control study[f]	Retrospective cohort study	Case–control study	Comparative study without concurrent controls: historical control study; two or more single-arm studies
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)[k]	Case series or cohort study of patients at different stages of disease	Cross-sectional study or case series	Case series

[a] Definitions of these study designs are provided on pages 7–8 of ref. *(1)*.

[b] The dimensions of evidence apply only to studies of diagnostic accuracy. To assess the effectiveness of a diagnostic test there also needs to be a consideration of the impact of the test on patient management and health outcomes *(2,3)*.

[c] If it is possible and ethical to determine a causal relationship using experimental evidence, then the "intervention" hierarchy of evidence should be used. If it is possible and ethical to determine a causal relationship only using observational evidence (i.e. cannot allocate groups to a potential harmful exposure, such as nuclear radiation), then the "aetiology" hierarchy of evidence should be used.

[d] A systematic review will be assigned a level of evidence only as high as the studies it contains, except where those studies are of level II evidence. Systematic reviews of level II evidence provide more data than the individual studies, and any meta-analyses will increase the precision of the overall results, reducing the likelihood that the results are affected by chance. Systematic reviews of lower-level evidence present results of likely poor internal validity and thus are rated on the likelihood that the results have been affected by bias, rather than whether the systematic review itself is of good quality. Systematic review quality should be assessed separately. A systematic review should consist of at least two studies. In systematic reviews that include different study designs, the overall level of evidence should relate to each individual outcome/result, as different studies (and study designs) may contribute to each different outcome.

[e] The validity of the reference standard should be determined in the context of the disease under review. Criteria for determining the validity of the reference standard should be prespecified. These can include the choice of the reference standard(s) and its timing in relation to the index test. The validity of the reference standard can be determined through quality appraisal of the study *(4)*.

[f] Well-designed population based case–control studies (e.g. population-based screening studies where test accuracy is assessed on all cases, with a random sample of controls) do capture a population with a representative spectrum of disease and thus fulfil the requirements for a valid assembly of patients. In some cases, however, the population assembled is not representative of the use of the test in practice. In diagnostic case–control studies, a selected sample of patients already known to have the disease is compared with a separate group of normal healthy people known to be free of the disease. In this situation, patients with borderline or mild expressions of the disease and conditions mimicking the disease are excluded, which can lead to exaggeration of both sensitivity and specificity. This is called spectrum bias or spectrum effect, because the spectrum of study participants will not be representative of patients seen in practice *(5)*.

[g] At study inception, the cohort is either non-diseased or all at the same stage of the disease. A randomized controlled trial with people who are either non-diseased or at the same stage of the disease in both arms of the trial would also meet the criterion for this level of evidence.

[h] All or none of the people with the risk factor(s) experience the outcome, and the data arise from an unselected or representative case series, which provides an unbiased representation of the prognostic effect. For example, no smallpox develops in the absence of the specific virus, and clear proof of the causal link has come from the disappearance of smallpox after large-scale vaccination.

[i] This also includes controlled before-and-after (pre-test/post-test) studies and adjusted indirect comparisons (i.e. use A vs B and B vs C to determine A vs C with statistical adjustment for B).

[j] Comparing single-arm studies, i.e. case series from two studies. This would also include unadjusted indirect comparisons (i.e. use A vs B and B vs C to determine A vs C with no statistical adjustment for B).

[k] Studies of diagnostic yield provide the yield of diagnosed patients, as determined by an index test, without confirmation of the accuracy of this diagnosis by a reference standard. These may be the only alternative when there is no reliable reference standard.

Source: Merlin T et al. Extending an evidence hierarchy to include topics other than treatment: revising the Australian "levels of evidence". BMC Med Res Methodol. 2009;9:34. Hierarchies adapted and modified from refs *(6–9)*.

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