Optimising patient involvement to improve migraine patient outcomes

Spotlight on migraine services and access to appropriate medicines

Information from the following organisations has been included within this Toolkit. This information was sourced directly, or indirectly through secondary resources.

American Migraine Foundation | Blodcancerforbundet, Germany | European Medicines Agency (EMA) | European Patient Academy on Therapeutic Innovation (EUPATI) | European Patients Forum (EPF) | Health Equality Europe | Health Technology International (HTAi) and their Patient and Citizen Involvement in HTA Interest Group (PCIG) | HTA agencies in Australia, Brazil, England, Denmark, Germany, Scotland and Sweden | Migraine Trust | Myeloma UK | World Health Organisation (WHO)

*This resource was created by KYNE in partnership with European Migraine and Headache Alliance (EMHA), the European Federation of Neurological Associations (EFNA) and Migraine Action.**

The development of the Toolkit was funded by Novartis.

**As of June 2018, Migraine Action has closed.*

Welcome to your toolkit

Dear Colleagues

Over the last five years a lot has been achieved in better meeting the needs of those living with migraine, even in the absence of new treatment innovations.

Yet, more still needs to be done to address the considerable burden of migraine.

In driving change, patients, their carers, and patient organisations that advocate for those with migraine, have a critical role to play.

Recognition of the important role patients have in informing decisions about their health and care, the continued drive for improved community-based headache services, and the potential for new migraine treatment options, means that now is the right time to further mobilise the patient voice.

Your Toolkit is a comprehensive resource that has been developed to support patient organisations throughout the world to optimise patient involvement to improve migraine outcomes. The focus of your Toolkit is the role of patient involvement in improving migraine services and access to appropriate medicines.

However, your Toolkit is just the start. Over the coming months and years, we hope to build on this Toolkit and its contents with a range of initiatives and programmes that further advance organisations' capacity and capability in this important area.

We hope that you find your Toolkit of value and we would welcome any feedback on the Toolkit and how its contents have supported your work.

Elena Ruiz de la Torre
Executive Director, Past President
European Migraine and Headache Alliance (EMHA)

Donna Walsh
Executive Director
European Federation of Neurological Alliances [EFNA]

Simon Evans
Chief Executive
*Migraine Action**

The Toolkit comprises original co-created copy and tried and tested educational materials from leading organisations such as WHO, European Patients Academy on Therapeutic Innovation (EUPATI), and Health Technology Assessment International's (HTAi) Patient and Citizen Involvement in HTA Interest Group (PCIG). The Toolkit partners thank these organisations.

**As of June 2018, Migraine Action has closed.*

Contents

Please use the hyperlinks to access the Toolkit contents and to return to the contents page.

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An introduction to your Toolkit

Module two – THE BURDEN OF MIGRAINE AND THE VALUE OF MEDICINES

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Section two: The value of medicines

Module three – ADVANCING PATIENT INVOLVEMENT

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MODULE ONE

About your Toolkit

> "Given that medicines remain the most common therapeutic intervention in healthcare, and colleagues in research and the broad pharmaceutical industry have worked hard to discover and develop safe and effective medicines, we must all work even harder together to ensure that individual patients and society gets as much value out of that effort as possible, and resources are used wisely and effectively."

Sir Bruce Keogh, National Medical Director, NHS England
Jane Cummings, Chief Nursing Officer for England
Dr Keith Ridge, Chief Pharmaceutical Officer.

Foreword, Royal Pharmaceutical Society Good Practice Guide, 2013

Section one - AN INTRODUCTION TO YOUR TOOLKIT

1.0 Toolkit Purpose

Your Toolkit is a best-in-class educational resource for migraine patient organisations and other organisations that support those living with, and affected by, migraine.

Its primary purpose is to support patient organisations in optimising patient involvement to improve migraine patient outcomes. It aims to achieve this by supporting you to advance patient involvement in improving migraine services and access to appropriate medicines.

The aims of this section are to:

- Support you in using and navigating your Toolkit
- Inform you how you can use the resources embedded in your Toolkit

2.0 Toolkit Development Partners

Your Toolkit was initiated and funded by Novartis. KYNE, a communications consultancy, was engaged by Novartis to work with the European Headache Alliance, the European Federation of Neurological Associations and Migraine Action to develop the Toolkit.

The European Migraine and Headache Alliance (EMHA) is a non-profit, patient umbrella group that was launched in 2006. Since then, the Alliance has grown to represent 25 patient groups from across the continent.

www.europeanheadachealliance.org

The European Federation of Neurological Associations (EFNA) brings together European umbrella organisations of neurological patient advocacy groups, to work with other associations in the field of neurology.

www.efna.net

Migraine Action* is the UK's leading charity offering support and advisory information to those affected by migraine, whether individuals, families, employers or employees or medical professionals.

www.migraine.org.uk

**As of June 2018, Migraine Action has closed.*

3.0 Who This Toolkit is For

This Toolkit has been developed to support all those with an interest in improving patient outcomes in migraine.

In addition to this comprehensive Toolkit, there is summary resource called, 'An introduction to patient involvement – improving services and access to appropriate medicines'. This is intended to be used by organisations that want an introduction to the subject.

It is hoped that following review of the summary resource, these organisations will feel confident in using this Toolkit, or that they will consider partnering with other organisations to help ensure that their voice is heard.

A copy of the summary resource can be downloaded **here**

4.0 The Use of the Term 'Patient'

Within your Toolkit, the term 'patient' is used to describe those that can inform decision-makers about the needs, experiences and preferences of those affected by migraine. Patients therefore include:

- **Individual patients.** People who have experience of migraine – sometimes termed "lived-experience"
- **Expert patients.** Patients who have experience of migraine and have been trained in areas such as medicines development or service delivery
- **Carers.** Those who provide care and support for people living with migraine, such as family members, friends or volunteers
- **Patient organisation representatives.** Individuals from a patient organisation that have accountability for representing the views of the organisation
- **Patient advocates.** Those who advocate for migraine patients and carers, but are not accountable for representing the views of a patient organisation

5.0 How to Use Your Toolkit*

Your Toolkit is divided into four main modules and an evaluation module. Each contains subject-specific sections that can be reviewed as and when they are needed. There is also a wide range of additional educational resources, tools, guidance, checklists and website links embedded within your Toolkit.

Individual sections can be accessed by using the hyperlinks in the contents table. The hyperlinks within the individual sections will return you to the contents.

It is important that you familiarise yourself with your Toolkit content from the outset. As well as its educational resources, your Toolkit provides a wide range of resources that can support you in your strategic planning and thinking about your role in optimising patient involvement.

5.1 Helping you get the best out of your Toolkit

To support you getting the best out of your Toolkit, key information is highlighted. In addition, the following are highlighted:

Key Learnings – a summary of the key learnings at the beginning of each section.

Toolkit Guidance – specific information on how to use your Toolkit content and resources.

Website Link – links to global websites, and country-specific websites where you can source guidance and information.

Resource – relevant resources embedded in your Toolkit to download and review.

*In developing the Toolkit, consideration has been given to the needs of patient organisations, variations in country healthcare systems, opportunities for patient involvement and patient organisation capacity and capability.

5.2 Downloadable resources

Downloadable resources are information, materials and training initiatives that are already available from reputable organisations and sources. Some of these evidence-based resources have been incorporated within your Toolkit. These downloadable resources:

1. Provide information in a range of different formats that can support your learning e.g. webinars
2. Provide specific tools to support your planning and patient involvement activities e.g. checklists for outreach to key influencers, detailed guidance on how to respond to a consultation

In addition, relevant website links are provided. These website links enable you to access country-specific guidance on your patient involvement activities e.g. timelines and bespoke templates used by country-specific organisations.

Table one summarises the type of Toolkit content, how to use this and Top Tips to maximise its impact.

Table One: Toolkit contents and how to use it

Content overview	How to use the resource	Top Tips
Partner content and original co-created copy generated by the Toolkit partners.	This forms part of the skills enhancing element of the Toolkit.	*This copy can be used to support you to generate content that supports patient involvement.*
Adapted copy from tried and tested resources already in the public domain.	This forms part of the skills enhancing element of the Toolkit.	*If using this copy, always acknowledge the fact that it has been adapted from a particular resource and who generated this.*
Educational materials and resources from leading organisations such as the European Patients Academy on Therapeutic Innovation (EUPATI), and Health Technology Assessment International's (HTAi) Patient and Citizen Involvement in HTA Interest Group (PCIG).	These are embedded into the document. Click on the document link to download and review them. Use the materials to further the understanding of you and your colleagues of key aspects of patient involvement.	*While these resources are intended for everyone's use, some of the materials are only available under a creative commons licence. This means that when these are used, the resources generated need to be made available to everyone.* *Learn more about creative commons licenses here.* ▶

Table One: Toolkit contents and how to use it (continued)

Content overview	How to use the resource	Top Tips
Referenced statements and facts & figures.	These can be used to support generation of content for a wide-range of materials and activities (e.g. responding to a consultation).	*When making a statement of fact, these should be referenced to the original information source.*
Links to a wide range of relevant organisations' websites, such as country specific HTA agencies.	Many country specific sites provide clear guidance and support for inputting into decisions about patient care and the assessment of medicines. Relevant country sites should be visited and reviewed in support of your activities.	*Bookmarking the websites will support regular review of the sites for updates.*
Case studies.	These demonstrate how patient involvement has successfully informed those responsible for service provision and for the assessment of medicines.	*Generating your own case studies will enable you to share your success and support other organisations in their patient involvement activities.*
Reports, white papers, clinical papers and publications.	These resources will support the generation of evidence-based content, while enabling you to consider topics contained within your toolkit in more depth.	*It is important to use the most up-to-date information when advancing patient involvement. Services such a Google Alerts can support this.*
Templates, checklists and bespoke guidance.	These can be used for generating materials, planning, strategic planning and to support the efficient delivery of activities and programmes.	*Always visit your relevant country specific organisations to see whether they provide specific guidance, tools and templates.*
Glossaries.	These can be used to support your understanding of key words and phrases that you may not be familiar with.	*Different organisations often use different terminology to describe the same thing. Use and distribution of the glossary will help overcome this challenge.*

6.0 About the Creative Commons Licence[1]

The Creative Commons copyright licences and tools forge a balance inside the traditional "all rights reserved" setting that copyright law creates. The tools give everyone from individual creators to large companies and institutions a simple, standardised way to grant copyright permissions to their creative work.

Under a Creative Commons Licence, you are free to:

Share – copy and redistribute the material in any medium or format

Adapt – remix, transform, and build upon the material

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Attribution – you must give appropriate credit, provide a link to the licence, and indicate if changes were made. You may do so in any reasonable manner, but not in any way that suggests the licensor endorses you or your use.

Non-Commercial – you may not use the material for commercial purposes.

ShareAlike – if you remix, transform, or build upon the material, you must distribute your contributions under the same licence as the original.

No additional restrictions – you may not apply legal terms or technological measures that legally restrict others from doing anything the licence permits.

Notices:

You do not have to comply with the licence for elements of the material in the public domain or where your use is permitted by an applicable exception or limitation.

No warranties are given. The licence may not give you all of the permissions necessary for your intended use. For example, other rights such as publicity, privacy, or moral rights may limit how you use the material.

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MODULE TWO

The burden of migraine and The value of medicines

> Headache disorders, including migraine and tension-type headache, are among the most prevalent disorders of mankind. They are under-recognised, under-diagnosed and under-treated. Financial costs to society through lost productivity are enormous – far greater than the health-care expenditure on headache in any country.[2]

WHO, Atlas of Headache Disorders

Section one - THE BURDEN OF MIGRAINE

The aims of this section are to:

- Provide you with referenced key messages, facts and figures that can help demonstrate the burden of migraine. These can be used to build the case for better migraine services and to support patient involvement in access to appropriate medicines.
- Provide you with infographics and video sources that can be used when communicating with decision-makers.

Key learnings

- Migraine is a distinct neurological disease that is associated with recurrent and often debilitating headaches.[2]
- Headache disorders, including migraine and tension-type headache, are among the most prevalent disorders of mankind. They are under-recognised, under-diagnosed and under-treated. Financial costs to society through lost productivity are enormous – far greater than the health-care expenditure on headache in any country.[2]
- Migraine is the third highest cause of disabilities in the under 50s.[3]
- Migraine has a profound and limiting impact on an individual's abilities to carry out everyday tasks.[4]
- Migraine is associated with significant financial cost to society.[4]

1.0 Insight into The Burden of Migraine

Migraine is a distinct neurological disease that is associated with recurrent and often debilitating headaches.

The 'burden of migraine' is a term that is used to describe the impact of migraine on individuals, their families, communities and society. It can also refer to the healthcare system costs of managing migraine, and to the economic impact of migraine on individuals, their employers and on local and national economies.

When building an argument for improving services and access to appropriate medicines, evidence regarding the burden of migraine is a critical component of patient involvement.

When this evidence comes from an established peer-reviewed and published source, the patient perspective on what this evidence means to patients is equally important.

For example:

- The data from clinical trials may record the number of migraine days experienced in a set period of time. Someone with migraine may offer the further insight that this means taking days off work in addition to a partner taking time off work to support childcare.

2.0 The Burden of Migraine Key Messages, Facts and Figures

The key messages, facts and figures below have been sourced from peer-reviewed medical publications and other respected sources of information. These should be supplemented by other information that you may have related to the burden of migraine and migraine patient needs, perspectives and experience.

In the absence of this, it is important to generate relevant information. For example, you could report the impact of migraine on those patients your organisation supports, uncovered through a survey using an online survey tool. As well as data, it can be helpful to get quotes from patients to add colour to your information.

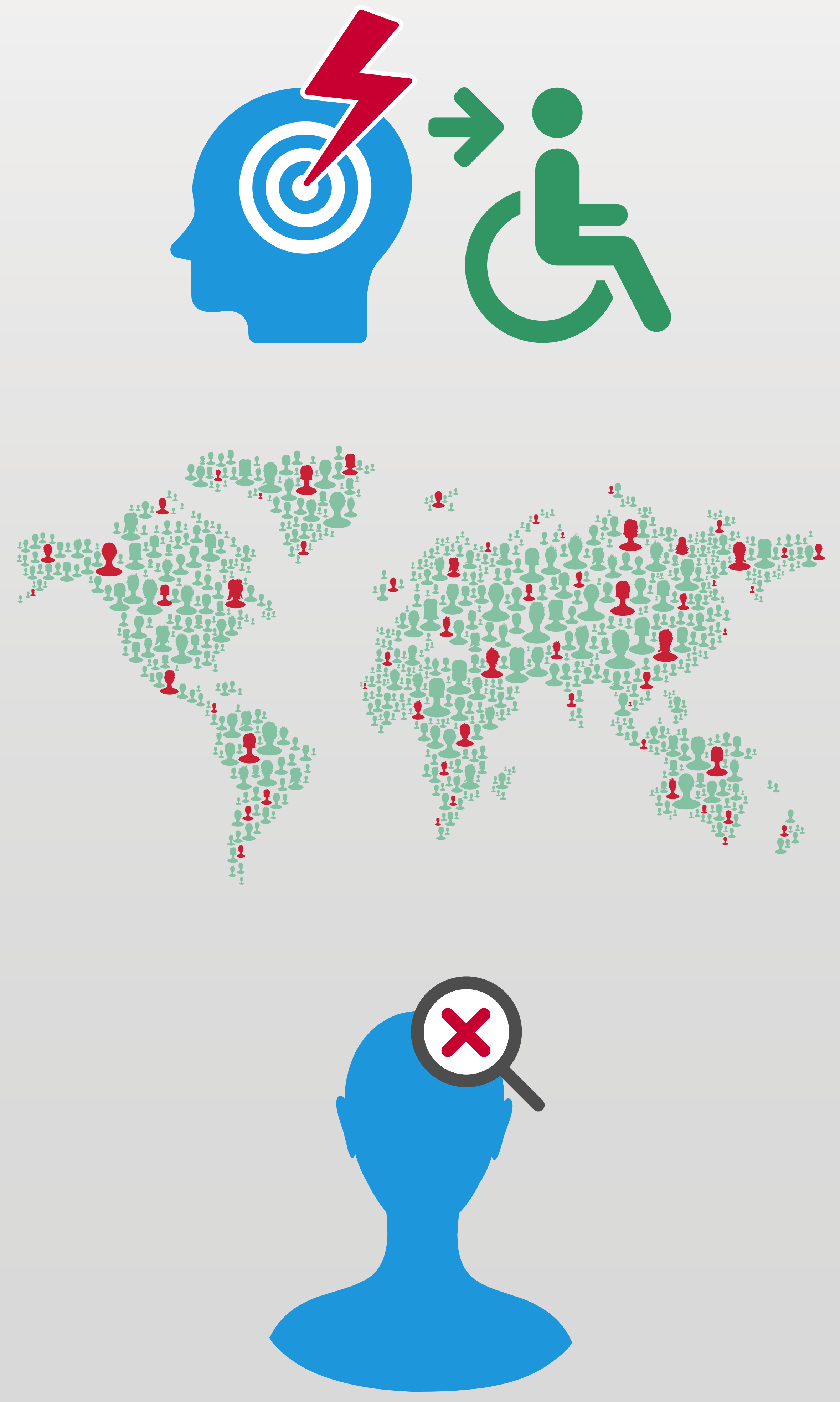
The importance of demonstrating migraine patient needs, perspectives and experience is considered in more detail in module three.

The importance of infographics and referencing

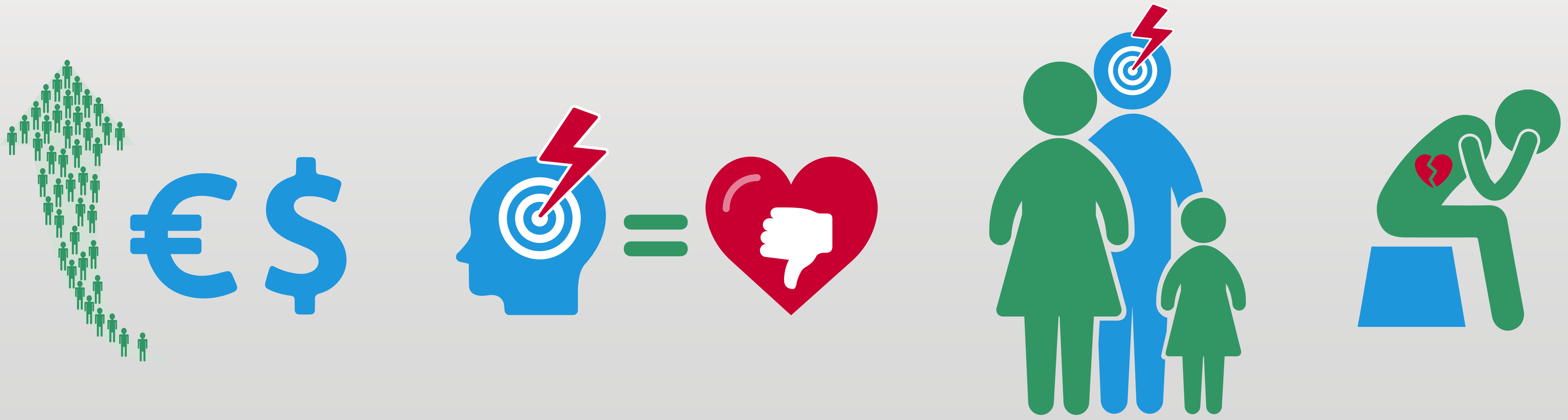
The burden of migraine

Click the images to be brought to relevant facts

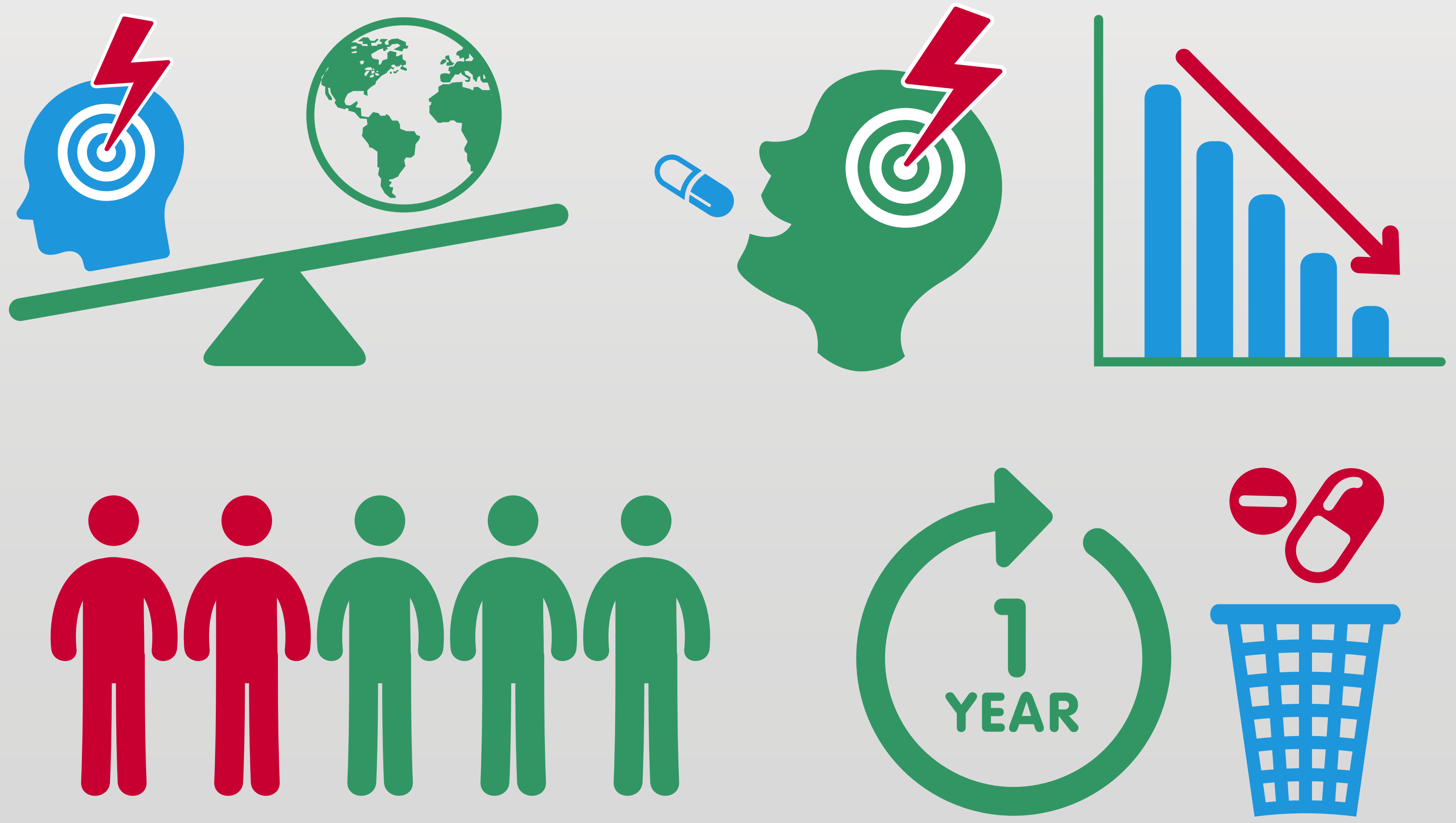
PREVALENCE OF MIGRAINE



THE IMPACT OF MIGRAINE



UNMET NEEDS IN THE TREATMENT OF MIGRAINE



POSITIVE ASPECTS

2.1 Prevalence of migraine

The World Health Organisation (WHO) ranks migraine as one of the most debilitating of all illnesses and in the Global Burden of Disease Study migraine was found to be one of the leading causes of years lost due to disability.[4]

- Migraine is the third highest cause of disabilities in the under 50s.[3]

More than 10% of people are affected by migraine worldwide.[5]

Prevalence: Australia (22%, females), Europe (15%); North America (13%), Asia (9%), Central/South America (9%) and Africa (5%).[6]

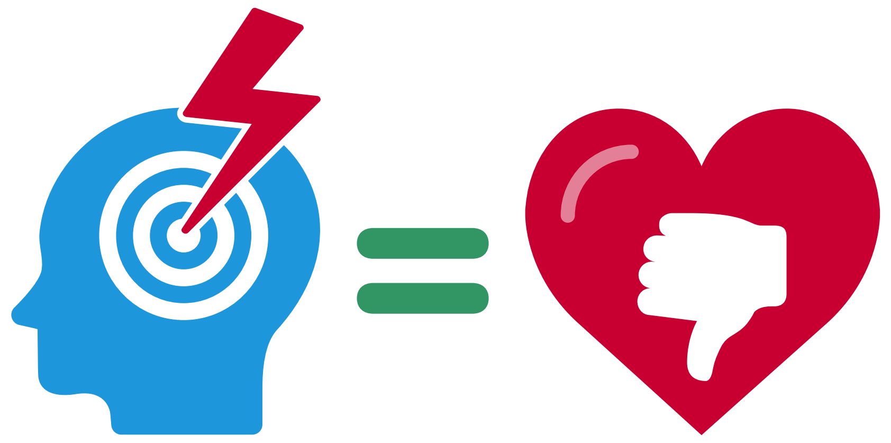
>50%

Migraine remains under-recognised and under-treated with more than 50% of people living with migraine going undiagnosed.[8]

2.2 The impact of migraine

Migraine is associated with significant financial costs to society.[4]

- Every year, almost 20% of men and 30% of women report losing more than 10% of workdays as a result of their migraine.[7]
- Migraine most often begins at puberty and most affects those aged between 35 and 45 years.[4] It is more common in women, usually by a factor of about 2:1, because of hormonal influences.[4]



Migraine is associated with disability and reduced quality of life.[4]

- More than 90% of people report they cannot work or function with a migraine.[8]
- Some individuals experience lingering effects of migraine following an attack. Symptoms include altered mood, nausea and fatigue.[9,10]

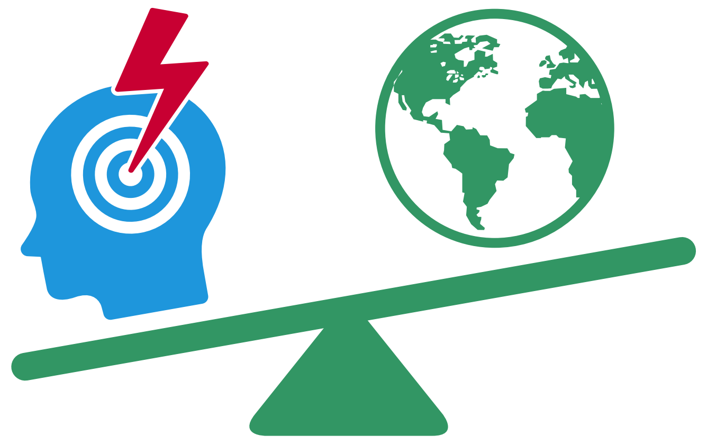
Migraine has a profound and limiting impact on individuals.[4]

- The main headache phase of migraine typically lasts for 4-72 hours.[5] In a study, 1 in 5 reported that the total length of their migraine attack is more than 3 days long.[11]
- Before this, some individuals experience pre-migraine signs, including fatigue and sleep issues, hours or even days before attacks[11]. For example, 83% of people living with migraine report difficulties sleeping.[12]
- Migraine causes more than just physical pain and symptoms, it also causes personal pain. Studies show that migraine negatively impacts family relationships and activities, including missing life milestones of loved ones (e.g., friends and family weddings, 'firsts' with children) and reduced time with partners and children. 45% of individuals report missing social and leisure activities.[13]

85% of people living with migraine feel helpless, depressed, or misunderstood and more than half of people with migraine live in fear of their next attack.[12]

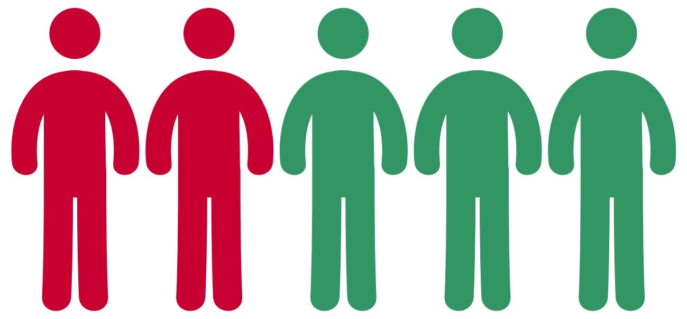
There is a strong link between migraine and both depression and suicidal ideation.[14]

2.3 Unmet needs in the treatment of migraine



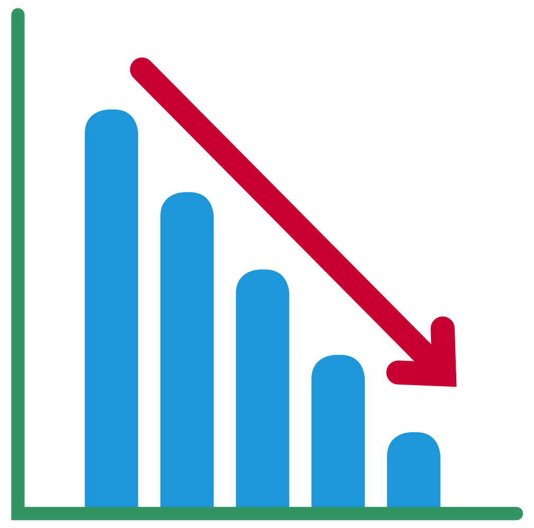
The scope and scale of the burden of headache is under-estimated, and headache disorders (including migraine) are universally under-recognised and under-treated.[15]

About half of individuals with migraine self-medicate with over-the-counter pain relief drugs.[4]



Nearly 2 in 5 people with migraine visit the emergency room an average of 3 times a year with almost 1 in 4 patients stay overnight.[16]

More than 80% of chronic migraine patients choose to discontinue treatments within one year.[17]



Preventive treatments may reduce the number of migraine days experienced each month. However, currently available preventive treatments have generally been developed for other indications, such as epilepsy, heart conditions, certain muscular conditions, anxiety and depression, and are generally associated with limited efficacy.[17]

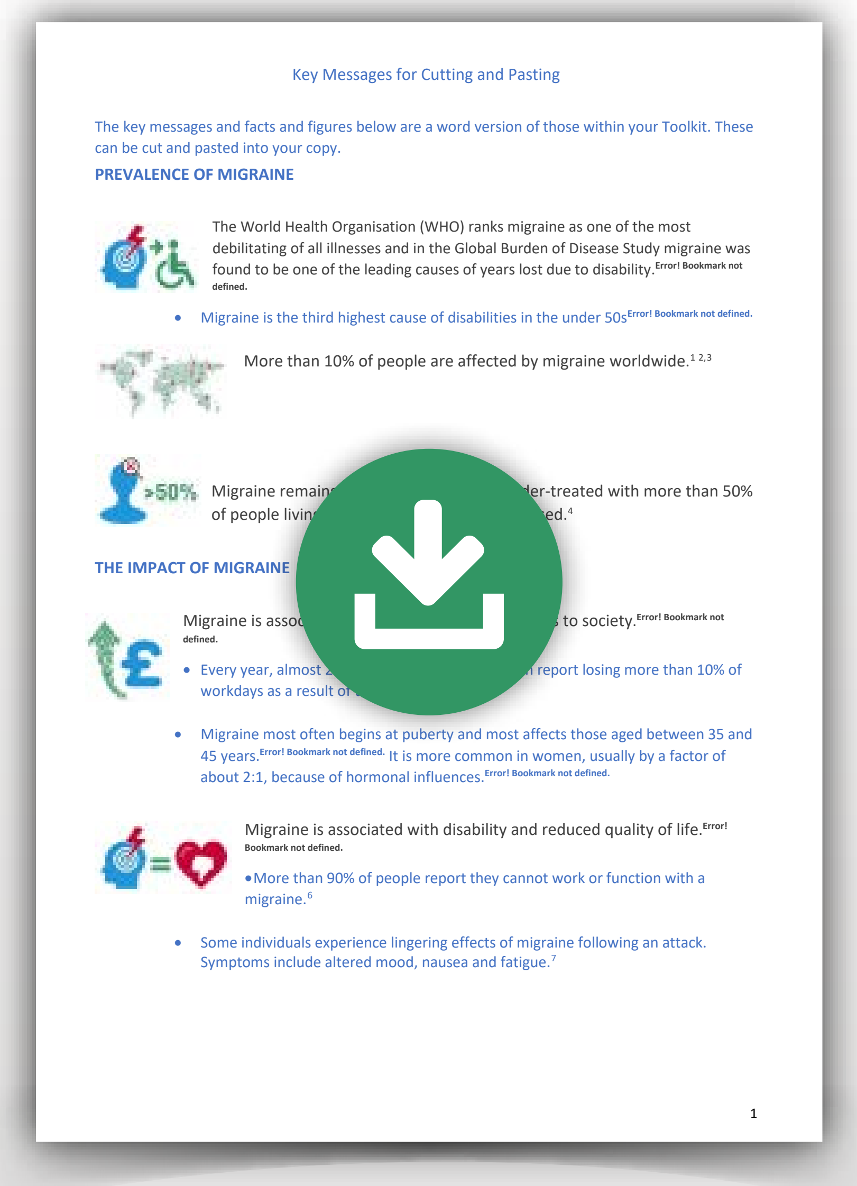
2.4 Positive aspects

Despite the difficulties of migraine, those living with migraine are resilient.

- 57% report positive aspects of their migraine.[12]
- 40% say they have learnt to cope with it.[12]
- 11% say it has made them stronger.[12]

Resources

The following are additional resources you may find useful.



Key Messages for Cutting and Pasting

The key messages and facts and figures below are a word version of those within your Toolkit. These can be cut and pasted into your copy.

PREVALENCE OF MIGRAINE

The World Health Organisation (WHO) ranks migraine as one of the most debilitating of all illnesses and in the Global Burden of Disease Study migraine was found to be one of the leading causes of years lost due to disability.Error! Bookmark not defined.

- Migraine is the third highest cause of disabilities in the under 50sError! Bookmark not defined.

More than 10% of people are affected by migraine worldwide.[1 2,3]

Migraine remain

der-treated with more than 50%

of people livin

ed.[4]

THE IMPACT OF MIGRAINE

Migraine is asso

to society.Error! Bookmark not defined.

- Every year, almost 2

report losing more than 10% of

workdays as a result of

- Migraine most often begins at puberty and most affects those aged between 35 and 45 years.Error! Bookmark not defined. It is more common in women, usually by a factor of about 2:1, because of hormonal influences.Error! Bookmark not defined.

Migraine is associated with disability and reduced quality of life.Error! Bookmark not defined.

- More than 90% of people report they cannot work or function with a migraine.[6]

- Some individuals experience lingering effects of migraine following an attack. Symptoms include altered mood, nausea and fatigue.[7]

1

Source and format

Your Toolkit

Two-page word document

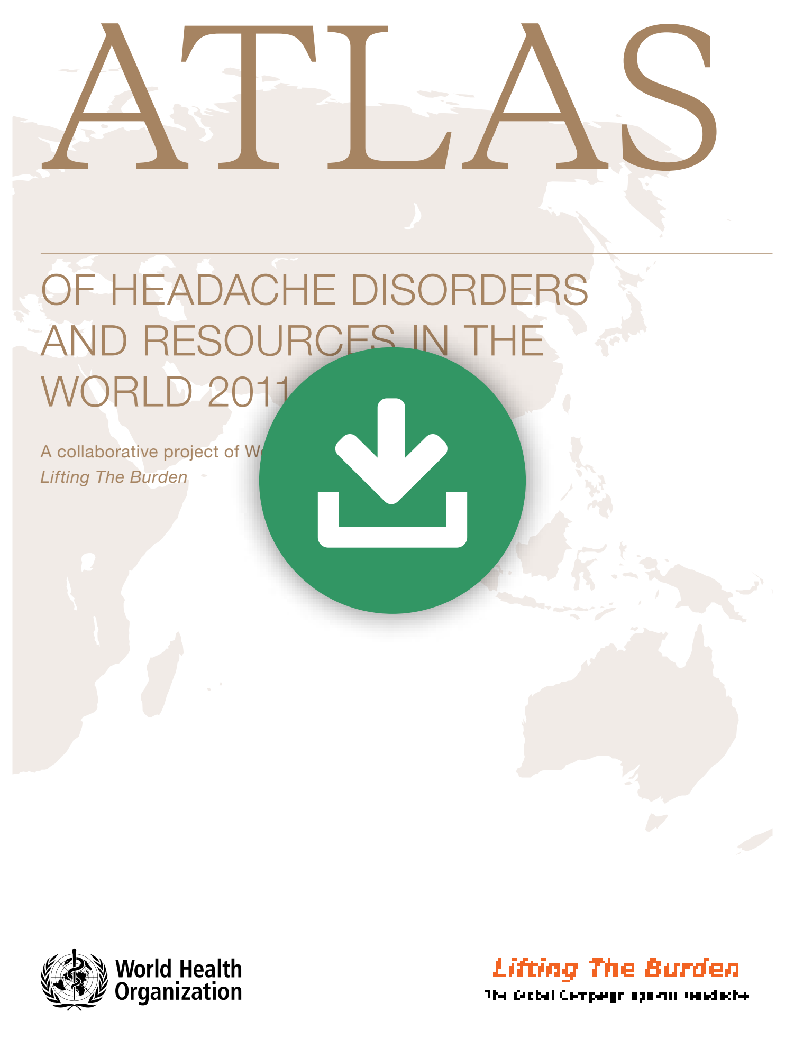
Resource title

Burden of migraine key messages and facts and figures.

Direction for use

This is a Word document of the messages above. Download and use the contents of this document by clipping the key messages and infographics into materials you may be generating.

This will also transfer the reference to the end of your document.



ATLAS

OF HEADACHE DISORDERS AND RESOURCES IN THE WORLD 2011

A collaborative project of W

Lifting The Burden

World Health Organization

Lifting The Burden

Source and format

WHO in partnership with Lifting The Burden

35-page PDF

Resource title

Atlas of Headache Disorders

Direction for use

Download and use this document to further your understanding of the burden of headache disorders and the resources available to reduce the burden.

Its content can also be used to highlight the worldwide neglect of this major cause of public ill-health and the inadequacies of responses to it in countries throughout the world.

Source and format

American Migraine Foundation

Two-minute video

Resource title

The Impact of Migraine

Direction for use

Incorporate the YouTube link into your outreach materials to provide a quick and highly impactful video on the burden of migraine.

The video includes comments from leading US-based physicians including David Dodick, Chairman of the International Headache Society.

Section two - THE VALUE OF MEDICINES

The aims of this section are to:

- Further your understanding of the value of medicines
- Signpost you to additional sources of information on the development of medicines if you are interested in knowing more

Key learnings

- Pharmaceutical innovations (including medicines and vaccines) accounted for 73% of the total increase in life expectancy between 2000 and 2009[18]
- Innovative medicines can put healthcare systems on a more sustainable path by reducing costs in other parts of the healthcare system, such as hospitalisations and clinicians' time
- Innovation can deliver significant societal value as development is strongly targeted at societal disease priorities, while innovative new therapies have enabled patients to continue contributing to society
- The biopharmaceutical industry generates essential economic value in terms of job creation, research and development investment, and medicines that improve patient productivity
- The pharmaceutical industry works closely with governments, HTA bodies and other similar organisations to agree an affordable price for medicines that reflects the value they bring to patients and the healthcare system
- Patients living with migraine and their carers have a critical role in supporting decision makers in their consideration of the value of a medicine

1.0 Introduction

Medicines have been around for thousands of years, and today medicines and vaccines are some of the most powerful tools we have in helping people live longer, healthier and more productive lives.

However, the benefits of medicines go far beyond the individual alone. Treating and preventing disease benefits families, communities, societies and both contribute to the economic success of countries and regions throughout the world.

With about 7,000 medicines in development,[19] a new wave of medical innovation will continue to play a key role in addressing the challenges faced by patients and healthcare systems. Yet it won't stop at 7,000. An aging population, advances in technology, and the many conditions for which there is still a high unmet medical need, mean that even more medicines will be developed.

Figure one. Summary of the benefits of medicines

PATIENTS

Patients live longer, healthier, more productive lives

ECONOMIES

The biopharmaceutical industry generates essential economic value in terms of job creation, R&D investment, and medications that improve patient productivity

HEALTHCARE SYSTEMS

Innovation medicines can put healthcare systems on a more sustainable path by reducing costs in other parts of the healthcare system such as hospitalisations

SOCIETY

Society benefits from health and wellness as individuals are able to continue being productive members of the community

2.0 The Positive Impact of Medicines

There is a wealth of information on the positive impact of medicines. This section provides insight as it relates to six areas:

1. Life-expectancy
2. A decade of drug advances
3. Reduction in deaths from non-communicable disease – cancer
4. Advances in the treatment of communicable disease – hepatitis C
5. The value of medicines to healthcare systems – cardiovascular disease
6. The value of medicines to society – cancer, with specific examples from France and the Netherlands

2.1 Life expectancy

Pharmaceutical innovations (including medicines and vaccines) accounted for 73% of the total increase in life expectancy between 2000 and 2009.[18]

2.2 A decade of drug advances[19]

Figure two presents a selection of the many advances in medicines for the period 2006 - 2016 across a range of conditions.

Figure two. Medicines advances 2006 – 2016 (US)

2006
- First vaccine for the prevention of cervical cancer
- First drug for chronic chest pain in 20 years
- First once-a-day HIV medicine

2007
- New class of medicines to treat high blood pressure
- First treatment for fibromyalgia

2008
- New type of treatment for Crohn's disease
- First drug for symptoms of Huntingdons disease

2009
- First treatment for peripheral T-cell lymphoma
- First new drug for gout in 40 years

2010
- 2 new multiple sclerosis drugs
- First therapeutic cancer vaccine

2011
- First lupus drug in 50 years
- 2 new personalised medicines

2012
- First drug to target root cause of cystic fibrosis
- First drug to treat Cushing's disease

2013
- 2 new personalised medicines to treat the most dangerous forms of skin cancer
- New oral treatment for multiple sclerosis

2014
- Oral treatments for hepatitis C provide cure rates of more than 90%
- 17 new drugs to treat patients with rare diseases

2015
- 2 new drugs for difficult-to-treat forms of high cholesterol
- New cystic fibrosis drug for patients with a genetic mutation that is the most common cause of the disease

2016
- First drug to treat spinal muscular atrophy
- New personalised therapy for chronic lymphocytic leukemia
- First drug to treat all 6 forms of hepatitis C

2.3 Non-communicable diseases

Example: Cancer

In the last 20 years, death rates from cancer have dropped by over 20%.[20]

2.4 Communicable diseases

Example: Hepatitis C

Tremendous research advances in recent years are transforming treatment of this debilitating disease. Today, more than 90% of patients with the most common form of the disease can expect to be cured in as little as eight weeks with newly approved antiviral therapies. This stands in stark contrast to cure rates of 41% over 48 weeks with severe side effects for the same patients just over a decade ago.[21]

Figure three demonstrates the rapid development of hepatitis C treatments.

Figure three. From discovery to cure in 25 years[21]

1989
Discovery of the hepatitis C virus.

1991
The FDA approves the first ever treatment for hepatitis C, an injectable drug called interferon which provides cure rates of about 6%.

1998
The FDA approves the first-ever interferon and ribavirin combination treatment improving care rates to 29% in patients with genotype 1.

2001
The FDA approves a "pegylated" form of interferon. Later that year, they approve that formulation of the drug for use in combination with ribavirin, improving cure rates to 41% in genotype 1 patients.

2007
U.S. deaths from hepatitis C surpass those from HIV.

2011
The first direct-acting antiviral agents (DAAs) are approved. These antiviral agents, called protease inhibitors, combined with 24-48 weeks of pegylated interferon and ribavirin improve cure rates among patients with genotype 1 to 70%.

2013
The FDA approves new DAAs in 2013, including the first polymerase inhibitor. Cure rates now range between 80-90% in just 12-24 weeks and for some patients (genotype 2-3), these results could be achieved without use of pegylated interferon and the accompanying side effects.

2014
Combination DAAs are introduced, which allow for the first entirely oral, interferon-free treatment regimen for genotype 1 and produce cure rates upwards of 94% in as little as 8 weeks.

TODAY
75 more drugs are in clinical development in the U.S., offering greater hope to eliminate the disease. Researchers predict that with the availability of new therapies hepatitis C will be a rare disease by 2036.

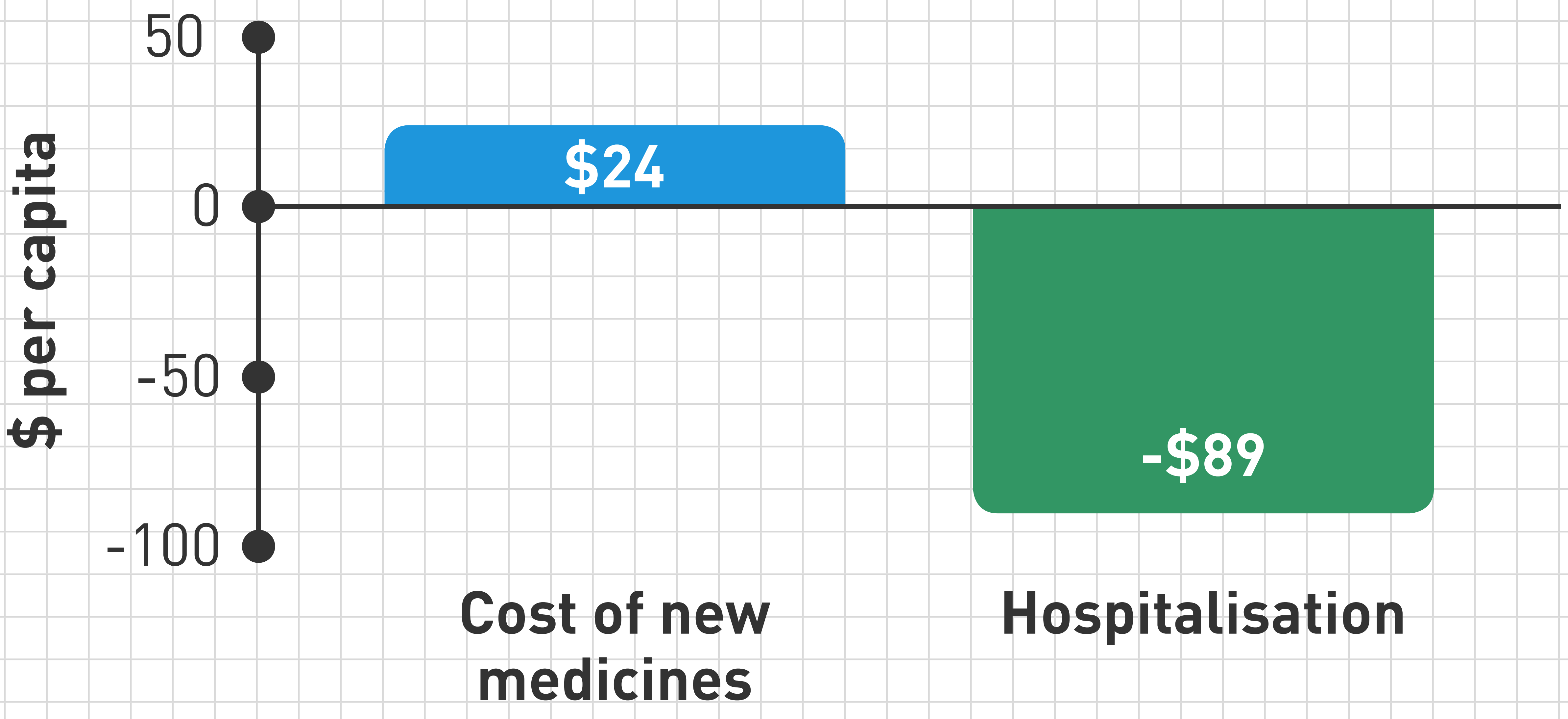
2.5 The value of medicines to healthcare systems

Innovative medicines can put healthcare systems on a more sustainable path by reducing costs in other parts of the healthcare system such as hospitalisations and clinicians' time.

Example: Cardiovascular disease

Per capita expenditure on cardiovascular hospitalisations in 20 OECD Countries* would have been $89 (70%) higher in 2004 had new cardiovascular medicines not been introduced in the period 1995–2004.[22]

Figure four. Hospitalisation savings due to new cardiovascular medicines from 1995-2004[22]



The FDA stands for the Food and Drug Administration, this is a federal agency of the United States Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the control and supervision of many issues including the regulation and approval of new drugs.

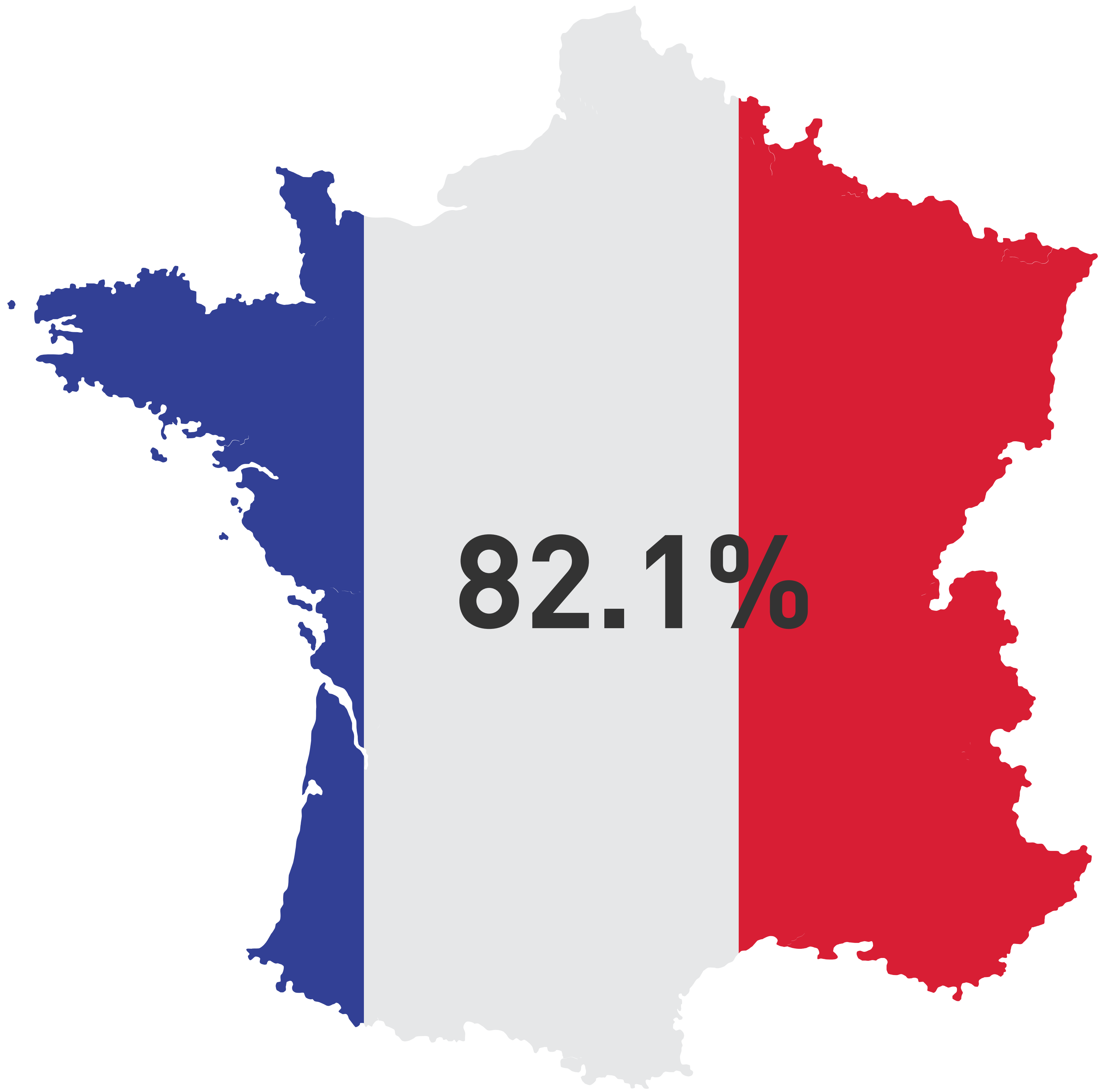
*OECD countries included: EU5, Australia, Austria, Belgium, Canada, Czech Republic, Finland, Hungary, Japan, Korea, New Zealand, Norway, Poland, Slovak Republic, Spain, Switzerland, Turkey, USA.

2.6 The value of medicines to society

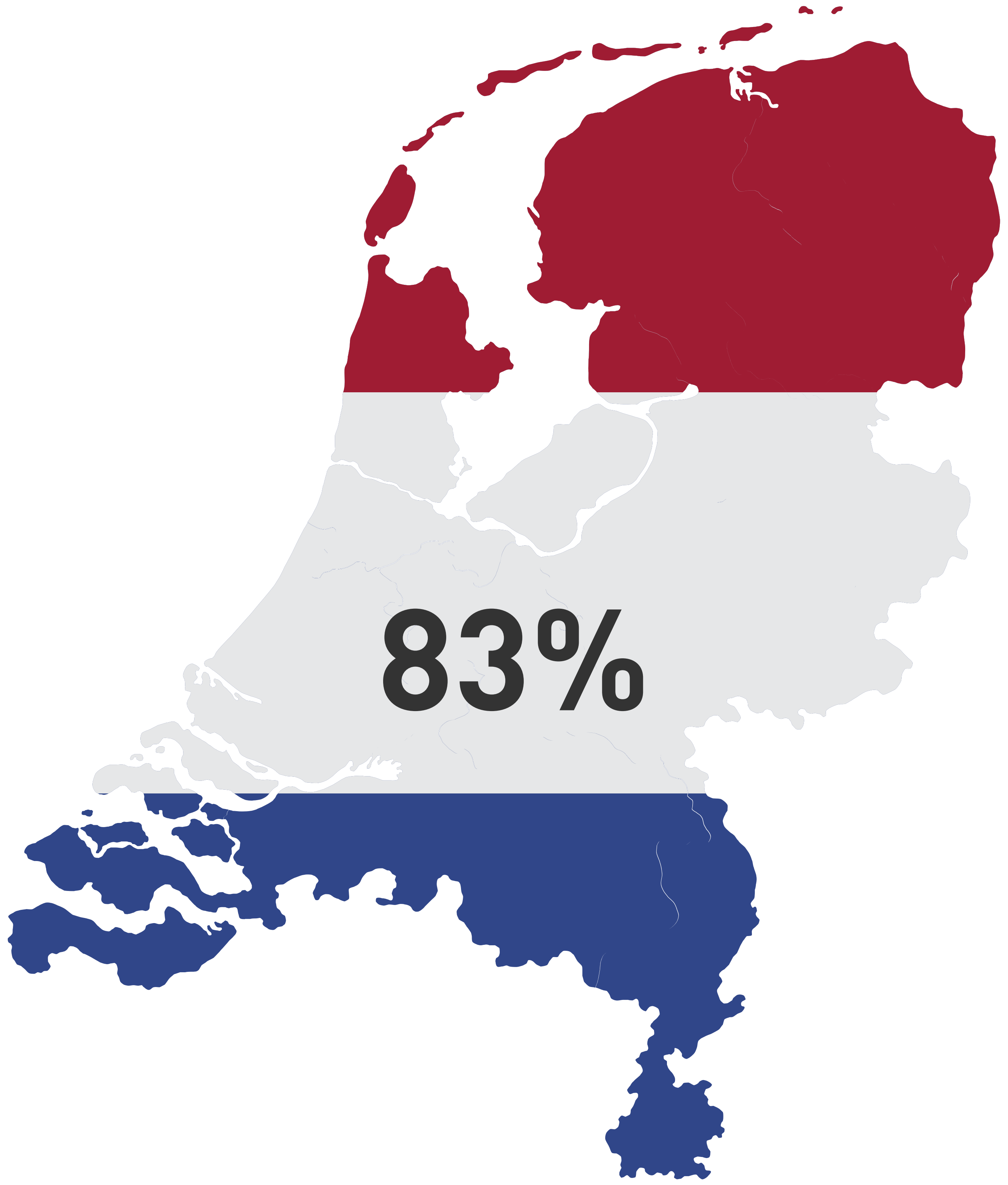
Innovation can deliver significant societal value as development is strongly targeted at societal disease priorities, while innovative new therapies have enabled patients to continue contributing to society.

Example: Cancer

The overall rate of returning to work following a cancer diagnosis has grown:



In France, 82.1% of working women diagnosed with breast cancer returned to full-time and part-time work after a median sick leave of 10.8 months.[23]



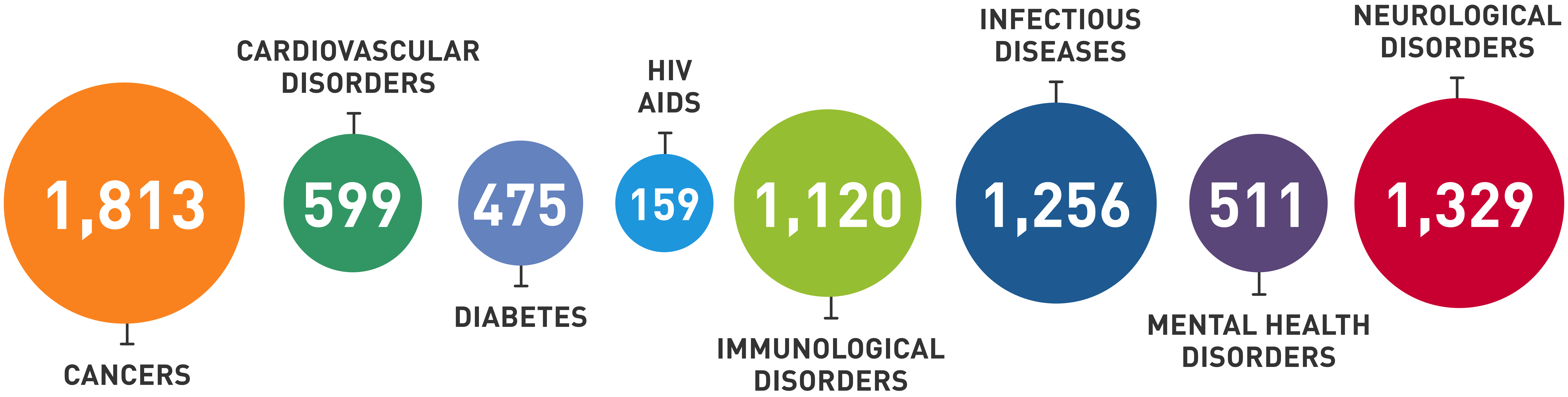
In the Netherlands, 83% of working individuals diagnosed with head and neck cancer returned to full-time and part-time work, most often within six months after treatment.[24]

3.0 Innovative Medicines in Development and Investment

Today, throughout the world there are approximately 7,000 medicines in development targeting areas of high unmet need. This includes 1,329 treatments undergoing investigation for neurological disorders.[25]

Figure five below provides a snapshot of the therapy areas in which new innovative medicines are in development.

Figure five. Medicines in development[25]



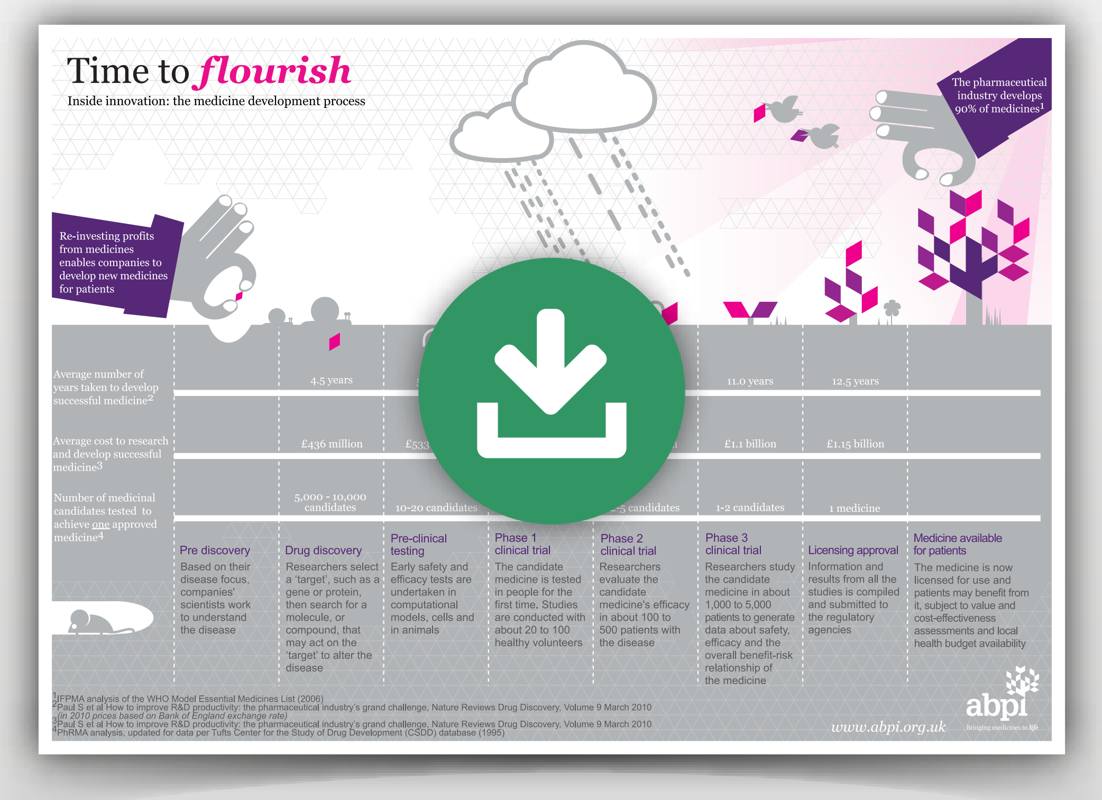
3.1 Investment in medicines development

Effective medicines are complex and take a long time to develop, and pharmaceutical companies invest significant resources into developing new medicines for areas of high unmet need. This means that there is a need for them to recoup their investment while making an appropriate profit to invest in researching new medicines. This is why pharmaceutical companies work in partnership with governments, HTA agencies and other similar bodies to ensure that patients have access to the new medicines they need, while the industry gets an appropriate return on their investment to continue meet the evolving health needs of patients.

3.2 Pricing of medicines

The pharmaceutical industry works closely with governments, HTA bodies and other similar organisations to agree an affordable price for medicines that reflects the value they bring to patients and the healthcare system. This is based on a range of factors and may include the burden of a disease, the potential to reduce other healthcare costs and a country's health and economic needs.

The assessment of new medicines is considered in more detail in module three, section one. ▶



Source and format

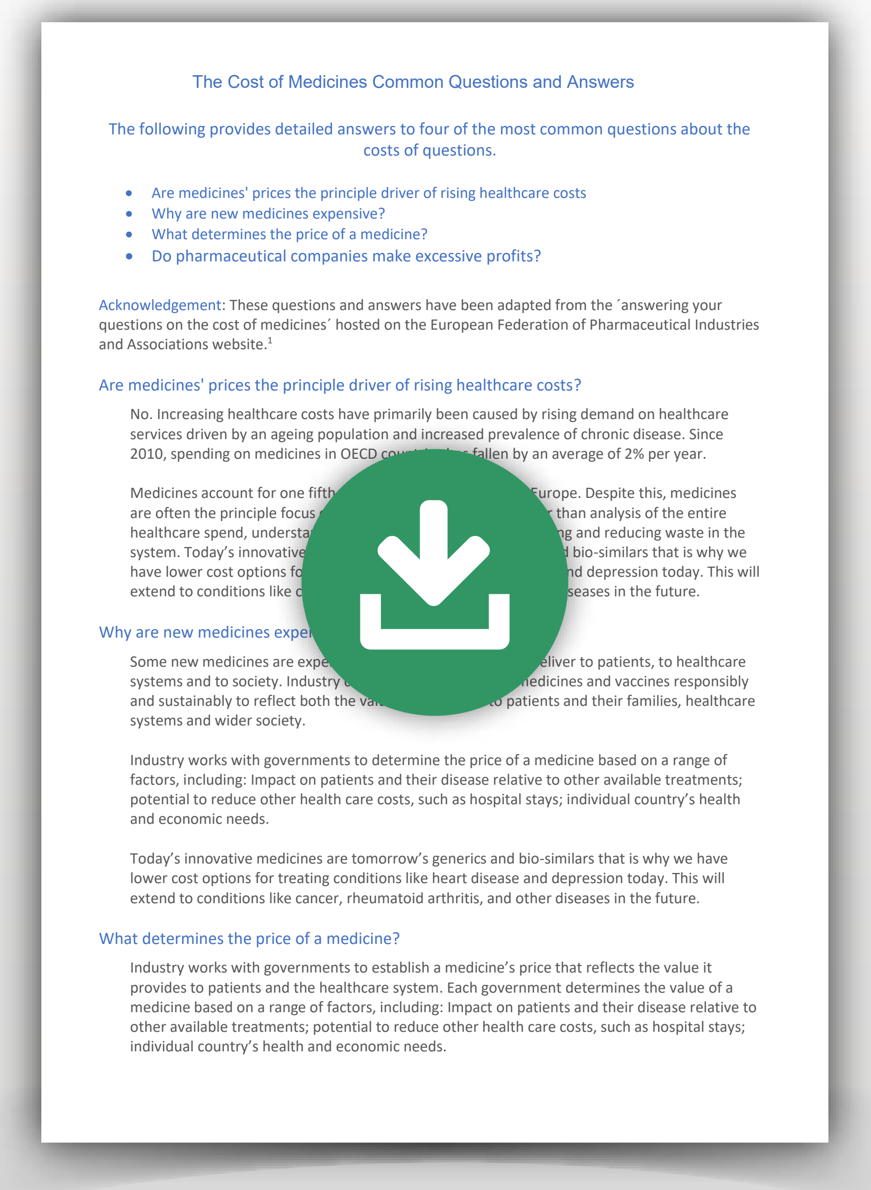
Association of British Pharmaceutical Industries (ABPI)
One-page PDF infographic

Resource title

Time to Flourish. Inside innovation: the medicine development process

Direction for use

Download and use this to help you understand the timelines for development of a medicine and the costs associated with this.



Source and format

European Federation of Pharmaceutical Industries and Associations (EFPIA)
Two-page pdf

Resource title

The Cost of Medicines Common Questions and Answers

Direction for use

Download and review this document if you have any further questions about the pricing of medicines.

3.3 The role of the patient

> Giving patients a voice in the development and evaluation of medicines is acknowledged as being of fundamental importance by the major stakeholders in the process.

European Medicines Evaluation Agency

Patients living with migraine and their carers have a critical role in supporting decision makers in their consideration of the value of a medicine. Just like researchers and doctors, patients are experience-based experts. People living with migraine know how it impacts on different aspects of their lives. They have experience of treatment. They know what needs are not being met in their care and they have preferences about their healthcare. No one else can explain the impact of a disease or a medicine better than a patient. Many of those who have an influence over decisions relating to whether a medicine adds value understand this and they are working to improve the way they involve patients in these decisions.

Module three, section one considers the role of the patient in supporting health technology assessment (HTA) agencies in their assessment of medicines in more detail. ▶

4.0 Medicines in Low and Middle-income Countries

The pharmaceutical industry works closely with public, private and non-governmental organisations to ensure that those living in low and middle-income countries have access to essential medicines and vaccines. This collaboration facilitates access to medicines and vaccines through approaches that reflect individual and population health need as well as the political and economic environment. The industry also works with its partners to strengthen health systems by addressing issues of infrastructure, capacity building and awareness raising.

5.0 Further Information

If you would like to know more about the value of medicines, visit the European Federation of Pharmaceutical Industries and Associations (efpia) website:

https://www.efpia.eu/about-medicines/use-of-medicines/value-of-medicines/

If you would like to know more about the research and development of medicines, here are a few sources of information you might find useful:

- **Pharmaceutical Journal.** 'Drug development: the journey of a medicine from lab to shelf'. This short article provides a summary insight into this complex area.

  http://www.pharmaceutical-journal.com/publications/tomorrows-pharmacist/drug-development-the-journey-of-a-medicine-from-lab-to-shelf/20068196.article

- **European Patient Academy on Therapeutic Innovation (EUPATI).** Provide a wide range of training materials on drug development.

  https://www.eupati.eu/non-clinical-studies/discovery-development-medicines/

- **European Federation of Pharmaceutical Industries and Associations (efpia).** Explores the process of medicine development.

  https://www.efpia.eu/about-medicines/development-of-medicines/

MODULE THREE

Patient involvement in the assessment of medicines and in improving migraine services

> If you're not involving patients, you're not doing health technology assessment!
>
> It's that simple. Patient involvement improves the quality, relevance, and value of HTA. It is difficult to conceive of health technology assessment being conducted in a meaningful way in the twenty-first century without the involvement of patients.[26]

Brian O'Rourke Canadian Agency for Drugs and Technologies in Health (CADTH), Ottawa, ON, Canada

Chair of the International Network of Agencies for Health Technology Assessment (INAHTA), Edmonton, AB, Canada

Section one - PATIENT INVOLVEMENT IN ACCESS TO APPROPRIATE MEDICINES

Patient involvement in access to appropriate medicines through health technology assessment (HTA) is a complex subject. In addition to using the contents of your Toolkit, it is recommended that you speak to other organisations who have experience of HTA, as well as your HTA agencies.

The aims of this section are to:

- Support your understanding of the HTA process, including the terminology used
- Enhance your skills in contributing to the HTA process
- Provide you with guidance to maximise the value of patient contributions to HTA

Acknowledgements: This section has been adapted from Understanding Health Technology Assessment, Health Equality Europe,[27] supported by relevant updates drawn from Patient Involvement in HTA, an academic publication published in July 2017 by Springer Nature.[26]

This section has been reviewed by Ann Single, co-Editor of Patient Involvement in HTA and member of HTAi's Patient and Citizen Involvement in HTA Interest Group (PCIG).

Key learnings

- Patients have a critical role in HTA; more needs to be done to support this involvement.
- What patients know about the impact of living with migraine, and its treatment, can inform assessments of medicines developed to treat migraine and its symptoms.
- The HTA process varies from country to country – and even within countries – if you wish to be involved, it is critical to ask the agency undertaking the HTA for advice about how you can contribute and when.
- A joint contribution to HTA from several patient organisations, who between them represent the views of a large number of patients, may be very powerful. By presenting a united voice, there may be a greater chance that this voice will be heard.
- Conflicts of interest may impact on the credibility of your organisation and the validity of your involvement in HTA. If you have any doubt about what constitutes a conflict of interest, contact the HTA agency undertaking the assessment to seek their advice. Many HTA agencies explicitly ask about potential conflicts – if in doubt declare!
- Where HTA processes are not well developed, or where they are absent, the sort of experience-based information that patients would otherwise contribute to HTA processes can be useful in raising public awareness about the impact of migraine and the need for effective management.

1.0 Introduction

The call to focus healthcare decisions on the needs of patients often seems overshadowed by the requirement to overcome financial pressures and ensure efficiency. The question is whether we can achieve value for money in a health service system, while taking account of the needs, experiences and preferences of patients.

The answer is yes. But, only through transparent, systematic processes to which all stakeholders can contribute and in which all evidence is judged fairly and rigorously. Health Technology Assessment is one such process.

Around the world HTA supports decisions about using medicines. It is a policy-making process based on scientific evidence that seeks to assess if a health technology produces useful outcomes for patients in real-world settings (clinical-effectiveness) that are good value for money (cost-effectiveness). It may also consider the social and ethical consequences of using the technology.

Given that HTA is a policy-making process, HTA agencies should also seek patient participation and consider experience-based information from patients.

Just like researchers and doctors, patients are experience-based experts. People living with migraine know how it impacts on different aspects of their lives. They have experience of treatment. They know how local healthcare services are provided. They know what needs are not being met in their care and they have preferences about their healthcare. No one else can explain the impact of a disease or a medicine better than a patient. Many HTA bodies recognise this and are working to improve the way they involve patients.

The HTA process varies from country to country – and even within countries – if you wish to be involved, it is critical to ask the agency undertaking the HTA for advice about how you can contribute and when.

Where HTA processes are absent, or not well developed, the sort of experience-based information that patients would otherwise contribute to HTA processes can be useful in raising public awareness about the impact of migraine and the need for better management. It can help make the case for better treatment in a variety of settings such as media campaigns and lobbying, or in individual consultations with doctors.

Stakeholder groups, and approaches to stakeholder engagement, including public relations, stakeholder meetings and public affairs, are considered in module four. ▶

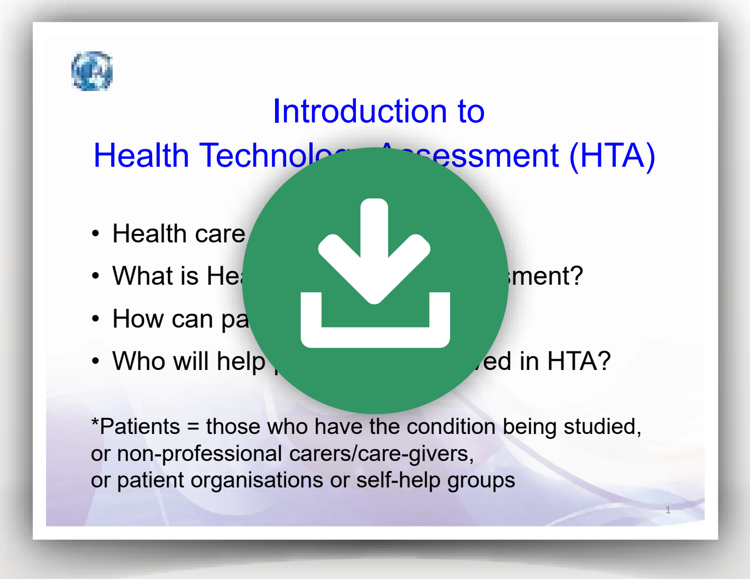
Definition of patients

Resources

The resources listed below provide additional information on patient involvement in HTA.

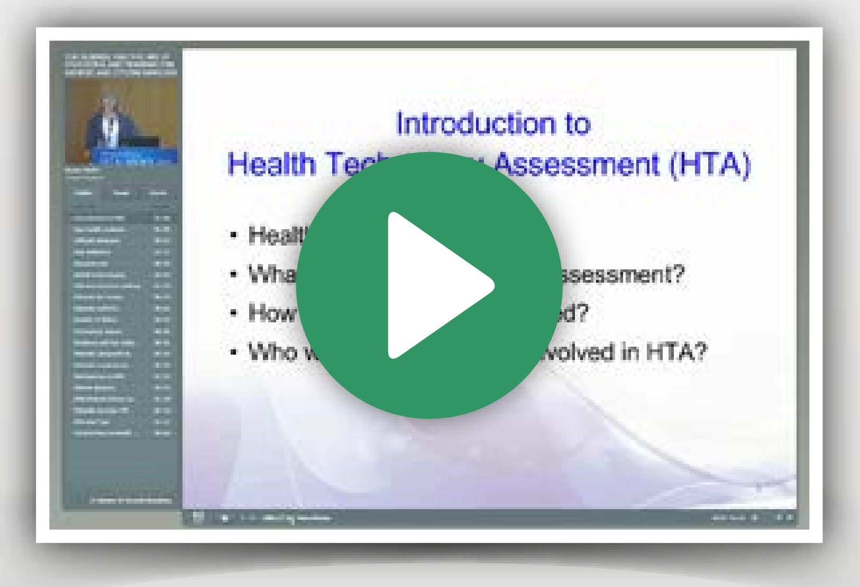
In addition, there are resources that address the role of patient involvement in the development and regulatory evaluation of medicines. These can be used if you want to learn more about patient involvement in other aspects of medicines development.

Health technology assessment


Introduction to
Health Technolo Assessment (HTA)

- Health care
- What is He ment?
- How can pa
- Who will help ed in HTA?

*Patients = those who have the condition being studied,
or non-professional carers/care-givers,
or patient organisations or self-help groups


Introduction to
Health Tec Assessment (HTA)

- Healt
- Wha ssessment?
- How d?
- Who w olved in HTA?

Source and format

Karen Facey, HTAi Patient and Citizen Involvement in HTAi Interest Group
19-page presentation on PDF format
22-minute webinar

Resource title

An introduction to HTA

Direction for use

Download the presentation, or view the webinar for an overview of HTA. This will help reinforce the key learnings from your Toolkit and provide additional insight into the topic.

EUPATI Netwo
September 2

Strengthening patient involvement in Health Technology Assessment (HTA)

Source and format

European Patient Academy on Therapeutic Innovation (EUPATI)
80-minute webinar

Resource title

Strengthening Patient Involvement in Health Technology Assessment

Direction for use

View the webinar for an introduction to patient involvement in a video format. This will help reinforce the learnings from your Toolkit and provide additional insight into the topic.

Good practices in volvement in HTA
Are the used?

Karen Facey
k.facey@btinternet.com @KMFacey
Coordinator – HTAi Patient Involvement Methods and Impact Working Group
http://www.htai.org/interest-groups/patient-and-citizen-involvement.html

Source and format

European Patient Academy on Therapeutic Innovation (EUPATI)
14-page PDF slide presentation

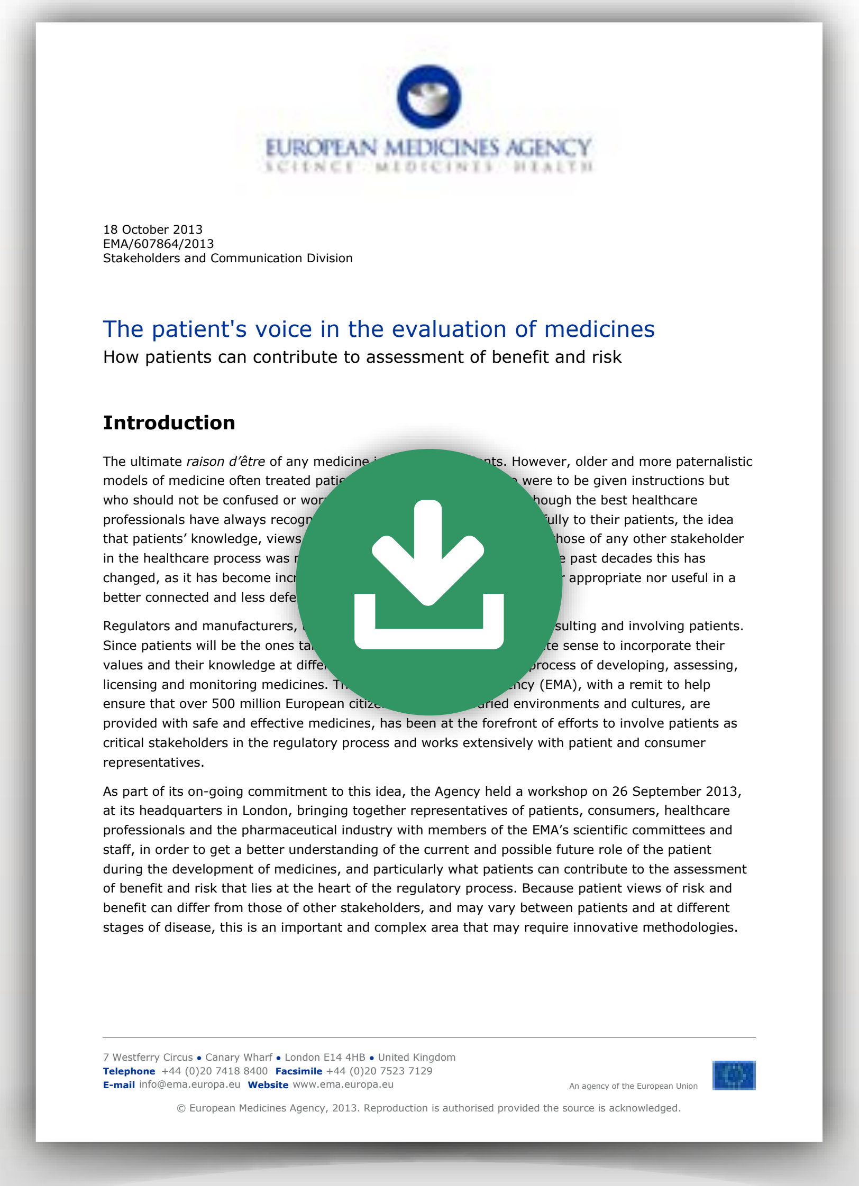
Resource title

Good practices in patient involvement in HTA

Direction for use

Download and view this presentation to learn more about good practices regarding patient involvement and to reinforce the learnings from your Toolkit.

Development of medicines



18 October 2013
EMA/607864/2013
Stakeholders and Communication Division

The patient's voice in the evaluation of medicines
How patients can contribute to assessment of benefit and risk

Source and format

European Medicines Agency, Stakeholders and Communication Division
7-page PDF

Resource title

The patient voice in the evaluation of medicines

Direction for use

Review this document to further your understanding of the role of patients in all aspects of medicines evaluation.

Kay Warner on behalf of the EUPATI team

Source and format

European Patient Academy on Therapeutic Innovation (EUPATI)
20-slide presentation
Webinar (90mins)

Resource title

EUPATI guidance document for patient involvement in industry-led R&D

Direction for use

Review this document to further your understanding of the role of patients in industry-led research and development.

2.0 Health Technology Assessment and its Use

Health technology assessment is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner. Its aim is to inform the development of safe, effective health policies that are patient-focused and seek to achieve best value as defined by decision makers. HTA underpins decisions such as:

- Should treatment A be reimbursed in a national healthcare system?
- For which patients should it be provided?
- For how long should patients receive the treatment?

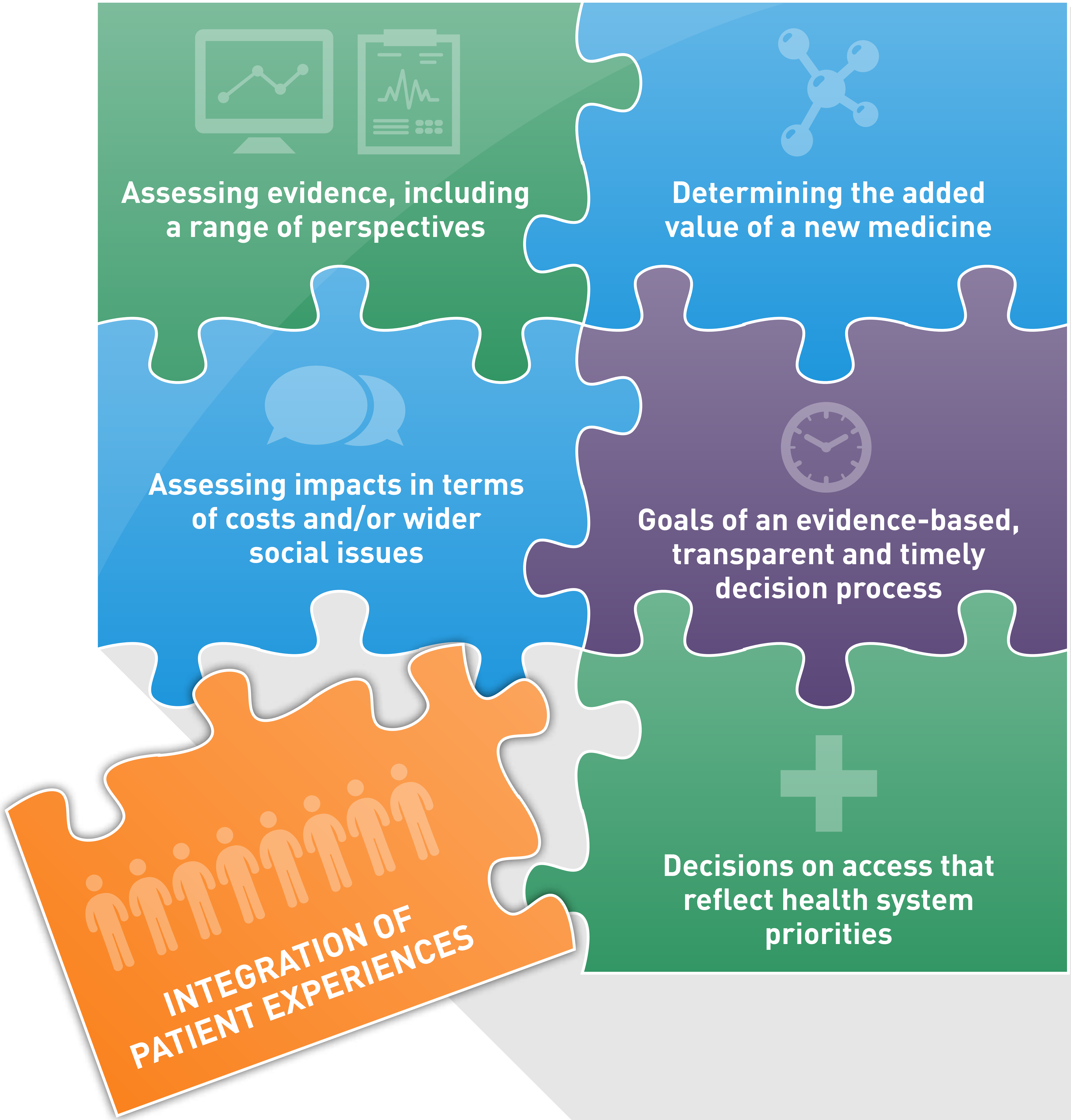
Health technology assessment may assess evidence from a range of sources, for example:

- Systematic reviews of clinical trials
- Economic analyses comparing the costs and benefits of different treatments for the same condition
- Economic models which estimate the cost and effects of a medicine over periods of time, or for patient groups beyond those covered in clinical trials
- Published research, including papers about patients' needs, preferences and experience

Health technology assessment processes may vary between HTA agencies and so may the evidence they consider and the questions they ask about the medicine.

Figure one provides an overview of the functions of HTA and how patient experiences can integrate into this.

Figure one: Functions of HTA



Assessing evidence, including a range of perspectives

Determining the added value of a new medicine

Assessing impacts in terms of costs and/or wider social issues

Goals of an evidence-based, transparent and timely decision process

INTEGRATION OF PATIENT EXPERIENCES

Decisions on access that reflect health system priorities

2.1 Why is HTA needed?

People facing the challenge of illness need to receive effective treatment and care to give them the best possible chance of health. At the same time, there is a public health need to prevent disease wherever possible. However, available resources need to be allocated appropriately based on their value for money. Health technology assessment provides information to inform these decisions.

2.2 How is HTA used?

Health technology assessment is used differently across countries. In some countries, it is used to guide decisions about if and how medicines and other technologies should be used in a health service, based on an assessment of whether they provide value for money. In other countries, it guides decisions about reimbursing the costs of medicines.

2.3 How is HTA carried out?

The assessment process varies from organisation to organisation and, therefore, before patients get involved, they need a clear understanding of the process and how the HTA will be used. This will ensure that time and resource is directed at those activities that add the greatest value.

The role of health economics in HTA

Health economics, in which the principles of economics are applied to health and healthcare, is used to provide evidence to support value for money considerations. Health economics data may cover both direct costs (such as the number of drugs used by a patient or the number of hospital visits in a given period) and indirect costs (such as the cost of time lost from work). The cost data combined with clinical-effectiveness data leads to cost-effectiveness estimates. Some HTA bodies also consider budget impact.

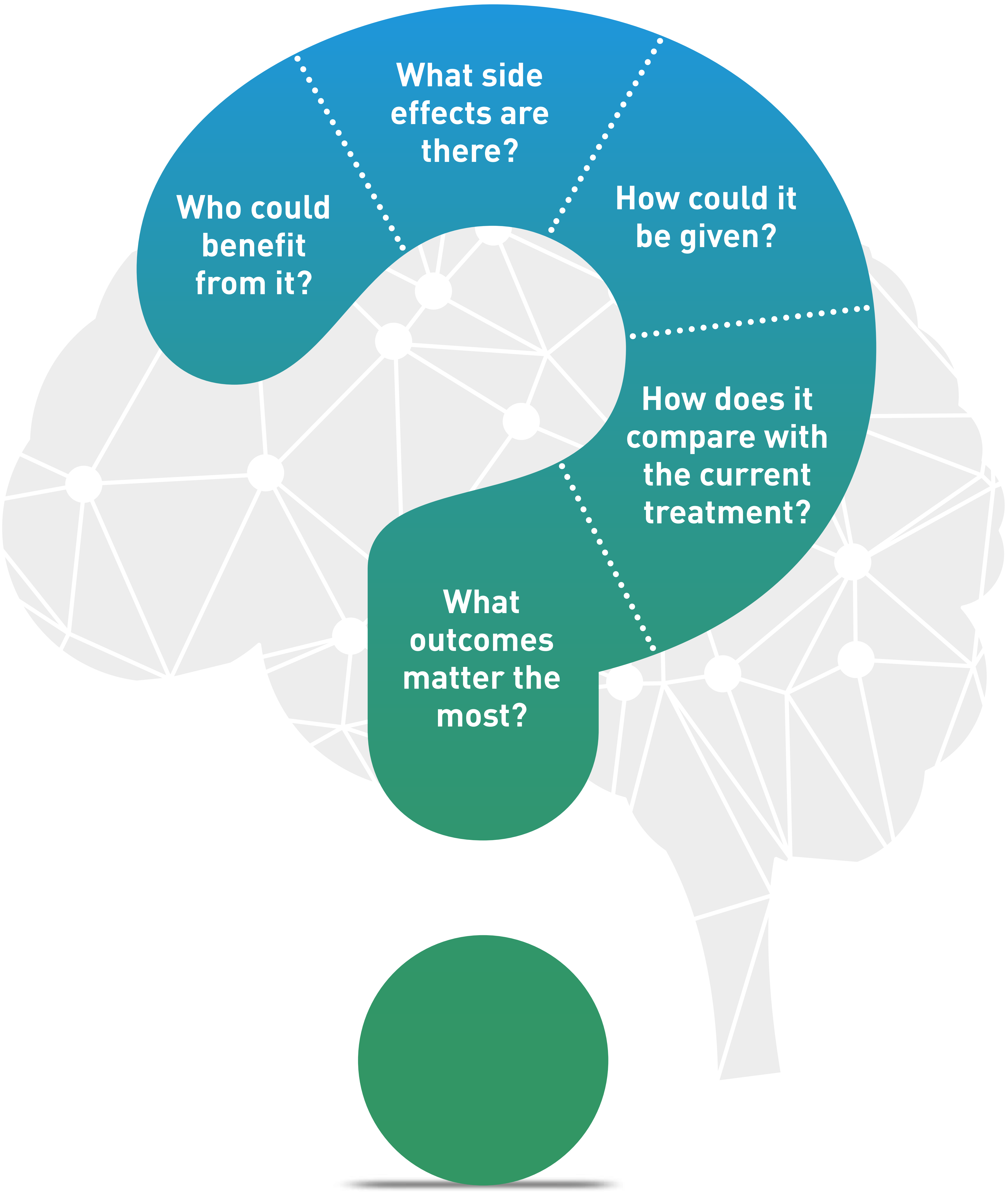
3.0 Patient Involvement in the Assessment of Medicines

This section of your Toolkit considers the following important areas as they relate to involvement in HTA. Working through these will help you appreciate the why, what, when and how of involvement.

1. Why patient involvement is important
2. Types of patient involvement – participation vs. research into patient aspects
3. When to become involved
4. How to become involved – finding out what HTAs are taking place
5. Deciding whether to contribute to a HTA
6. What if you are *not* asked to contribute information?
7. Preparing for participation – generating your evidence, validity of your involvement, ethical considerations and conflicts of interest
8. Providing written input
9. Participation in HTA in person
10. What will happen to your contribution
11. Working in partnership

3.1 Why patient involvement is important

Health Technology Assessment is a process in which questions are asked about a medicine. These include:



These questions form the scope of an HTA and shape what is known about the medicine, and in turn the HTA agency's conclusions or recommendations.

Often, it is an expert panel or committee that asks these questions and who interprets the evidence in the context of how healthcare is provided locally, while highlighting gaps and uncertainties in the evidence-base.

Traditionally, these have been made up of researchers and health professionals who specialise in the area. However, increasingly HTA bodies are involving patients and their representatives on these panels or committees, or they seek patient input into their deliberations.

The reasons for this are clear. Patients and their carers are often the group most directly affected by HTA decisions. They are experience-based experts. It is important, therefore, that patient needs, perspectives and individual experiences are considered in the HTA process.

A person living with migraine and their carers can inform HTA bodies what outcomes matter the most to them, what problems they experience in daily life, how healthcare services vary in their country or region. They can also provide a range of information on areas of uncertainty, or information which may not be available in the published literature.

For example, in migraine:

- The data from clinical trials may record the number of migraine days experienced in a set period of time, but someone with migraine may offer the insight that this means days off work and a partner taking time off work to support childcare.
- The scientific literature may record that people with migraine may suffer from anxiety, but someone living with migraine may explain that the anxiety caused by not being able to manage their migraine is so severe that it means they have no social life and avoid exercise.

What patients know about the impact of living with migraine and its treatment means that evidence from patients can inform the assessment of medicines being developed to treat migraine and its symptoms.

Values for patient involvement in HTA[28]

The characteristics of good quality patient involvement in HTA have been defined by Health Technology Assessment international's (HTAi) Patient and Citizen Involvement in HTA Interest Group (PCIG), through their five values for involvement:

Relevance: Patients have knowledge, perspectives and experiences that are unique and contribute to essential evidence for HTA.

Fairness: Patients have the same rights to contribute to the HTA process as other stakeholders; have access to processes that enable effective engagement.

Equity: Patient involvement contributes to equity by seeking to understand the diverse needs of patients with a particular health issue, balanced against the requirements of a health system that seeks to distribute resources fairly among users.

Legitimacy: Patient involvement facilitates those affected by HTA recommendations/decisions to participate in the HTA, contributing to the transparency, accountability and credibility of the decision-making process.

Capacity building: Patient involvement addresses barriers to involving patients in HTA and builds capacity for patients and HTA bodies to work together.

3.2 Types of patient involvement in HTA

Figure two below summarises the two approaches to patient involvement in HTA.

Figure Two. Patient involvement in HTA

Patient involvement encompasses two distinct but complementary approaches, both of which can add value to decision making:

Patient participation	Research into patient aspects
Patients interacting in the HTA process e.g. presenting to a committee, inputting into the process by submitting a written response to a public consultation	Patient-based evidence from qualitative and quantitative research into patients' needs, preferences and experiences such as peer-reviewed research into the unmet needs in migraine management

In terms of patient involvement, patient participation through input into HTA tends to be the primary area of focus. However, supporting this input with patient-based evidence is an important consideration in maximising the value of your involvement. It is also important to help to put the patient based-evidence into context through linking this to patient needs, perspectives and individual experiences.

3.2.1 Patient input

Patient input describes information provided by patients, their carers or those who advocate for them, such as patient organisations. It may be written, such as a submission, or verbal, such as taking part in an expert committee or hearing. It should never be a one-off, one-way interaction.

As a form of participation, it needs to be a two-way dialogue. This enables real-world perspectives and experiences to be shared. Dialogue helps fill gaps in the literature and address uncertainties, while helping you and the HTA body understand each other better and work together to address issues as they arise in an HTA.

Given that HTAs are often performed before a medicine is widely available, you may struggle to identify patients with real-world experience of a medicine being assessed. This should not deter you from taking part in an HTA, as you can add great value in terms of experience of living with migraine and its current management, and identifying outcomes that matter most to you.

Figure three below gives examples of the type of information that is likely to be of value in an HTA.

Figure three. Patient input that can be of value to HTA

Burden of illness	Experience of current treatment	Impact on caregivers	Medicine being assessed
• Migraine symptoms that are difficult to live with • Limitations migraine imposes on daily life, social life and ability to work • Impact of migraine on mental wellbeing • Approaches to managing migraine pain	• The benefits of the medicines on daily life, social life and ability to work • Side effects that are troublesome • Whether it works well and any problems taking the treatment • Any challenges patients have faced with the delivery of care that supports effective treatment	• Costs associated with supporting a person living with migraine • Limitations migraine imposes on relationship, daily life and social life • Paying for childcare because the patient cannot look after the child/children • Taking time off work to deal with things a person having a migraine attack cannot do	• Expectation from the medicine • How important the medicine's benefits are and how they compare to other treatments • How potentially unwanted effects compare to current treatment • The benefits of the medicines on daily life, social life and ability to work

Before considering your input into HTA, always check with the relevant agency what you should provide and in what format. Individual agencies may have their own guidance for you to follow.

3.2.2 Patient-based evidence

While equally valuable, patient input should not be confused with, or be seen as a substitute for, patient-based evidence, although it is complementary to it.

Patient-based evidence is generated through robust research. It helps HTA agencies understand patient experiences, perspectives, needs, preferences or attitudes about their health and care.

Some of the defining characteristics of patient-based evidence described by Sophie Staniszewska, RCH Research Institute, Warwick University and Sophie Werkö, Agency for Health Technology Assessment and Assessment of Social Services (SBU), Sweden, are:

- It is produced through research, generally peer-reviewed, that draws on robust scientific methods to provide a conclusion that can be interpreted
- It directly addresses questions of bias and balance, which provides some assurance of quality
- It can be based on a synthesis of studies

Generating patient-based evidence requires experienced researchers and may involve a range of quantitative (numerical information) and qualitative (descriptive information) methods. These include patient-reported outcomes, ethnographic fieldwork and synthesis of qualitative research. Each method has its own merits.

Most patient organisations will need to collaborate with universities and/or other patient organisations to generate patient-based evidence as they may not have the skills and resources in-house.

Careful planning is also essential so that the research addresses issues that can be used for multiple HTAs. Before beginning, it is important to know what evidence the local HTA agency will accept, the schedule for relevant HTAs and what critical gaps in the evidence you seek to address.

Before considering whether to develop patient-based evidence, always check with the relevant agency what the patient-based evidence needs are. Individual agencies may have their own guidance for you to follow.

3.3 When to become involved

Patients may have an opportunity to be involved at all stages of the HTA process, but this will vary between, and within countries. For example, there may be opportunities to suggest topics for assessment that have a particular impact on people living with migraine, such as an intervention that reduces the number of migraine attacks. Check with your local HTA agency.

3.4 How to become involved

One of the most important aspects of patient involvement is planning. Understanding when HTAs are taking place, how you can take part, what information is needed and how long this will take to generate is important in deciding if you have the capacity and time to support meaningful patient involvement.

Section seven provides useful insight into a number of country specific HTA approaches to patient involvement.

3.4.1 Finding out what HTAs are taking place

If there is a national or regional HTA agency/unit you should look at their website to see whether they provide their work plan. There may also be more than one agency performing HTAs, each of which may specialise in a particular aspect of HTA, so you may need to check several websites. Information may also be available on government health websites.

If this information is not available on the internet, write to or call the agency and ask for it. Some HTA agencies sign-up patient organisations as partners and provide training and alerts.

Useful website links

HTAi global list of HTA bodies and their networks, including a brief overview of the organisation.

http://vortal.htai.org/?q=about/producers_and_networks

3.4 Deciding whether to contribute to a HTA

You should consider contributing information to an assessment about migraine or its treatment if the HTA will impact on you or someone close to you, or the people who use the services of your organisation and you have the resources to do it. It is important that the panel carrying out the assessment understand what living with migraine is like, and know patients' unmet needs and what outcomes matter to them most.

3.5 What if you are not asked to contribute information?

If you are not asked to contribute information to an HTA, you should contact the agency carrying out the assessment and offer your help. People who are affected by the assessment have an important perspective to provide. You should explain the experience you have (with the clinical situation and/or the medicine) and the relevance of what you are able to contribute.

3.6 Preparing for your patient participation

The key to effective patient involvement in HTA is to ensure that the important messages you want to get across are clear to you and to the agency. These should be backed-up by the evidence you have collected on patient needs, preferences and experience.

3.6.1 Generating your evidence

The precise content supporting your involvement will depend on the assessment agency requirement. For this reason, it is a good idea to ask the agency for advice.

Migraine and associated patient organisations may be able to collect information on the needs, preferences and experience of migraine patients from a range of sources. These may include:

- Data from enquiries to a helpline that uncover relevant information
- Information from other groups in your network that may be useful
- A survey of patients' experiences. For example, by using an on-line survey tool
- Focus groups or one-on-one discussions with patients
- Support groups you can talk to about the problems patients and carers face
- Issues that have been discussed on websites or at official meetings

Don't produce a long contribution if it isn't needed as the amount of information an assessment panel may have to digest is likely to be large. If there are a lot of data supporting your input or presentation to a committee, such as the results of a survey, include these as an appendix so it doesn't dilute the messages you want to emphasise. Instead, summarise the key messages and explain their breadth, strength and source.

Learn from the experience of others. Ask groups which have participated how they have put their patient evidence together – ask them what worked and what didn't.

Personal quotes or experiences

3.6.2 Demonstrating the validity of your involvement

In order to appreciate the value and validity of your involvement, the panel undertaking the HTA need to understand the basis on which it is provided. It should include:

- A description of your organisation and your users' experience
  - An indication of the people your organisation reaches
  - The type of services you provide to your users
- How the information you use was collated and whether it was newly collected or already existed.

A particular challenge for patient organisations is that the people who use their services and whose views they represent may not reflect the interests of all patients. This does not make their views less important, but you should acknowledge that the views expressed may not be those of all patients.

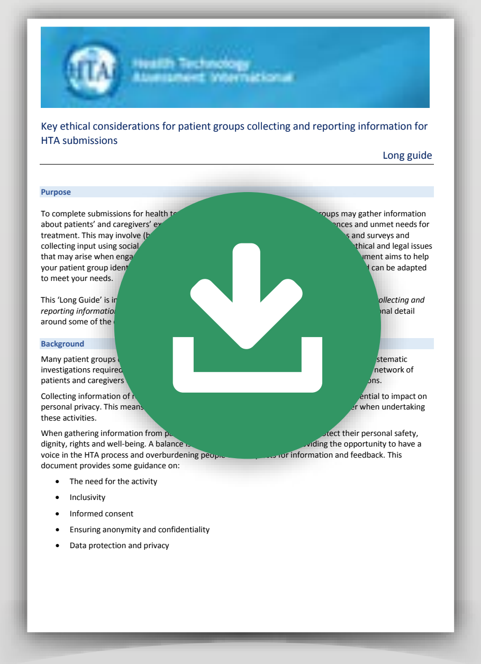
Your involvement must not lose sight of the medicine that is being appraised. A patient's life story is relevant only as a way of explaining the experience of living with an illness. The emphasis should be on information that is only available from the patients and carers.

3.6.3 Ethical considerations

To complete submissions for HTAs, you will be gathering information about patients' and caregivers' experiences of living with migraine, their preferences and unmet needs for treatment. For example, using a survey.

As a result, you need to think about any ethical and legal issues that may arise when engaging with people and using their personal information. Health Technology Assessments (HTAi) Patient and Citizen Involvement in HTA Interest Group (PCIG) provides very useful information on this subject that can be adapted for your own use.

Resource



Source and format

HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG)
Two-page short-form PDF
Seven-page long-form PDF

Resource title

Key ethical considerations for patient groups collecting and reporting information or HTA submissions

Direction for use

Download, review and adapt this information to ensure that your activities in seeking and presenting patient input and evidence follow best-practice.

3.6.4 Conflicts of interest

Conflicts of interest are always an important consideration for patient organisations, and you most likely have conflict of interest policies in place for dealing with commercial organisations, such as the pharmaceutical industry.

Following these policies when getting involved in HTA is particularly important as patient organisation conflicts of interest are a real concern among HTA bodies. As a result, they have adopted approaches that ensure that organisations disclose any interests they may have.

For example, the Scottish Medicines Consortium (SMC) request disclosure of the % funding from industry and whether any of this is associated with the appraisal being undertaken. The Committee then takes a view on any conflict of interest.

Beyond organisational funding, conflicts of interest also include other activities such as direct input from a pharmaceutical company in support of your involvement in HTA.

This doesn't mean that organisations should not be supported by the pharmaceutical industry. It means that any support from the pharmaceutical industry should be totally transparent.

Conflicts of interest, whether perceived or actual, may impact on the credibility of your organisation and the validity of your involvement in HTA. If you have any doubt about what constitutes a conflict of interest, contact the HTA agency undertaking the assessment to seek their advice.

3.7 Providing written input

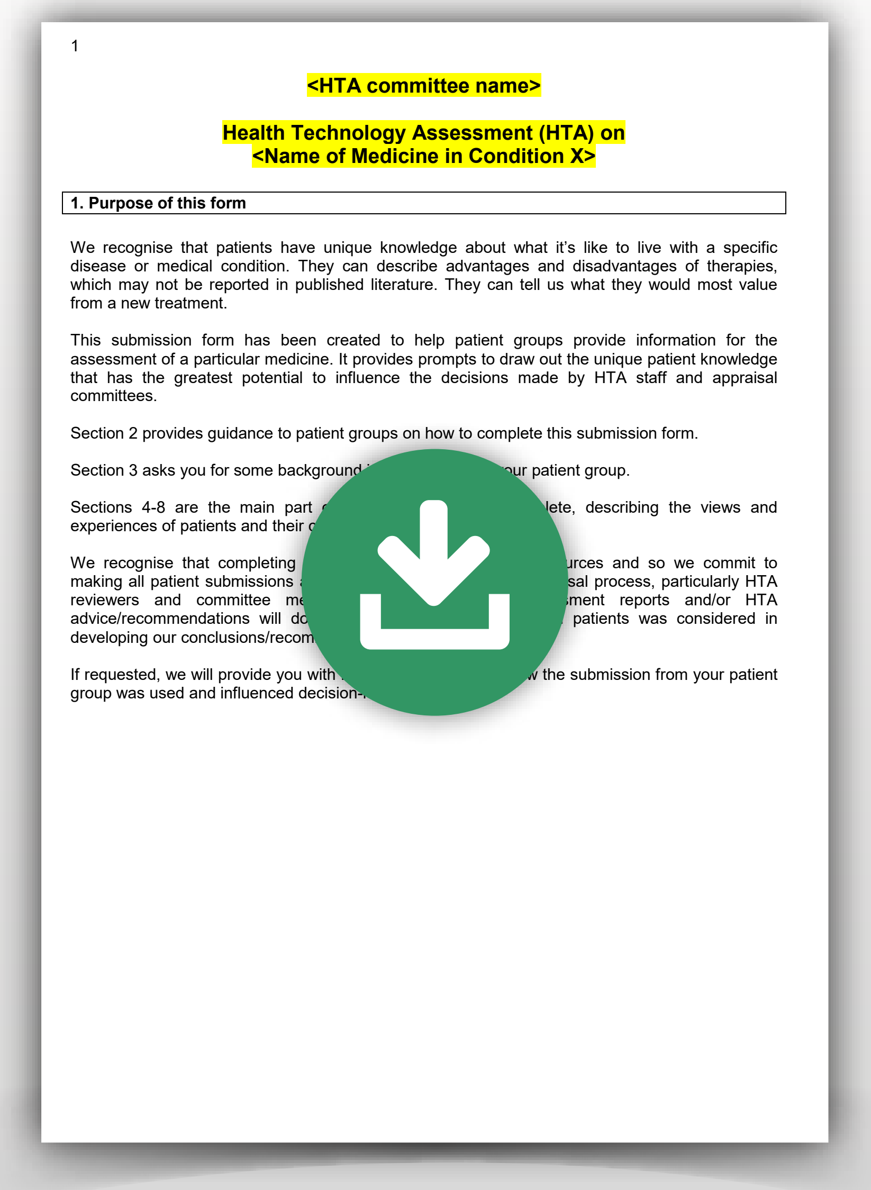
Written input can take a range of formats. For example, it could involve completing a submission to share the patient perspective, responding to a consultation or answering specific questions requested by an HTA agency. Contact your local agency to find out what approaches they use.

Written input can also address a range of topics. For example, it could focus on experience of the illness or more on the impact of the technology. Contact your local HTA agency to find out what information they need that will add value to their decision-making.

Written input could also include commentary on existing data. Explaining how it is relevant to people affected by migraine may help to illustrate the patient perspective. The data could include clinical trial reports which can be accessed through science libraries or from patient groups' medical or scientific advisors.

When providing written input, use the HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG) ***Patient HTA Submission Template*** and use the ***Completing a patient organisation submission template: Guidance for patient organisations for Health Technology Assessment and appraisal of medicines.*** These have been developed in conjunction with HTA agencies and they are widely used and adopted. These resources can be downloaded below.

Resource



1

<HTA committee name>

Health Technology Assessment (HTA) on
<Name of Medicine in Condition X>

1. Purpose of this form

We recognise that patients have unique knowledge about what it's like to live with a specific disease or medical condition. They can describe advantages and disadvantages of therapies, which may not be reported in published literature. They can tell us what they would most value from a new treatment.

This submission form has been created to help patient groups provide information for the assessment of a particular medicine. It provides prompts to draw out the unique patient knowledge that has the greatest potential to influence the decisions made by HTA staff and appraisal committees.

Section 2 provides guidance to patient groups on how to complete this submission form.

Section 3 asks you for some background our patient group.

Sections 4-8 are the main part lete, describing the views and experiences of patients and their c

We recognise that completing urces and so we commit to making all patient submissions sal process, particularly HTA reviewers and committee me ment reports and/or HTA advice/recommendations will do patients was considered in developing our conclusions/recom

If requested, we will provide you with w the submission from your patient group was used and influenced decision-

Source and format

HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG)
Seven-page word document

Resource title

Patient HTA Submission Template

Direction for use

Download and use this and its prompts to draw out unique patient knowledge that has the greatest potential to inform the decisions made by HTA staff and appraisal committees.

Health Technology Assessment international
An International Society for the Promotion of Health Technology Assessment

COMPLETING A PATIENT GROUP
SU TEMPLATE:
G R PATIENT
NISATIONS

for Health essment and Appraisal of Medicines

Prepared by HTAi Patient and Citizen Involvement in HTA Interest Group
Version 2-2015

Note:
We would be grateful to know if and how you have used this document, and how we can make it better. All comments and document will be reviewed in February 2017.
Comments to: Ann Single, email: singlehaworth@gmail.com

Source and format

HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG)
38-page PDF

Resource title

Completing a patient organisation submission template: Guidance for patient organisations for Health Technology Assessment and appraisal of medicines

Direction for use

Download and use its extensive and detailed guidance when completing your submission.

3.8 Participation in HTA in person

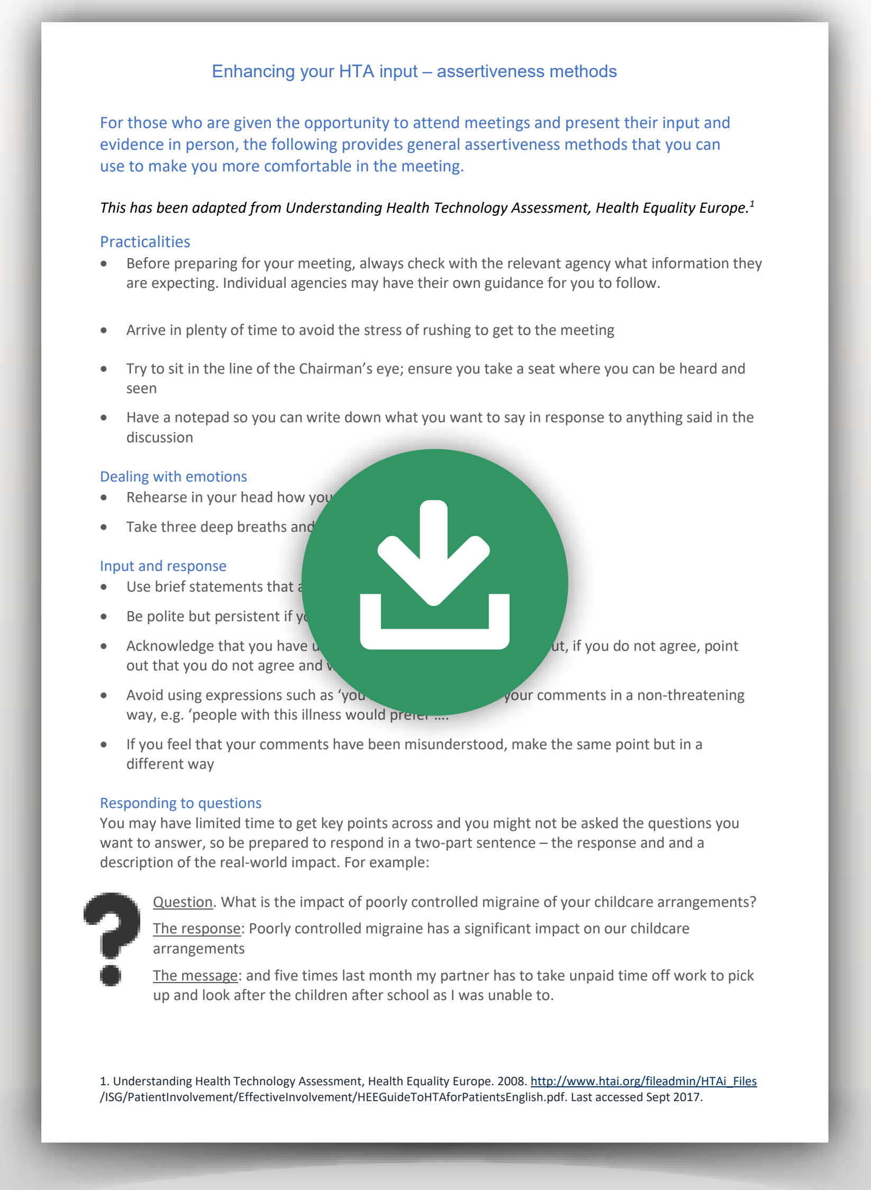
In some HTA processes, patient organisations and people living with a condition are given the opportunity to attend meetings and present in person.

In preparing for face-to-face meeting, the same preparation as for written input should be considered. These resources will support you to develop the messages you want to get across.

When presenting in person, make sure you deliver the two or three key messages you want to deliver at the beginning of any presentation while you have the panel's attention. You can then illustrate the points and return to reinforce them at the end of your allotted time.

When presenting in person, don't assume that the panel will understand all the implications of migraine – it is more likely that they will not (although they may think they do). At the same time, don't get stuck on small details, make sure you put the emphasis on things that matter.

Resource



Enhancing your HTA input – assertiveness methods

For those who are given the opportunity to attend meetings and present their input and evidence in person, the following provides general assertiveness methods that you can use to make you more comfortable in the meeting.

This has been adapted from Understanding Health Technology Assessment, Health Equality Europe.[1]

Practicalities

- Before preparing for your meeting, always check with the relevant agency what information they are expecting. Individual agencies may have their own guidance for you to follow.
- Arrive in plenty of time to avoid the stress of rushing to get to the meeting
- Try to sit in the line of the Chairman's eye; ensure you take a seat where you can be heard and seen
- Have a notepad so you can write down what you want to say in response to anything said in the discussion

Dealing with emotions

- Rehearse in your head how you
- Take three deep breaths and

Input and response

- Use brief statements that a
- Be polite but persistent if y
- Acknowledge that you have u ut, if you do not agree, point out that you do not agree and w
- Avoid using expressions such as 'you your comments in a non-threatening way, e.g. 'people with this illness would prefer ….
- If you feel that your comments have been misunderstood, make the same point but in a different way

Responding to questions

You may have limited time to get key points across and you might not be asked the questions you want to answer, so be prepared to respond in a two-part sentence – the response and and a description of the real-world impact. For example:

Question. What is the impact of poorly controlled migraine of your childcare arrangements?

The response: Poorly controlled migraine has a significant impact on our childcare arrangements

The message: and five times last month my partner has to take unpaid time off work to pick up and look after the children after school as I was unable to.

1. Understanding Health Technology Assessment, Health Equality Europe. 2008. http://www.htai.org/fileadmin/HTAi_Files/ISG/PatientInvolvement/EffectiveInvolvement/HEEGuideToHTAforPatientsEnglish.pdf. Last accessed Sept 2017.

Source and format

Adapted from Understanding Health Technology Assessment, Health Equality Europe[27]
One-page PDF

Resource title

Enhancing your HTA input – assertiveness methods

Direction for use

Download and use this list to support you in preparing for a face-to-face meeting.

Supporting a patient to present

3.9 What will happen to your contribution?

Patient involvement in HTA does not ensure that the medicine will be approved. Indeed, the HTA process can lead to medicines being rejected or not recommended.

The needs, perspectives and experience of people living with migraine will be considered with all the other available data by the expert group whose role is to assess the evidence.

How this is used will depend on the HTA process. It is important to clarify with the HTA agency how your contribution will be used, for example:

- Will it be considered with all the other available evidence?
- Will it carry as much weight as the other evidence?
- Is there a particular stage in the process when it is relevant?
- Will there be more than one chance to contribute to the process?

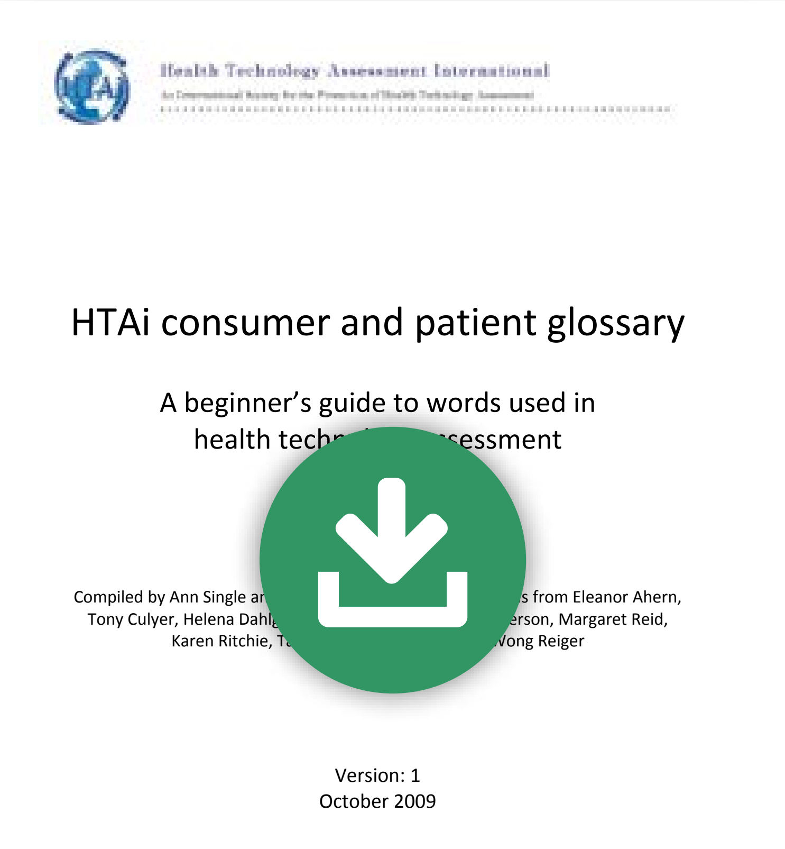
In addition, it is important that you clarify with the HTA agency if you will be getting feedback on your contribution. If not, ask them why not and see if there is an opportunity to get feedback.

What happens after the assessment will vary. There is likely to be a report with a recommendation on how the medicine should be used, in which group(s) of people and when. They may recommend that the medicine is not used at all or it may limit the group of patients for whom it is recommended.

If this is produced as a draft report, you may have the chance to provide comments on the draft. You may need to read the technical information in the report although this might be difficult to understand.

You may need to ask for help in interpreting the technical information. To help with this, you can download HTAi PCIG's ***Consumer and patient glossary. A beginner's guide to words used in health technology assessment.*** You can download this below.

Resource



Health Technology Assessment International

HTAi consumer and patient glossary

A beginner's guide to words used in

Version: 1
October 2009

Source and format

HTAi Patient and Citizen Involvement Group in HTA
Forty-page PDF

Resource title

HTAi consumer and patient glossary. A beginner's guide to words used in health technology assessment

Direction for use

Download and use this list to support you in all aspects of your involvement in HTA

Website link

International Network of Agencies for Health Technology Assessment (INHATA) provides a full glossary of words in an interactive format in English, German, Spanish and French. You can either click on the word/ phrase from the drop-down list or you can type in a word/phrase to access its meaning.

Help may also be available from your organisation's scientific advisers, from an academic department that specialises in this type of work (try searching the local university or college website for 'HTA', or 'public health', or 'health administration' or 'health economics'), from the producer of the medicine or from the HTA agency. It is important that you understand the implications of the draft report so do ask for help if you need it.

Once the report is finalised, decisions will be taken on whether or how to implement the recommendations.

3.10 Appeals

In some assessment processes, if you do not agree with the recommendations there may be the chance to appeal. If this is the case, the appeal process will be explained to the groups or individuals that have provided evidence.

There may be an opportunity to explain to the expert panel that they have failed to take account of issues that are important to patients. For example, the expert panel may not have understood that patients need a choice of treatments because some patients can tolerate certain treatment-associated side effects that others cannot.

Not all patient organisations or other contributors will choose to appeal. It can be frustrating if you feel that your views have not been heard but it may be that other factors were considered to be more significant. Other contributors may not have their views incorporated either – don't assume that the reason your input and evidence was not influential was simply because you represent patients and the public.

3.11 Working in partnership

Patients may benefit from working with their colleagues in a range of settings, including other patient organisations, scientific societies and universities. Many of these groups will be involved in the HTA process; for example, they may contribute evidence that is considered in the process, or they may clarify how the technology would be used.

Think about who might make good partners: are there other patient organisations that you can work with to make a submission? A joint contribution from several groups, who between them represent the views of a large number of patients, may be very powerful. By presenting a united voice, there may be a greater chance that this voice will be heard.

Professional groups [e.g. groups of doctors, nurses, or pharmacists] may also share your organisation's views of a medicine. If so, try to ensure that your submissions are coordinated so the assessment panel can see that there is a uniform view about the medicine's value. Be aware if other stakeholders have a different view of the medicine to yours: if they do, address this in your patient input.

When working in partnership with other organisations, always be aware of potential conflicts of interest. This is considered in section 3.6.4.

Undertaking broader outreach regarding the impact of migraine may also be beneficial in raising awareness of the unmet needs in migraine. Stakeholder groups, and approaches to stakeholder engagement, including public relations, stakeholder meetings and public affairs, are considered in module three. ▶

4.0 Next Steps and Checklist for Immersing Yourself in HTA

This section builds on previous sections and considers some additional practical recommendations for getting involved in the work of HTA agencies and for getting involved in the decision-making processes on the introduction of medicines.

Acknowledgements: The recommendations below have been adapted from the European Patients Forum (EPF) 2013 report on Patient Involvement in HTA in Europe – results of EPF survey.[29]

The full report can be downloaded here.

EPF European Patients Forum

Patient Involvement in
Health Technology Assessment
in Europe

Results
Survey

European Patients' Forum • Rue du Commerce 31 • 1000 Brussels • Belgium
Office Phone number: +32 (2) 280 23 34 • Email: info@eu-patient.eu • www.eu-patient.eu

A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE

4.1 Recommendations for getting involved in the work of HTA bodies

In order to get more involved into HTA bodies' activities, EPF recommends that you:

1. **Educate your organisation's representatives** so that they have a basic understanding of Evidence Based Medicine (EBM) and HTA. This covers two things: a broad-based understanding of the nature of HTA and its role in the allocation of healthcare resources and in decision-making; increasingly, some of the more scientific aspects of a medicine and knowledge of cost-effectiveness issues should be understood, and the organisations' representatives should be trained in these aspects.
2. **Approach the HTA agency pro-actively** to ask for involvement and respond to invitations to participate in HTA activities. Following up on information about medicines and the work of an HTA agency will help organisations stay pro-active.
3. **Engage in different HTA forums** where the producers meet and suggest how patient involvement can be achieved in HTA through clear proposals and comments on existing HTA. Provide input towards the identification of relevant assessment topics.
4. **Meet with staff from the agency** to learn about the processes and how best to get involved (who to send to meetings, what to put on forms, what type of evidence is most useful). Ideally this should be someone whose job is to support patient organisation involvement.
5. **Understand the processes of the HTA agency**. There are often very clearly defined methods and processes that have to be followed and strict timelines that must be adhered to.
6. **Ask for the agency's glossary** and use this to better understand the language/jargon/acronyms the agency uses.
7. **Contact other patient organisations** that are experienced in engaging with the agency's work and see whether you can learn from them.
8. **Demonstrate independence** by diversifying the organisation's financial support and having a transparent framework for cooperating with pharmaceutical manufacturers. This will help support one of the core principles of HTA, i.e. to remain transparent.

4.2 Recommendations for getting involved in the decision-making processes on the introduction of medicines

In order to get involved in the decision-making processes, you should:

1. **Ensure that there are two lay representative members** of your organisation in the planning and decision-making processes.
2. **Stay in contact and build links** with decision-makers and ask for more accountable and transparent decisions. Cooperate in building the rules for transparency. This can also be achieved by calling for more transparency in decision processes, using the media, and demanding the legal regulation of patient involvement.
3. **Ensure that lay people or citizens** represent the views, beliefs and opinions of patients and carers affected by the condition. They should also champion the evidence sent in by your organisations, and make sure it is raised in the decision-making discussions.
4. **Ask for payment and relevant training** that is tailored to your needs and background. Lay members should have equal status on the committee and have full-voting rights, as all other committee members do. There should always be at least two lay members on a group, to ensure the patient and public voice is a real one and it is not just tokenistic, or a box-ticking exercise.
5. **Participate in review processes of HTA reports** and ask for a version that is understandable by patients/patient organisations where applicable.
6. **Be a member of hearing boards** at any local hospital and consider lobby work in the national health department.
7. **Try to have a representative participate** in one of the committees that judge the value of HTA research.
8. **Actively initiate and participate in public debates on introduction of medicines.**

Section four provides practical hands on information and resources for undertaking media and lobbying work as proposed above. ▶

5.0 Conclusion

Health technology assessment is likely to become an increasingly important influence in decisions about what is provided in healthcare, including patient access to new migraine medicines.

It is important that HTA takes account of the needs, experiences and preferences of the people who will be most affected by its recommendations: patients and their caregivers.

While participating in a HTA can be time consuming and challenging, it is a real opportunity to influence the delivery of healthcare. Patient input and patient-based evidence can help determine whether a new treatment is made available and how it can best be used.

6.0 Case Study

Experience of the HTA setting by Myeloma UK

– what went well • issues we faced • what would we do differently –

The following case study is re-used with permission from Facey *et al*. Where pronouns such as "we" are used, this refers to Myeloma UK

Key learnings

- Work in partnership with other groups / representatives to mount a unified approach
- Gather together evidence and meaningful case studies to support the emotional arguments
- Seek advice from others who have been through the process before you

Background

Myeloma UK has been involved with two NICE technology appraisals – one drug for cancer treatment-induced anaemia and another for treatment of relapsed / refractory myeloma. NICE is the National Institute for Health & Care Excellence, England's HTA agency.

What went well during these appraisals?

While Myeloma UK spearheaded the appraisal submissions, we recognised that submitting evidence jointly with other leading charities was a stronger approach to take. Working in partnership with other charities towards a common goal is a positive way of demonstrating unity to NICE, and is also a constructive means of brainstorming and sharing differing levels of knowledge about the NICE system.

We also worked very closely with the doctors submitting evidence to the appraisals. It is valuable to share thoughts, ideas and approaches but more importantly, it is crucial to have integrated tactics when submitting to NICE. The arguments used by all stakeholders are given much more weight by NICE if they are consistent.

Finally, we spent a considerable amount of energy mobilising the UK myeloma community, communicating the importance of the HTAs to them and the consequences of the subsequent decisions. The volume of support we got, and the action that the community took throughout the appraisals, was fundamental to sensitising the issues and keeping them alive in both the minds of the media and NICE.

What issues did we face?

An HTA presents a very steep learning curve for most patient groups / representatives, and it is easy to suppose that submitting emotional arguments from the patient perspective will be enough to win NICE over. Not the case. Rather it is meaningful, experiential evidence that can resolutely demonstrate the effects of approving and rejecting the technology on patients that is most effective.

It is also critical that patient groups / representatives quickly learn the practical requirements of an appraisal as the theory can only teach you so much about the process. For example, facing a panel of inquisitorial experts in an appeal setting can be quite a nerve-wracking experience, but one that becomes less daunting by speaking with others who have been through it in the past.

What would we have done differently?

From the get go we would have placed more importance on the power of supportive case studies and quantitative evidence to support our arguments.

7.0 Insight into Patient Involvement in HTA – A View from The Agencies

This section of your Toolkit provides a brief insight into patient involvement in HTA in Australia, Brazil, Canada, Denmark, England, Germany, Scotland and Sweden. In addition, it provides a number of case studies as reported by representatives of some of these HTA bodies.

Acknowledgement. This summary insight has been adapted from Springer Nature's academic book entitled Patient Involvement in Health Technology Assessment.[26]

Australia

At a national level, the HTA committee responsible for making recommendations to the health minister/government for public funding of medicines is the Pharmaceutical Benefits Advisory Committee (PBAC).

The main approaches to patient involvement in Australian HTA include the appointment of a **patient representative** (sometimes two) on the PBAC expert committee and opportunities for **input** from individual patients, their caregivers, patient groups, and others. The committee has incorporated a position for at least one patient representative over the last 15 years.

Brazil

The main HTA organisation in Brazil is the National Committee for Health Technology Incorporation (CONITEC).

According to Brazilian law, public participation in HTA occurs through **participation** of a member of the National Health Council (CNS), who represents citizens and users of the Brazilian public health system.

Public participation is also achieved by **public consultation** on all recommendations coming out of CONITEC and by **public hearings** in relevant cases.

Canada

Health technology assessment in Canada takes place at the hospital, regional, provincial/territorial and pan-Canadian levels. As a result, HTA programmes have a different remit, depending on stake-holder needs.

However, Canadian HTA organisations share common goals for patient involvement but have developed different approaches to achieve them that fit within available resources, timelines and expertise.

Patient involvement strategies used within Canadian HTA organisations fall into five broad categories: **stakeholder feedback**, use of **patient input templates**, synthesis of **published literature**, **interviews** and **focus groups** and **committee participation.**

Denmark

In Denmark patient involvement in HTA has been developed since the 1980s at both national and regional level.

The strategy for patient involvement has explicitly introduced **scientific analysis** of patient-related aspects to produce **patient-based evidence** as an essential part of HTA.

Secondary research into patients' perspectives has played a major role in patient involvement in HTA in Denmark, and **primary research** has been carried out when existing research was insufficient to create an understanding of central patient aspects.

In addition, patients have participated as stakeholders in HTA processes through **representation in stakeholder groups.**

England

Patient involvement in HTA is integral to the work of England´s HTA agency – the National Institute for Health and Care Excellence. NICE has a dedicated team, the Public Involvement Programme (PIP) that helps identify, train and support patients and organisations involved in each piece of guidance.

Figure four below provides an overview of patient involvement in HTAs undertaken by NICE

Example of Patient Organisation NICE Submission (available in the public domain)

Ulcerative Colitis

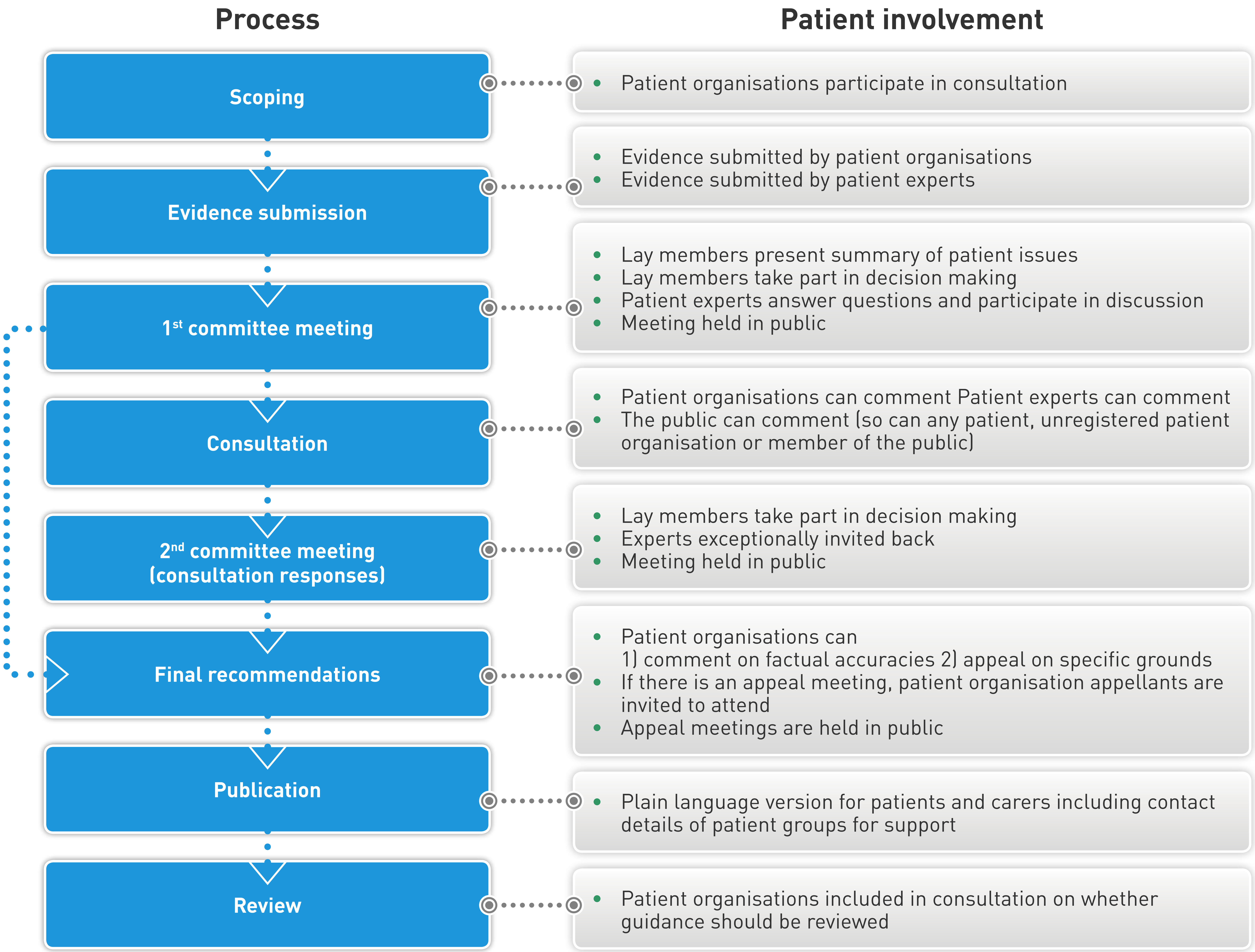
Patient input informed the committee that the condition meant that patients are often housebound or hospitalised and unable to work or study. It stated that the population is often teenagers or young adults, whose quality of life is affected by the debilitating nature of the condition; they are unable to study or socialise and it also reduces their possibility of meeting a partner. The submission explained why surgery is an inappropriate comparator for young adults; surgery is irreversible, with risks, and has life-long effects, including on fertility. The committee was told that the treatment being considered gave them complete remission and thus 'their life back'.

Example of a Patient Organisation Response to a NICE Consultation

Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis (TNF-alpha inhibitors)

The patient organisation agreed with most of the committee's recommendations with two exceptions. Firstly, a particular drug was not recommended and, secondly, that a second or subsequent drug from the same class of drugs for people whose disease has not responded to treatment with the first one, or those who had an initial response which was then lost, was also not recommended. To inform their consultation reply, they ran a survey, gaining 858 responses in eight days, and the results were submitted to the committee. The recommendations were subsequently amended; firstly, the committee stated that the originally not-recommended drug might benefit people with memory problems, learning disabilities, dexterity problems or a fear of needles and, secondly, that there was also anecdotal evidence suggesting that a second or third drug from the same class can be clinically effective if the first has failed.

Figure four. NICE involvement opportunities (with permission from NICE)



Process	Patient involvement
Scoping	Patient organisations participate in consultation
Evidence submission	Evidence submitted by patient organisations Evidence submitted by patient experts
1st committee meeting	Lay members present summary of patient issues Lay members take part in decision making Patient experts answer questions and participate in discussion Meeting held in public
Consultation	Patient organisations can comment Patient experts can comment The public can comment (so can any patient, unregistered patient organisation or member of the public)
2nd committee meeting (consultation responses)	Lay members take part in decision making Experts exceptionally invited back Meeting held in public
Final recommendations	Patient organisations can 1) comment on factual accuracies 2) appeal on specific grounds If there is an appeal meeting, patient organisation appellants are invited to attend Appeal meetings are held in public
Publication	Plain language version for patients and carers including contact details of patient groups for support
Review	Patient organisations included in consultation on whether guidance should be reviewed

Germany

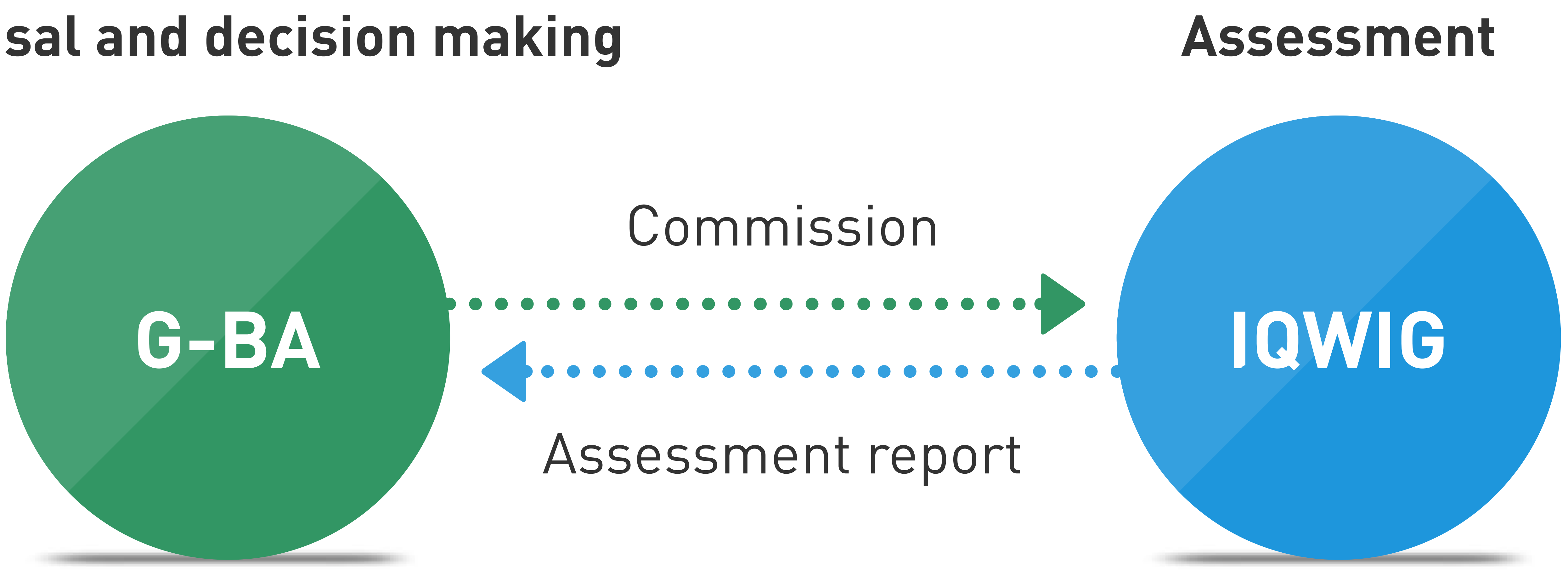
In Germany, the Institute for Quality and Efficiency in Healthcare (IQWiG) drafts HTA reports that are commissioned by the Federal Joint Committee (G-BA).

Since 2004, legislation has supported comprehensive patient participation in both. This includes participation of individual patients or their carers, as well as representatives of patient groups, advocacy groups or consumer organisations. The aim is to help ensure that all possible patients' perspectives are covered.

Those appointed to the committees of G-BA are chosen as knowledgeable persons by relevant patient organisations. Currently, around 250 patient representatives are active in G-BA committees.

Figure five below, provides an overview of patient involvement in German HTAs.

Figure five. Patient involvement in German HTA



Appraisal and decision making

Assessment

G-BA

Commission

Assessment report

IQWIG

Patient involvement

- Participation in committees
- Participation in discussion, entitled to submit petitions, not entitled to vote

Patient involvement

- Invited discussion
- Input via questionnaires
- Submission of comments on IQWiG products

Scotland

Patient involvement has been a feature of HTA in Scotland since a national body to assess the clinical and cost-effectiveness of health technologies was established in 2000.

The impetus for involving patients in HTA may be linked to the Scottish Parliament's principle of encouraging public participation in decision-making (The Scottish Parliament 1999) and a UK-wide push for greater transparency and patient involvement in healthcare following an inquiry into a serious failure in health services in Bristol. As a result, Scotland follows the wider Danish model for HTA that evaluates organisational and patient issues, alongside clinical and cost-effectiveness.

Scottish example of HTA process – Chronic Wounds

The impact of chronic wounds on people's lives is considerable. The persistence, recurrence and symptoms of a chronic wound can have severe physical, psychological and social consequences.

Scottish HTA recommendations relating to patient issues

Information obtained through the patient issues section were directly reflected in the final recommendations made.

- When selecting a dressing for people with chronic wounds alongside holistic clinical assessment, consider the factors of importance to the patient such as odour, pain/discomfort, leakage and mobility as well as healing.
- A national patient leaflet should be developed, which can be used as an aid to support shared decision-making between patients with chronic wounds and healthcare professionals.

Information obtained through the patient issues section

The patient issues section provided rich information and findings about the experiences of patients with chronic wounds.

- There is often a 'trial and error' approach to dressing selection, and this process can continue until the wound begins to heal. People may then credit a particular dressing type with healing their wound.
- Wound healing was usually the most important outcome to patients, but control of symptoms (in particular pain, odour and exudate) and prevention of infection and wound deterioration were also important outcomes. People often report wanting to 'try anything' to achieve these outcomes.
- The primary research revealed a positive view of antimicrobial wound dressings. People felt that they helped (or were helping) to heal their wound(s) and/ or they helped with wound symptoms. One size did not fit all — an antimicrobial wound dressing that worked for one person may not work for another.
- Patients report that the extent and impact of pain from chronic wounds can be considerable. Reports of pain are not always acknowledged by healthcare professionals, and it seemed that pain frequently remains uncontrolled.
- People value care that they feel is personal and from healthcare professionals who they trust and who are persistent with treating their wounds even when wound healing is slow.
- The primary research indicated inconsistent access to antimicrobial wound dressings across healthcare settings. This led to frustration and inconvenience. This inconsistency is a likely influence on people who believed that the best treatments may be withheld from them because of costs.

Sweden

In Sweden, The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) is responsible for the assessment of medicines. SBU is an independent national authority, tasked by the government with assessing healthcare interventions from a broad perspective, covering medical, economic, ethical and social aspects.

Founded in 1987, it is one of the oldest HTA organisations in the world. SBU uses a range of mechanisms to involve patients in its HTA processes. These include:

- Patient reference groups
- Consultative meetings
- Multi-stakeholder reference groups
- Patient as project members
- Reviewing reports in some areas where patient insight is deemed valuable
- Setting Priorities in Scientific Uncertainties
- Representation on SBU's Board

Section two - PATIENT INVOLVEMENT IN IMPROVING MIGRAINE SERVICES

Many people using this Toolkit will have a lot of experience in helping to improve migraine services. However, while there is a range of guidance and support for healthcare providers on how to engage patients in improving migraine services, there is limited guidance specifically for patients and those that advocate on their behalf. Therefore, this section considers some of the basics and it adapts some of the learnings from patient involvement in Health Technology Assessment (HTA) where there is evidence-based guidance that supports patient involvement.

The aims of this section are to:

- Support your understanding of the principles and benefits of patient involvement in improving migraine services
- Consider some of the approaches that are used to support patient involvement
- Provide you with guidance on how you can generate meaningful evidence to support your involvement

Key learnings

- Better involvement of patients in their migraine services is not a nice-to-have, it is fundamental to the effective delivery of services
- Migraine patients have a critical role to play in improving their services. The insight, experience and expertise of patients can help improve migraine management by making it more tailored and more sustainable, and by helping to ensure that new services and service changes have legitimacy
- The key to effective patient involvement in improving migraine services is to ensure that the important messages you want to get across are clear and that they are supported by evidence from patients
- Where there are limited, or no opportunities for patients to get involved in how their migraine services are delivered, other approaches to informing decision-makers should be considered

1.0 Introduction

Headache disorders, including migraine and tension-type headache, are among the most prevalent disorders of mankind. They are under-recognised, under-diagnosed and under-treated. Financial costs to society through lost productivity are enormous – far greater than the health-care expenditure on headache in any country.[2]

Migraine remains under-recognised and under-treated with more than 50% of people going undiagnosed.[17]

More needs to be done to address the significant burden of migraine. This has been recognised by the European Headache Foundation and *Lifting The Burden:* the Global Campaign against Headache. In 2011, they highlighted that migraine, tension-type headache and medication overuse are a major public-health priority and that there is a pressing need for effective solutions to them. They also highlighted that the principle objective of headache services must be to reduce the burden of the conditions.[2]

As it is migraine patients and their carers who are using these services, they are the experience-based experts. Therefore, patient needs, perspectives and experience should be considered when providers construct, deliver and evaluate migraine services.

Toolkit definitions

Headache services vs. migraine services

Headache services include the management of migraine. For the purpose of this Toolkit they are sometimes referred to as ‘migraine services’.

Enhancing migraine services refers to:

- Supporting the development of new migraine services e.g. Migraine Clinics
- Supporting improvements to current migraine services

2.0 Identifying and Addressing the Unmet Needs in Migraine Services

As a starting point, it is important to understand how migraine services are delivered in your country and how this compares to what would be considered best practice.

The European Headache Foundation and Lifting The Burden: the Global Campaign against Headache provides a basic model of healthcare organisation for Europe that can be used as a basis for assessing services. Table one below is an adaptation of this as it includes additional information you might find useful that has been taken from their paper on this subject.[2]

In terms of identifying the unmet needs in migraine services at a national, regional or local level it is widely accepted that seeking the views, opinions and experience of migraine patients and their carers is the most appropriate way to identify gaps in migraine services and/or areas for service improvement.

Where there are no opportunities for direct patient involvement, many organisations adopt other approaches to improving migraine services. For example, running a media campaign – based on patient and carer feedback – calling for improved services.

Figure one summarises the four steps to patient involvement in improving migraine services.

Module four provides you with guidance on how to undertake decision-maker outreach through PR and public affairs. ▶

Figure one. Patient involvement in services

1. HEADACHE SERVICES

Understand how services are delivered

2. UNMET NEEDS

Survey patients and carers to get their views, opinion and experience

3. PATIENT INVOLVEMENT

Identify opportunities to input into and inform service delivery and improvement

4. BROADER OUTREACH

Use other approaches to raise awareness of the unmet needs for migraine patients

Table one. Headache services (which include migraine) organised on three levels

Level 1. General primary care • Non-specialist healthcare providers • Migraine diagnosed and managed • Should meet 90% of headache patient needs	Frontline headache services (easily accessible first point of contact for most patients) Ambulatory (outpatient) care delivered by primary-care professionals Referring to level 2 services if required and acting as the gatekeeper to these services
Level 2. Special-interest headache care • Specialist healthcare providers • About 10% of headaches managed here	Outpatient care delivered by a physician with a specialist interest in headache Referring to level 3 services if required and acting as the gatekeeper to these services
Level 3. Headache specialist centres • About 1% of headaches managed here	Advanced multidisciplinary care delivered by headache specialists in hospital-based centres

3.0 Patient Involvement in Improving Migraine Services

Older models of migraine care often treat patients as a passive group who are simply told what to do and are managed accordingly.

However, times are changing. Increasingly it is being recognised that the views and opinions of patients are as significant as those of any other stakeholder in the healthcare process and that patient involvement goes beyond an individual's care. It includes the systems, processes and care pathways that are developed for patients.

3.1 A definition of patient involvement

As for HTA, patient involvement encompasses two distinct, but complementary approaches.

- ***Patient participation (patient input*** through interacting in service enhancement)
- ***Research into patient aspects (patient-based evidence*** obtained from robust research)

In terms of enhancing migraine services, patient involvement normally involves patient input through sharing their needs, perspectives and experience.

3.1.1 Patient input

Patient input describes information provided by patients, their carers or those who advocate for them, for example, patient organisations. It may be written, such as responding to a survey, or verbal, such as taking part in a focus group. Ideally, it should be a two-way dialogue. This enables real-world perspectives and experiences to be shared.

3.2 The importance of patient involvement

Migraine patients have a critical role to play in enhancing their services. The insight, experience and expertise of patients can help improve migraine management by making it more tailored and more sustainable, and by helping to ensure that new services and service changes have legitimacy.

Decision makers responsible for migraine services should engage with, involve and empower patients. Patients are not just experts in their own lives, conditions and care needs, they also hold vital knowledge about local services that can be used to improve their care.

Migraine patients who use services also see the best and the worst that is on offer, and understand the emotional toll of ill-health and caring.

Patient needs, experience and perspectives are therefore critical to driving improvements and making services more responsive to people's actual needs.

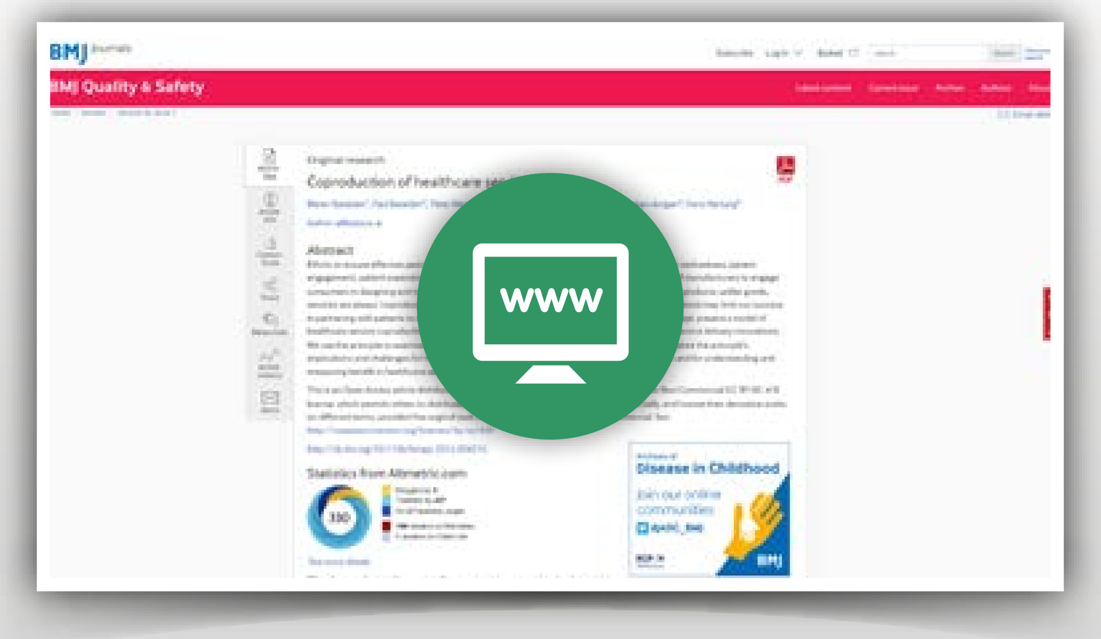
Definition of patients

3.3 Patient involvement opportunities

There are a range of approaches used by migraine service providers that support patient involvement. However, these tend to be restricted to sharing needs, experiences and perspectives to inform services, and not in the actual co-production of services.

While times are slowly changing, and in the absence of approaches for patient involvement throughout the process, it is recognised that maximising the impact of contributions through established approaches is an important consideration.

Website link



If you would like to know more about co-production, one of the newer approaches to patient involvement, the BMJ provides a good introduction to the concept.

Figure two below presents a number of traditional approaches to patient involvement, many of which you will be familiar with. These are often used by individual healthcare practices where patient organisation involvement may be limited, within regions or they could be used in the development of national services.

Figure two. Approaches to patient input

Surveys
Often used to obtain input from lots of patients through their response to a number of pre-determined questions

Market research
A more formal approach to undertaking a survey, often facilitated by an expert in market research. This can be one-on-one or with a group and all participants are asked the same questions

Patient Polls
Often a simple 'yes' or 'no' response to a few questions such as "Were you happy with our services today?"

On-line feedback
Feedback often requested from patients following an appointment with their physician

Story telling
Patients telling a story of their migraine management in person or in writing

Patient pathways
Patients creating a picture of their management pathway, or commenting on a pre-developed picture

Focus groups
A demographically diverse group of patients who participate in a guided discussion

3.4 What to do when there are limited or no opportunities for patient involvement

Where there are limited, or no opportunities for patients to get involved in how their migraine services are delivered, patient organisations often use other approaches to informing decision-makers about the needs, perspectives and experiences of patients.

Figure three below presents some of the approaches that patient organisations across different therapy areas have used to raise awareness of the unmet needs in services. These are usually supported by burden of disease key messages and a call to action that addresses the specific service issue they want to address.

Key messages, facts & figures on the burden of migraine can be found in module two, section one. ▶

Figure three. Some approaches to raising awareness of unmet services needs

What	Description
Patient survey and launch	A patient survey that uncovers the unmet needs in services and the impact that these have on patients. Written up as a formal report and sent to decision-makers.
Expert Report and launch	A multi-stakeholder group develops an Expert Report on the need for improved services. The Expert Report is sent to decision-makers.
Media awareness campaign	Using the survey/Expert Report, supported by patient case studies, to run a media awareness campaign.
On-line petition	An on-line petition calling for a specific action, while encouraging patients and carers to sign this. Highlight the reach and number of signatures and forward the petition to decision-makers.
Migraine and employment media campaign	A partnership with a national employer organisation to identify the cost to industry of the condition. A national media campaign for enhanced services and better support by employers.
Social media campaign	A social media campaign that encourages patients and their carers to use their social media channels to mobilise family and friends behind a call to action.
Lobbying	Reaching out to elected officials with evidence on the unmet needs in services and the consequences of this on individuals, their families and the economy.

3.4.1 Platforms for engaging with decision-makers

Once content has been created, different patient organisations use different platforms to reach decision-makers. These are guided by the information sources decision-makers are known to use and the resources available to capitalise on these. Figure four considers some of these platforms and it can be used as a checklist when planning your outreach.

Migraine stakeholder groups, and approaches to stakeholder engagement – including public relations, stakeholder meetings and public affairs are considered in module four. ▶

Figure four. Platforms for decision-maker engagement

MEDIA

- ☐ News
- ☐ Consumer health article
- ☐ Medical article/opinion piece
- ☐ Policy and payer article
- ☐ Peer-reviewed publication
- ☐ Advertorials/ advertisement
- ☐ Broadcast (radio/TV)

SOCIAL MEDIA

- ☐ Linkedin
- ☐ Facebook
- ☐ Twitter
- ☐ Patient videos/vignettes
- ☐ Blogs
- ☐ On-line forums

DIRECT TO DECISION MAKER

- ☐ Face-to-face meeting/ lobbying
- ☐ Teleconference
- ☐ Email communication
- ☐ WebEx
- ☐ Policy paper
- ☐ Briefing paper
- ☐ White paper/expert report
- ☐ Engaging your elected representative to act on your behalf

MEETINGS

- ☐ Conference presentation
- ☐ Conference seminar
- ☐ Conference poster
- ☐ Exhibition stand
- ☐ Bespoke meeting
- ☐ Networking
- ☐ Breakfast/dinner meeting
- ☐ Information in delegate pack

ESTABLISHED PLATFORMS

- ☐ Website update
- ☐ Newsletter or similar
- ☐ Email distribution
- ☐ Annual meetings, AGM or similar
- ☐ Reciprocal links to websites

3.5 Planning for patient involvement

It is widely recognised that for patient organisations, one of the most important aspects of patient involvement in improving migraine services is monitoring and planning. This involves:

- Identifying what service reviews are taking place, and where possible registering as a stakeholder
- Clarifying whether there is a role for you directly, or indirectly through supporting migraine patients
    - Where there is a direct role for your organisation: clarifying what information is needed, whether you can generate this and how long it will take
    - Where you are supporting patients: what support needs they have and whether you can provide this support

Including a section on your website that provides users with guidance on how they can prepare for input into their migraine services is a cost-effective approach to supporting patients.

3.5.1 Finding out what service reviews are taking place

While you are likely to be aware of any national service reviews, patients who use your services or visit your website are a good source of insight into regional and local service reviews. Other neurology patient organisations and medical organisations may also be a good source of information.

Indirect support

3.5.2 Preparing for patient participation

The key to effective patient involvement in improving migraine services is to ensure that the important messages you want to get across are clear and that they are supported by evidence from patients.

Building relationships with patient groups from other disease areas can also be useful, especially in sharing ideas & approaches that have and haven't worked. Larger groups with paid staff may even offer a mentoring service or offer free advice.

In addition to those approaches to uncovering patient needs, experiences and perspectives considered in figure two, additional sources of evidence could include:

- Relevant information uncovered by enquiries to a helpline
- Insights from support groups regarding the problems patients and carers face
- Issues discussed in chat rooms or at an official meeting

Don't produce a long contribution if it isn't needed. If there is extra information you want to include, in written feedback, put this into an appendix so it doesn't dilute the messages you want to emphasise.

3.5.3 Demonstrating the validity of your involvement

In order to appreciate the value and validity of your involvement, it is important that you provide:

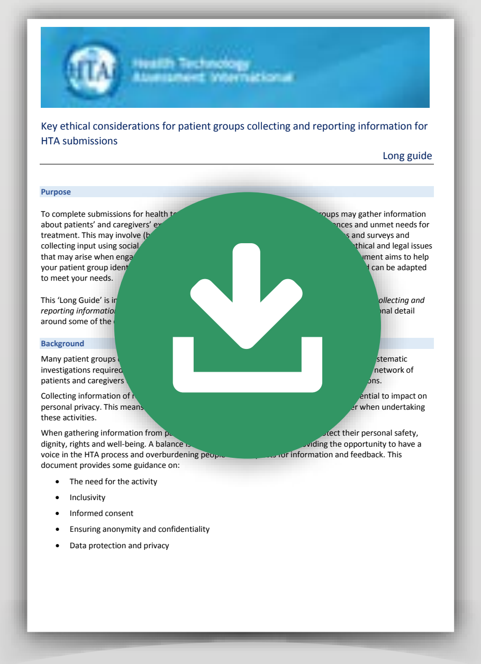
- A description of your organisation
- How the information you use was collated and whether it was newly collected or already existed

3.5.4 Ethical considerations

When inputting into a review of services, you may be gathering information about patients' and caregivers' experiences of living with migraine and using migraine services. As a result, you need to think about any ethical and legal issues that may arise when engaging with people and using their personal information.

Health Technology Assessment International´s (HTAi) Patient and Citizen Involvement in HTA Interest Group (PCIG) documents provide very useful information on this subject in support of the assessment of medicines which can be adapted for your own use in your input into service reviews.

Resource



Source and format

HTAi Patient and Citizen Involvement
in HTA Interest Group (PCIG)
Two-page short-form PDF
Seven-page long-form PDF

Resource title

Key ethical considerations for patient groups collecting and reporting information or HTA submissions

Direction for use

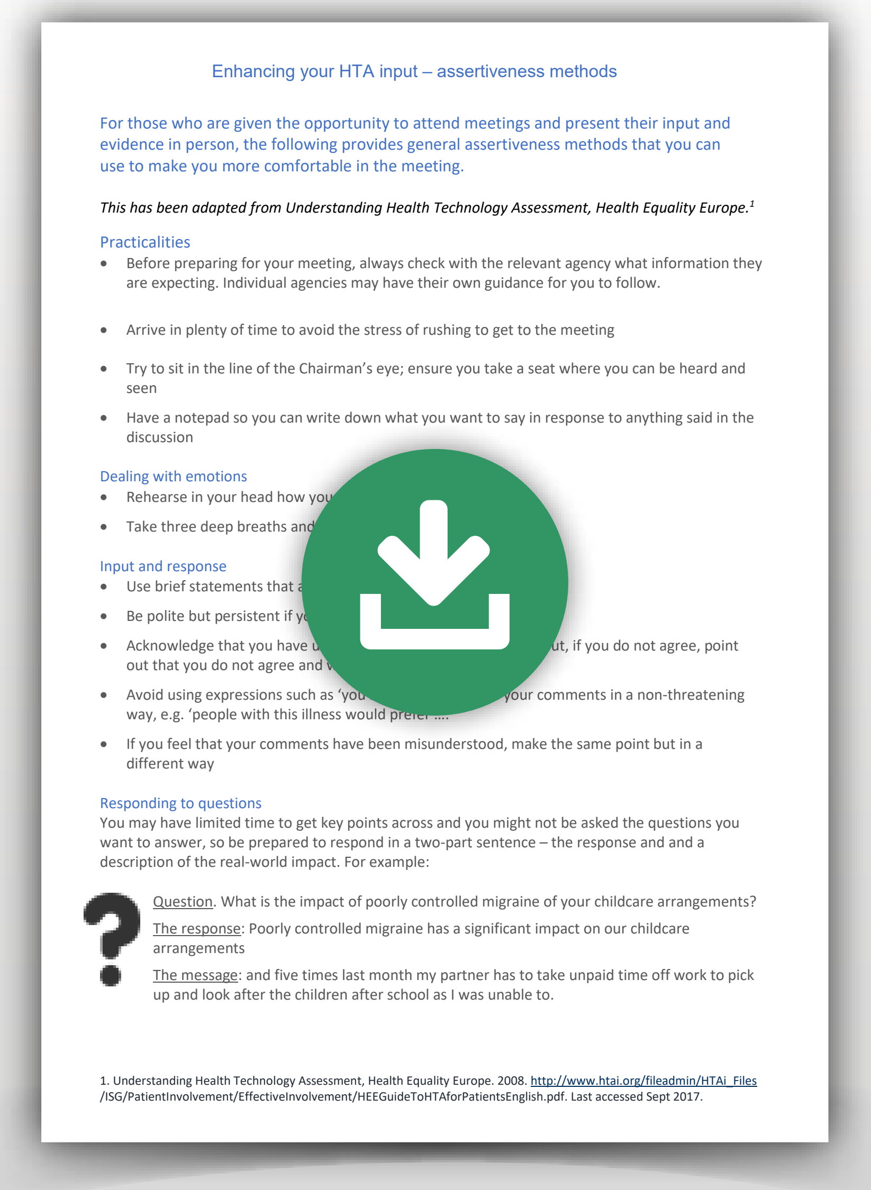
Download, review and adapt this information to ensure that your activities in seeking and presenting patient input and evidence follow best-practice.

3.5.5 Contributing in person

When contributing in person (e.g. by attending a focus group), make sure you prepare for this and have the key messages you want to communicate. Also, be prepared to contribute to any discussion and to answer any questions you may be asked.

Before contributing in person, it is a good idea to contact the person organising this to confirm what they will be asking.

Resource



Enhancing your HTA input – assertiveness methods

For those who are given the opportunity to attend meetings and present their input and evidence in person, the following provides general assertiveness methods that you can use to make you more comfortable in the meeting.

This has been adapted from Understanding Health Technology Assessment, Health Equality Europe.[1]

Practicalities

- Before preparing for your meeting, always check with the relevant agency what information they are expecting. Individual agencies may have their own guidance for you to follow.
- Arrive in plenty of time to avoid the stress of rushing to get to the meeting
- Try to sit in the line of the Chairman's eye; ensure you take a seat where you can be heard and seen
- Have a notepad so you can write down what you want to say in response to anything said in the discussion

Dealing with emotions

- Rehearse in your head how you
- Take three deep breaths and

Input and response

- Use brief statements that a
- Be polite but persistent if yo
- Acknowledge that you have u ut, if you do not agree, point out that you do not agree and w
- Avoid using expressions such as 'you your comments in a non-threatening way, e.g. 'people with this illness would prefer ….
- If you feel that your comments have been misunderstood, make the same point but in a different way

Responding to questions

You may have limited time to get key points across and you might not be asked the questions you want to answer, so be prepared to respond in a two-part sentence – the response and and a description of the real-world impact. For example:

?

Question. What is the impact of poorly controlled migraine of your childcare arrangements?

The response: Poorly controlled migraine has a significant impact on our childcare arrangements

The message: and five times last month my partner has to take unpaid time off work to pick up and look after the children after school as I was unable to.

1. Understanding Health Technology Assessment, Health Equality Europe. 2008. http://www.htai.org/fileadmin/HTAi_Files/ISG/PatientInvolvement/EffectiveInvolvement/HEEGuideToHTAforPatientsEnglish.pdf. Last accessed Sept 2017.

Source and format

Adapted from Understanding
Health Technology Assessment,
Health Equality Europe[17]
One-page PDF

Resource title

Enhancing your HTA input – assertiveness methods

Direction for use

Download and use this list to support you in preparing for a face-to-face meeting.

3.6 Follow-Up

It is important that those who input into services know how the information has been used. If there is no formal feedback mechanism, ask the provider for feedback.

For patient organisations it is also important that you follow up at a later date to ensure that the services have been improved. In the absence of a formal approach to co-designing services, patient organisations have an important role in holding migraine service providers to account.

4.0 Conclusion

Gathering information about patients' experience of migraine services is not new. However, approaches that gather data and insight only may not be the most effective in the development of services that really matter to patients.

Given that new approaches to seeking meaningful patient input are not widely adopted, it is important that patient input through established approaches maximises the impact of the information shared in relation to patient needs, experience and perspectives.

Patient organisations have always had a very important role in improving migraine services, either directly, or indirectly through support for patients. Key to this has been success in ensuring that the important messages are communicated and that they are supported by real-world evidence from patients.

If there are limited or no opportunities for patients to get involved in how their migraine services are delivered, other approaches to informing decision-makers have been shown to drive positive change.

5.0 Reaching decision makers case study

Migraine Action Call for More Training for General Practitioners (GPs)

– using media and partnerships to drive change –

This case study is reported from Migraine Action's campaign – the facts and text below were provided to us with permission by Migraine Action*

Key learnings

- Work in partnership with other organisations that are aligned with your aims
- Have a clear call to action
- Gather together evidence to support the need for change and your call to action

Background

Whilst most people living with migraine could be managed successfully in a primary care setting, many do not receive adequate care due to a lack of understanding about the condition. This can lead to numerous costly repeat consultations, unnecessary referrals into secondary care and inappropriate treatments.

Appropriate management of migraine requires training of health professionals, accurate diagnosis, appropriate treatment with cost-effective medications, simple lifestyle modifications, and patient education.

Poor awareness extends to the general public. Headache disorders are not perceived by the public as serious since they are mostly episodic, do not cause death, and are not contagious. The low consultation rates for headache/migraine may indicate that many affected people are unaware that effective treatments exist.

**As of June 2018, Migraine Action has closed.*

Activity

Following the publication of 'Atlas of Headache Disorders and Resources in the World 2011', by the World Health Organisation and Lifting the Burden, The Global Campaign against Headache, Migraine Action partnered with City of London Migraine Clinic (now the National Migraine Centre) to call for more training for GPs after a new report revealed that only four hours were committed to headache disorders in formal undergraduate training.

The launch of the campaign coincided with Migraine Awareness Week 2011 when a media release was circulated to the media, and journalists were followed up to encourage them to report on the call to action.

Outcomes

The immediate outcomes were limited to some national and local press coverage, but the campaign enabled all the headache charities to use as a consistent message. This outreach, combined with other efforts, led the All Party Parliamentary Group on Headache Disorders (a nonpartisan special interest group at the UK Parliament) to lead an inquiry in 2013/14, and report on Headache Services in England.[31] Since then the number of specialist headache nurses has been increasing significantly albeit from a very low base.

MODULE FOUR

Stakeholder engagement and communications

This module considers

Stakeholder Identification, Profiling and Planning

Media Relations

Public Affairs

Section one - STAKEHOLDER IDENTIFICATION, PROFILING AND PLANNING

1.0 Background

Throughout the world, patient organisations are working with other individuals who support them in delivering on their mission.

Many of these will be decision-makers who don't work for the organisation. In securing their support, many organisations will have an established approach to stakeholder development and management.

However, experience has shown that approaches to engaging with decision-makers are often based on a single individual's relationships and activities, as opposed to a more objective approach to planning.

This section of your Toolkit provides a tried and tested approach to effective decision-maker identification, profiling and planning or engagement.

Whether starting from the beginning, or refining current activities, this approach has been used by a range of organisations with great success.

Understanding who your opinion-formers are, knowing how you can engage with them, and being clear on what you want to achieve as a result of this, are the first steps to effective communication planning.

The aims of this section are to:

- Provide you with a focussed approach that can be used to help you identify, profile and plan for building relationships with decision-makers that matter to you

Data Protection Laws

Different countries have different laws that control how personal information is used by organisations, businesses or the government. Everyone responsible for collecting and using a person's personal information needs to be aware of these rules.

Check out your data protection laws to understand what – beyond basic contact information - you can hold on decision-makers and how this can be used.

Stakeholder

2.0 Overview of the Steps to Stakeholder Identification, Profiling and Planning

The following provides an overview of a rational step-by-step approach to support decision-maker engagement. Specific topics (as indicated by the underlined title) are then considered in more detail following this.

1

Decide where decision-makers can add value to your improving patient services and access to appropriate medicines work, or where your work can be used to inform decision-makers.

2

Make a list of current decision-makers you currently have a working relationship with. This is likely to involve pooling the knowledge from you and your colleagues.

3

Identify and list additional decision-makers who you may need to engage with in your road towards improving services and access to appropriate medicines.

4

Review the list and categorise your decision-makers into four segments

a. Gold – the 10-15 decision-makers that are most important to your work. These become your priority focus
b. Silver – the next 20-25 most important decision-makers. These become your secondary focus.
c. Bronze – all the other decision makers that may be important to your work.

Please note, when compiling these lists, you should be aware of and take into account local data protection laws.

5

Develop a simple data capture database in excel to capture the details of your decision makers using different tabs for your Gold, Silver and Bronze. A template is provided below to support you with this.

6

Plan engagement activities for each of your Gold/Silver decision makers and complete a one-page planning tool that:

a. Clarifies your development aim by decision-maker – improve relationship, maintain relationship, improve their profile or monitor their activities
b. Identifies what you need to do to support your development aim
c. Details how, when and who will engage with them

7

Deliver your plan and evaluate progress at month six and month 12.

3.0 Identifying and Listing Decision-Makers

There is a wide range of decision-makers that can help inform the improvement of services and access to appropriate medicines. It is important that you understand who these are. In addition to those you may already know, speaking to other patient organisations and undertaking desk-based research can help complete a list of appropriate decision-makers.

While decision-makers and their roles vary, both between and within countries, table one details some of the decision-makers and their potential role.

Source and format

Original document
Excel database

Resource title

Migraine decision-makers Gold/Silver/Bronze database

Direction for use

If you don't have a system for recording who your decision-makers are, download this document and use it to maintain a database of your Gold/Silver and Bronze decision-makers.

Table one. Decision Makers and their Roles

	Name	Role
National	**Ministry for Health**	Responsible for overseeing delivery of health and care.
	Ministry for Finance	Responsible for allocating funds for delivery of health and care.
	Health Insurance companies	Responsible for funding aspects of healthcare, most notably medicines.
	Statutory health and care bodies	Those that have a legal duty to deliver health and care services.
	Academia	Academic organisations that generate outcomes of an academic nature, for example Think Tanks and those economic institutions that may support Health Technology Assessment (HTA) Agencies.

Table one. Decision Makers and their Roles (continued)

	Name	Role
National, regional and local	**Local elected officials**	These may sit in national parliaments or in local elected bodies, such as City Mayors or local councillors.
	Local Authorities	Often responsible for delivering non-healthcare services that may include adult social care.
	Service commissioners	Those who are responsible for assessing the migraine needs of a community and who then instruct the development of payment for these services. These can be regional or local.
	Payers	A broad term used to describe those that are responsible for paying for services and medicines.
	Health Technology Assessment Agencies	Those organisations responsible for assessing new technologies, including migraine medicines.
	Professional Organisations	Professional organisations that represent specific healthcare disciplines such as a Royal Society of Neurology.
Healthcare providers	**Primary care doctors**	Doctors that operate in the community. These manage the majority of migraine patients.
	Primary care doctors with an interest in migraine	Doctors with a specialist interest who may deliver services and clinics in primary care.
	Migraine nurses	Nurses with a role in delivering migraine services in the community.
	Neurologists/migraine specialists Community neurologist	Neurologists whose work may also support migraine clinics delivered in the community.
	Migraine nurses	Specialists nurses who support the management of migraine in secondary or tertiary care.
	Pharmacists	Either located within the community or in hospitals, the latter may specialise in CNS medicines.

4.0 Planning Engagement Activities

Planning engagement activities is one of the most important steps in stakeholder engagement as it can:

- Focus resources on those activities that matter most
- Support planning and evaluation
- Align internal teams behind a pre-agreed plan

Effective planning is based on understanding:

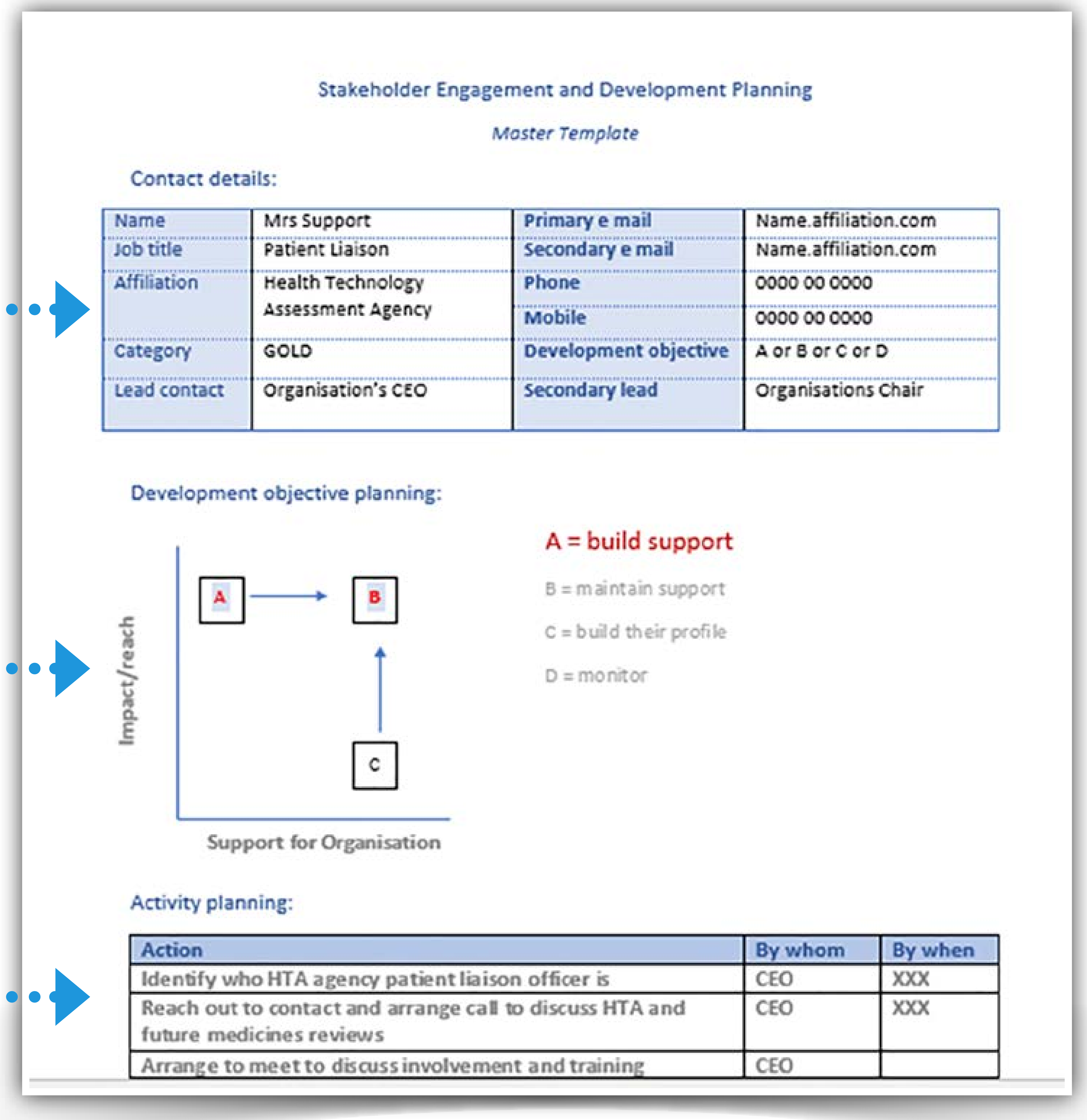
- Who the decision-maker is and what their role is
- How you can engage with them
- What you will do to engage with them
- What you want them to do as a result of this engagement
- Who is responsible for doing this
- What success would look like and how you can evaluate this

In support of your planning you might consider using a one-page planning tool. Figure one is an example of a mocked-up planning sheet.

Basic contact details

What your primary aim is in terms of development

Specific activities



Stakeholder Engagement and Development Planning

Master Template

Contact details:

Name	Mrs Support	Primary e mail	Name.affiliation.com
Job title	Patient Liaison	Secondary e mail	Name.affiliation.com
Affiliation	Health Technology Assessment Agency	Phone	0000 00 0000
		Mobile	0000 00 0000
Category	GOLD	Development objective	A or B or C or D
Lead contact	Organisation's CEO	Secondary lead	Organisations Chair

Development objective planning:

A = build support

B = maintain support

C = build their profile

D = monitor

Activity planning:

Action	By whom	By when
Identify who HTA agency patient liaison officer is	CEO	XXX
Reach out to contact and arrange call to discuss HTA and future medicines reviews	CEO	XXX
Arrange to meet to discuss involvement and training	CEO	

In terms of how you can engage with decision makers and through what platforms, figure three on the next page provides an overview of all the main platforms that can be used. This is also provided as a checklist that you can download here.

Figure three. Platforms and approaches to decision-maker engagement

MEDIA

☐ News
☐ Consumer health article
☐ Medical article/opinion piece
☐ Policy and payer article
☐ Peer-reviewed publication
☐ Advertorials/advertisement
☐ Broadcast (radio/TV)
☐ Other...

SOCIAL MEDIA

☐ Linkedin
☐ Facebook
☐ Twitter
☐ Patient videos/vignettes
☐ Blogs
☐ On-line forums
☐ Other...

DIRECT TO STAKEHOLDER

☐ Face-to-face meeting/lobbying
☐ Teleconference
☐ Email communication
☐ WebEx
☐ Policy paper
☐ Briefing paper
☐ White paper/expert report
☐ Engaging your elected representative to act on your behalf
☐ Other...

Primary stakeholder group or stakeholder e.g.

○ HTA committee member
○ HTA scientific advisor
○ HTA patient involvement lead
○ Health policy maker
○ Commissioner of services
○ Payer of local services
○ Healthcare professional
○ Other...

Those that stakeholders turn to support their informed decisions

○ Public health
○ Local clinical experts
○ Academic institutions
○ National databases
○ Government information sources
○ Other patient organisation
○ Other...

ESTABLISHED PLATFORMS

☐ Website update
☐ Newsletter or similar
☐ Email distribution
☐ Annual meetings, AGM or similar
☐ Reciprocal links to websites
☐ Other...

HTA

☐ Meeting with patient involvement lead or similar
☐ Scientific advice on study design
☐ HTA scoping/proposal development
☐ Proposing HTA topics
☐ Primary of secondary research
☐ Submission or patient input
☐ Consultation on draft report
☐ Attendance advisory meeting or similar
☐ Appeal
☐ Other...

SERVICE REDESIGN

☐ Attendance at planning meeting
☐ Attendance at public meetings
☐ Response to consultation
☐ Response to specific request for information
☐ Attendance at committee meeting
☐ Engage your medical advisors to act on your behalf
☐ Other...

MEETINGS

☐ Conference presentation
☐ Conference seminar
☐ Conference poster
☐ Exhibition stand
☐ Bespoke meeting
☐ Networking
☐ Breakfast/dinner meeting
☐ Information in delegate pack
☐ Other...

5.0 Conclusion

Understanding who your decision-makers are, knowing how you can engage with them, and being clear on what you want to achieve as a result of this, are the first steps to effective communication planning.

It can be very beneficial to use a step-by-step approach to planning in order to make the best use of internal knowledge, prioritise those you wish to engage with and inform, and to allocate the appropriate resources to achieve this. Adopting such a planning approach may also deliver the best return on effort in those activities that advance patient involvement in improving migraine patient services and access to appropriate medicines.

Section two - MEDIA RELATIONS

1.0 Background

The media is a cost-effective route for communicating key messages to your target audiences, including specific calls to action. All media can help inform the attitudes and behaviours of your decision-makers in support of improving migraine services and access to appropriate medicines.

The aims of this section are to:

- Provide you with insight into how to undertake effective media outreach

2.0 Media Relations Objectives

Setting the objectives for your media outreach is important in refining your activities and in evaluating their outcomes. Below are two examples of objectives:

Communicate the importance of effective and high-quality migraine services, through reinforcing the unmet needs in the delivery of services for those living with migraine and the impact this has on their contribution to the economic prosperity of their country.

- Highlight the impact of poorly diagnosed and poorly managed migraine on a person's ability to work properly, and the monetary loss to them and to their employer
- Demonstrate the variations in the quality of migraine services in different areas of the country
- Call for improvements in migraine services to ensure equity of access regardless of where a person lives

Communicate the important role that patients have in ensuring they get access to appropriate migraine medicines.

- Highlight the number of patients who suffer multiple migraine attacks even when they have access to treatment
- Highlight that many patients stop treatment
- Call for new and more effective treatments that can help reduce the burden of migraine on all those affected by migraine

3.0 Understanding Your Target Media

The media can be broadly divided into two main categories: **professional** (e.g. medical publications) and **consumer** (e.g. national newspapers) and within these two broad categories they can be segmented into **print, broadcast** and **on-line (digital and social media)** categories.

By considering the needs of individual outlets and tailoring your approach accordingly, the likelihood of achieving media coverage can be dramatically increased.

Figure four below, considers the different types of media in more detail.

Figure four. Overview of the media

PROFESSIONAL MEDIA

These provide the healthcare community with current medical news and views. In terms of securing media coverage, the content of these publications is not peer-reviewed.

There may be a number of specific CNS, headache and migraine titles that can be targeted. Many of the medical publications also have an accompanying website and a regular e-news service for subscribers.

Your coverage could therefore take a number of forms e.g. news stories reporting on the launch of a campaign calling for improved migraine services, features or paid for advertorials on best practice in management or letters to editors commenting on local patient access to migraine medicines issues.

POLICY MEDIA

In certain markets, specialist titles exist that communicate information about health policy matters. These are often read by government officials, payers, purchasers, national and local policy makers and healthcare professionals who are involved in healthcare management decisions.

Your coverage could include a review of current policy regarding the construction of community-based migraine services, written by a high-profile neurologist with an interest in the delivery of better migraine diagnosis and management services.

CONSUMER MEDIA – SCIENCE AND MEDICAL SECTIONS

The consumer media provide a great mass media tool to reach a broad audience with your key messages. Don't forget that decision-makers are consumers too.

Consumer media include national and regional newspapers and web-based media. Consumer media are generally interested in the effect of a clinical issue on patients' lives. These stories can take the form of both news and in-depth feature stories, both of which are normally backed up by real-world case studies.

3.1 Target media for your activities

The media you wish to target in support of your outreach should be informed by a number of things:

- Who you want to reach and with what messages
- What your target audiences reads
- Who can inform your target audience and/or who do they turn to in support of their decision making

3.2 Generating a media list

One of the first steps to any successful media campaign is to compile a comprehensive media list of publications that are regularly read (and respected) by your target audiences.

It is possible to buy up-to-date media lists from third party companies, or you can develop your own lists. Once you have compiled your media list, you should:

- Obtain sample copies of your target media
- Contact the publications to identify which journalist your media materials should be sent to
- Confirm contact details
- Agree whether they would prefer to receive your information in hard copy or by e-mail

3.3 Questions and answers

A Questions and Answers (Q&A) document is an internal document that is developed to help ensure that media spokespeople use the same key messages. Questions and Answers can also prove a useful tool for briefing external spokespeople – for instance a Key Opinion Leader (KOL) who has agreed to speak to the press on your behalf.

Media spokespeople

4.0 Generating the Evidence and Content for Your Media Campaign

Different approaches to generating content for media activities that advance patient involvement in improving services and access to appropriate medicines are considered in Module Three, Section Two ▶ and Module Three, Section One. ▶ These sections also consider the principles behind generating evidence that demonstrate migraine patient needs, perspectives and experience.

5.0 Constructing Your Media Campaign

When constructing a media campaign, it is important to consider:

- Your target audiences
- What the media landscape is within your country
- What key messages you want to communicate
- What you want decision-makers to do as a result of reading your key messages? (the call to action)

Once you have clarified the points above, you will then need to decide the angle and approach for your story that will appeal to individual journalists. It is also helpful to provide a broad range of materials to journalists, in a relevant format, so that they have as much information as possible to put the story into context for their readers or viewers.

Some of the approaches you could consider include:

- Media spokespeople
- Press briefing
- Press release
- Media backgrounders
- Feature articles
- Advertorials, supplements and other paid for opportunities
- Case studies
- Visuals and infographics
- Digital and social media

Each of these is considered in more detail below, followed by some Top Tips for media relations.

5.1 Media spokespeople

If you choose to conduct media outreach in your country, you will need several people who can speak to the media.

These may include representatives from your organisation, patients and clinical spokespeople such as a national neurologist. All media spokespeople should be able to provide their views to the media and these should be aligned with what you want to achieve through your media outreach.

Once you have identified your media spokespeople, you should hold a meeting with them to explain how you plan to roll out your media programme and their role within this. You may also want to offer them some media and/or message training.

Once briefed and ready, your media spokespeople will be able to:

- Present at media events
- Conduct interviews with journalists
- Author feature articles and/or paid for advertorials
- Send letters to the media

5.2 Press briefings

Face-to-face contact between journalists and third-party spokespeople is an effective means of securing media coverage.

A word of caution: Journalists have little time to attend events, so it is important that you only spend time organising a media briefing if the topic is highly relevant to their readership.

5.3 Press releases

Press releases are a very effective way of communicating your key messages to the media.

Writing a press release is all about developing a piece of persuasive communication that includes key messages within a traditional news story format. By writing a press release in the standard format, and seeing the story from a journalist's perspective, the chances of generating coverage will be greatly increased.

Press releases should be supported by a media backgrounder that provides more information on the subject.

Module Two. Section One provides key messages on the burden of migraine that you could consider using. ▶

Press materials should be distributed to target media at your media briefing (if you are holding one) or by post, in the body copy of an email or by fax, depending on each journalist's preference.

Distribution of your press release should always be followed up with a phone call to the journalist to discuss the story in greater detail and to identify if they would like any further information.

Just like all media outreach, writing a press release requires thought and planning. Figure five below provides a checklist to support you write an engaging press release.

Figure five. Tips for writing a press release

Press Release should appear at the top of your release.

Structure your release. Keep it focused and to the point.

Make the title as relevant as possible; consider your audience and develop a title that is engaging and has impact.

Use a sub-title. This can be effectively deployed to further explain the story.

Use a 'Notes to Editor' section to provide information on your organisation and its work.

Provide an embargo. Ensure you detail when the information can be reported. If there is no embargo, insert *'for immediate release'* at the top of the release.

Detail where the release has been issued from. Under the title, the body of your release should begin with a dateline and the city your press release is issued from and the date

Communicate the story in the first paragraph.

Keep it short. Ideally a release should be no more than two pages.

Use independent quotes.

Provide contact details.

5.4 Media backgrounders

Backgrounders form an essential part of materials issued to the press and they should include more perspectives, facts and insights than would appear in a press release.

Fully referenced backgrounders provide journalists with credible and accurate information that they will feel confident in using.

These materials will save them considerable time, while also supporting them in the generation of accurate copy.

5.5 Feature articles

Feature articles are in-depth reviews of a subject. They are normally an effective way of gaining coverage with 'softer' news angles or for exploring a topic in more detail. Generally, features are between 800 and 1500 words long. They provide a range of views from independent parties and are not normally time-sensitive.

Features should be individually and exclusively placed with specific publications that you have selected as part of your planning. Generally, you, or a KOL should approach the publication and discuss the feature with them. The editor of the publication may have some specific needs or concerns that they think should be addressed for their audience. Once you have agreed with the editor the content, style and length of what you are supplying, you can adapt and send the copy.

Topics you might like to consider could include:

- Challenges in the provision of effective and high-quality migraine services
- The unmet needs in the treatment of migraine with current preventive therapies
- The impact of migraine and the fear of attacks on all aspects of patients' lives – what can be done to address this?

Just like all media outreach, securing features requires planning. Figure six provides a checklist to support this planning.

Referencing

Figure six. Feature article checklist

1. Who are my target audiences?
2. What publication is my preferred option, and which is my second option?
3. How can I secure a feature in this publication? Questions to consider include:
    - Can I liaise directly with the editorial team?
    - Does the publication have a features schedule?
    - Does the publication commission their own features or will they accept a pre-written feature?
    - Who will author the feature? Can I appoint a KOL as author?
4. Do I have a case study or two to support the feature?
5. Have I generated the evidence that demonstrates patient needs, preferences and experience to back up my arguments?
6. Can I enhance the feature with pictures and infographics?

5.6 Advertorials, supplements and other paid for opportunities

In addition to news and features, there is a range of media coverage opportunities that you can pay for. These include:

- **Paid for features** – feature opportunities secured through payment to a publication
- **Advertorials** – copy submitted by the sponsor for publication
- **Supplements** – normally a four to eight page insert on a specific subject
- **Meeting reports** – similar to advertorials, these are paid for reviews of a meeting or event

While paid for opportunities may be viewed as a less credible source of information by a publication's readership, they do enable the sponsor to better manage the messages and timing.

5.7 Case studies

If you are planning on undertaking any outreach to science or medical consumer journalists, patient case studies can be an important part of an effective media campaign. Most journalists like to use a case study supported by their name and a picture. However, this is not always the case and you should discuss this with the publication.

If you are working with new people who are willing to be the focus of a case study but have limited or no experience of the media, it is important that you spend some time getting to know them and that you support them fully in any activities they may undertake on your behalf.

In addition, in some countries it may be important that you include the patient's doctor in any activities you undertake in accordance with best practice.

5.8 Visuals and infographics

A visual, such as a photograph, often increases the likelihood of securing media coverage. Indeed, up to four times as many people will look at a picture than read the text on a page.

Visuals could include:

- Photographs of your spokespeople
- Pictures of a person who is featured as a case study
- Photographs of an event undertaken by your organisation that is relevant to the media story
- Graphs and charts taken from relevant clinical papers

Photographs and infographics are particularly useful for digital and social media, as are short videos that can visually communicate the importance of your media outreach activities.

5.9 Digital and social media

Digital and social media should be considered within your overall media planning and not as a separate activity.

However, the content used for digital and social media outreach should be adapted to reflect the need for more succinct messages and copy.

While those digital and social media channels you use should be guided by which decision-makers you want to engage with and how they can be reached, common platforms include:

- **Twitter** – very widely used among healthcare professionals
- **LinkedIn** – often used by professional organisations and other patient charities
- **Facebook** – less often used by medical professionals and health and care decision makers
- **Bulletin boards** – often discipline-specific and hard to post on unless a member
- **Chat rooms** – widely used by patients and their carers. They can be effective at engaging patients behind an activity or campaign
- **WebEx's, Google Hangouts or similar** – these enable you to engage with a number of journalists and spokespeople in real-time, or they can be used to communicate directly with your decision makers

Benefits of infographics

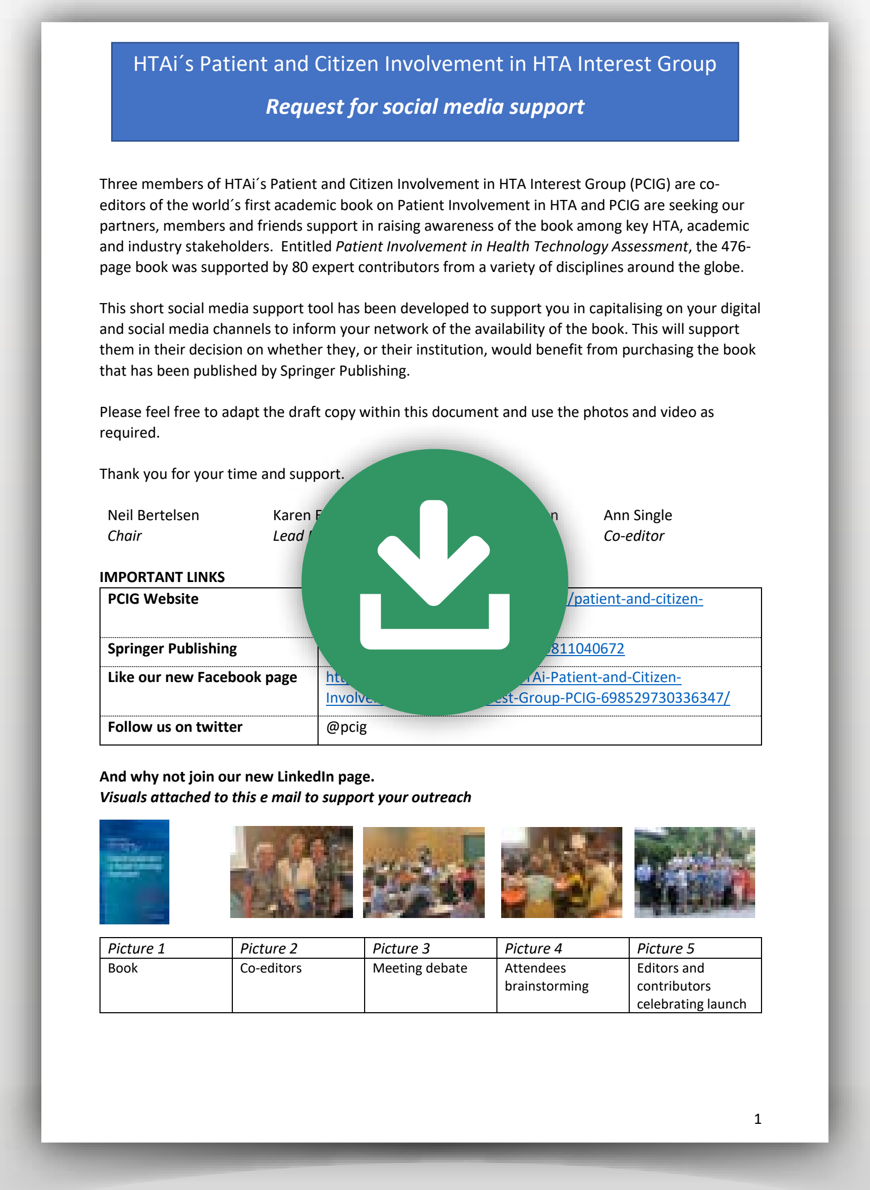
5.9.1 Aligning other patient organisations behind your digital and social media campaign

One of the advantages of using digital and social media in support of your outreach activities is that it is easy to engage with other organisations to support you in this outreach.

One of the easiest ways to do this is to develop a two/three page digital and social media engagement resource.

This easy to use resource should include the what, why and how of digital and social media outreach. It should also contain pre-drafted copy that can be used to support organisations who can clip and paste this into their digital and social media channels.

Resource



HTAi´s Patient and Citizen Involvement in HTA Interest Group

Request for social media support

Three members of HTAi´s Patient and Citizen Involvement in HTA Interest Group (PCIG) are co-editors of the world´s first academic book on Patient Involvement in HTA and PCIG are seeking our partners, members and friends support in raising awareness of the book among key HTA, academic and industry stakeholders. Entitled *Patient Involvement in Health Technology Assessment*, the 476-page book was supported by 80 expert contributors from a variety of disciplines around the globe.

This short social media support tool has been developed to support you in capitalising on your digital and social media channels to inform your network of the availability of the book. This will support them in their decision on whether they, or their institution, would benefit from purchasing the book that has been published by Springer Publishing.

Please feel free to adapt the draft copy within this document and use the photos and video as required.

Thank you for your time and support.

Neil Bertelsen
Chair

Karen F
Lead

Ann Single
Co-editor

IMPORTANT LINKS

PCIG Website	/patient-and-citizen-
Springer Publishing	811040672
Like our new Facebook page	ht Ai-Patient-and-Citizen- Involve est-Group-PCIG-698529730336347/
Follow us on twitter	@pcig

And why not join our new LinkedIn page.
Visuals attached to this e mail to support your outreach

Picture 1	*Picture 2*	*Picture 3*	*Picture 4*	*Picture 5*
Book	Co-editors	Meeting debate	Attendees brainstorming	Editors and contributors celebrating launch

1

Source and format

HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG)
Four-page word document

Resource title

Example: HTAi PCIG digital and social media guide for book promotion

Direction for use

This is a Word document that provides an example of a digital and social media guide that was used to support the promotion of Springer Publishing's book on Patient Involvement in HTA.

Use this as a guide to drafting your own similar guidance.

6.0 Summary

Media relations can be a very effective way to reach key decision-makers. With effective planning and with the support of independent media spokespeople, it can form the bedrock to other decision-maker outreach activities.

The table below provides some concluding thoughts on effective media relations.

Table two. Media outreach Top Tips

Be clear on who you want to reach	Make sure you know who you want to reach, why, what you want them to do and what media they may be informed by, or what media that they may turn to in support of their informed decision-making.
Know the media outlet and its target audience	Don't just buy media lists. It is important to research and read the publication to find out more about their preferences and editorial profile. Try to find out when and how they have reported about the disease area.
Contact the right person	Knowing who to contact saves you time and ensures the information gets to the right person. Remember, most journalists are so pressed for time that they don't bother forwarding materials to an appropriate colleague.
Respect deadlines	All publications are time sensitive, whether it be daily, weekly or monthly deadlines. Always find out deadlines and avoid calling just prior to these.
Tailor your story and make it relevant	Try to find a different angle or a different aspect of the same story for key publications.
Choose the right way of communication	All journalists have their own preferences for being contacted. If you do call via the telephone, try to grab their attention within 10 seconds or be prepared to leave a concise message on an answering machine. Media releases are not necessary in some cases. An e-mailed set of facts can do the job and may spark more interest and encourage a call.
Get noticed	Write an informative subject line, "press release" is not strong enough. The first paragraph counts: put the most relevant information here and give the reporter a reason to scroll down. Try to avoid attachments as they are often viewed as unsafe and inconvenient (may take too long to download by travellers) – plain text is best.
Prepare for media calls	If you receive a call from a reporter, remember that time is of the essence and most reporters prefer to speak to medical experts or top-level executives. Make your colleagues and thought leaders available, brief and train them. Always call the journalist back once you are prepared, however, take notice of their deadlines.
Follow up intelligently	Do not call to find out if your press release has been received or when coverage is expected. This is a major turn-off to reporters and editors alike. Plan your call and offer something of relevance to the publication readership.
Repeat your key messages	Reinforce your key messages at all opportunities. Keep them focused, simple and have no more than five.
Be enthusiastic	If you are not enthusiastic about the story, it is unlikely that a journalist will be.
Nothing is ever 'off the record'	Never say anything to a journalist that you would not want to see in print.

Section three - PUBLIC AFFAIRS

1.0 Introduction

As the demand for healthcare rises, and budgetary pressures on governments increase, the external environment becomes a much more difficult arena. Understanding the policy environment and taking steps to inform those that make policies around patient involvement, and in improving migraine services and access to appropriate medicines should be considered as an important component of any programme.

Government decisions on healthcare, political attitudes, and the perception of unmet needs in disease management (and the priorities within these) can have a significant impact on reducing the burden of migraine.

The aim of this section is to:

- Provide you with an introduction to public affairs and how you could use this in support of your advancing patient involvement in improving migraine services and access to appropriate medicines activities

Sharing knowledge with the external environment through public affairs can therefore help create a more favourable environment for other activities you may wish to undertake to advance patient involvement in improving migraine services and access to appropriate medicines.

The ultimate aim of public affairs is to have governments and regulatory authorities view you as an important contributor in informing their views on healthcare delivery before a new policy is developed, or decisions relating to specific services or medicines are made.

Public affairs

2.0 Who are your policy stakeholders?

- Politicians
- Those involved in taking relevant healthcare decisions e.g. officials, ministers, parliamentarians
- Politicians/political bodies and political advocacy groups (official and otherwise) who influence healthcare decisions

3.0 Questions to Consider Before Undertaking Policy Stakeholder Outreach

While policy makers should be considered as part of your overall Gold/Silver/Bronze stakeholder planning, specific questions relevant to them are:

- Who has the power and who is the decision maker?
- Who influences them?
- How far down the influence chain should you go?
- How best to engage with them?
  - Directly?
  - Through contacts?
- Who are potential allies?
  - Trade associations?
- Who knows the legislative process (e.g. your lawyers)?
- What contacts do you have already? How could these be leveraged?

4.0 Summary Overview Public Affairs

The following provides a step-by-step overview to planning a public affairs programme.

Activities A to C are aligned with the stakeholder mapping and engagement activities.

A.0 Decide where policy-makers can add value to your improving patient services and access to appropriate medicines work, or where your work can be used to inform decision-makers.

B.0 Build a list of policy makers that you may need to engage with in your improving services and access to appropriate medicines. Incorporate these into your Gold, Silver and Bronze database.

When building your list of policy-makers you should be aware of the fact that the target audiences are likely to be small.

C.0 Plan engagement activities for each of your Gold/Silver policy-makers and complete a one-page planning tool that:

a. Clarifies your development aim by policy-maker – improve relationship, maintain relationship, improve their profile or monitor their activities

b. Identifies what you need to do to support your development aim

c. Details how, when and who will engage with them

When developing your engagement activities, you should be aware of the fact that many policymakers may not be medically qualified. Messages should always be kept simple and short, with the opportunity for them to seek further, more detailed information if they wish.

In addition, you need to consider that policy-makers will nearly always have their own agenda. You should therefore:

- Know their priorities
- Align with them wherever possible
- Position yourself as part of the solution
- Try to build relations for the long-term

C.1 Engagement activities

There are a number of engagement activities you could undertake. This section considers the four most common activities undertaken by migraine patient organisations.

C.1.1Position papers – stating your case

Position papers are an important component to any public affairs activity and should be developed from the core messages you are using for your activity.

Guidance:

- Be positive and constructive
- Align your paper to existing national priorities
- Tailor your paper to your audience – align as much as possible with their politics/ administrative culture
- Remain as concise as possible and get to the point quickly
- Always try to provide an executive summary
- Support your arguments with evidence on real-word patient needs, perspectives and experience
- Back up your contents with additional information in the appendices. For example, clinical papers, results from a patient survey you may have undertaken

C.1.2Letters - simple and concise

If you are sending a position paper, a short, personal covering letter adds considerable impact.

Within this letter adapting the position paper or the executive summary can:

- Demonstrate that you believe the recipient merits special attention
- Increase your chances of attracting attention, and therefore it being read
- Increase the chances that you will receive a positive response

Personalised letters should always be used when targeting high-level politicians, officials, or other decision-makers.

Realistically, however, face-to-face meetings will often be the only way to ensure a particular point gets received as you intend it.

C.1.3Face-to-Face meetings

Face-to-face meetings are an important approach to engaging with policy makers, although they may be hard to book. Speaking to your local elected representative is always a good start to understanding how to book appointments with those policy makers you wish to meet.

Before meeting in person, make sure that you have all your key messages and evidence that backs this up prepared. Also, be clear in what you want to ask the policy maker to do.

When meeting in person, make sure you deliver the two or three key messages you want to deliver while you have the person's full attention. You can then illustrate the points and return to reinforce them as you progress with your discussion.

Also, when meeting in person, don't assume that those you are meeting will understand all the implications of migraine – it is more likely that they will not (although they may think they do). At the same time, don't get stuck on small details, make sure you put the emphasis on things that matter.

C.1.4Parliamentary/political events

Parliamentary and political events provide an opportunity to engage with key political decision makers. For example, a seminar or a conference can be valuable in:

- Raising the profile of your organisation
- Raising awareness of the unmet needs in migraine management
- Lobbying for better involvement of patients in decisions about access to medicines

As with face-to-face meeting, be ready to deliver your key messages in a succinct and clear way, while offering to provide more information at a later date.

5.0 Coalition Building

In any public affairs campaign, a coalition of stakeholders is often more effective than an individual or single organisation.

Indeed, patient organisations may benefit from working with their colleagues in a range of settings, including other patient organisations, scientific societies and universities. Many of these groups may already be involved in public affairs; for example, they may have contributed to previous policy in the area of CNS.

Joint activities by several groups, who between them represent the views of a large number of patients, may also be very powerful. By presenting a united voice, there may be a greater chance that this voice will be heard.

Professional groups (e.g. groups of doctors, nurses, or pharmacists) may also share your organisation's views. If so, it may be worth reaching out to them to discuss a potential partnership.

6.0 Summary

Government decisions on healthcare and political attitudes on the unmet needs in diseases management (and the priorities within these) can have a significant impact on reducing the burden of migraine. However, these decisions cannot and should not be made without the voice of the patient and those that represent them being heard.

Patients are experience-based experts. People living with migraine know how it impacts on different aspects of their lives. They have experience of treatment. They know how local healthcare services are provided. They know what needs are not being met in their care and they have preferences about their healthcare. No one else can explain the impact of a disease or a medicine better than a patient.

Public affairs is one approach to ensuring that the patient voice is heard, and it should be considered as an integral part to any programme that aims to advance patient involvement to improve migraine services and access to appropriate medicines.

The 10 well-known golden rules of successful public affairs

Public affairs, like marketing, is as much an art as it is a science. The 10 golden rules of public affairs contain the guidelines for good lobbying practice in any situation:

1 **Build a compelling case**

It is vital that you fully understand the issues before you can expect others to understand you. Build your case on facts and data, and design it with your results in mind. Seek the support of experts to help you do this.

2 **Plan carefully**

As with any project, it is essential to plan before embarking on any action. However, make sure you exploit any unexpected opportunities that may arise.

3 **Aim for realistic goals**

There is no point trying to move the immovable. Set objectives that are achievable and will have the most impact on your business. In setting these be pragmatic, be clear on your own capabilities and don't expect overnight success.

4 **Behave with integrity**

Integrity, honesty and transparency are essential to any communication programme.

5 **Keep it simple**

It is easy to make things too complicated. Simplicity is key.

6 **Take a positive approach and look for solutions**

Positive, solution-orientated communication always delivers the best results. For example, while you may have identified that there is an issue with patients accessing appropriate medicines, you should propose a solution to dealing with this also.

7 **Form alliances wherever possible**

An argument is usually stronger if it comes from more than one source. Principles of alliance building follow in the points below.

8 **Understand and respect all parties**

You will find it much simpler to effectively inform others if you know where they are coming from. Building relationships is an important part of successful lobbying.

9 **Take a disciplined approach**

Make sure you stay in control of the lobbying process. The more people that are involved, the more important it is to take a co-ordinated approach.

10 **Ask for assistance of experts**

If you do not have the relevant skills in-house, think about who else can help you. Also think about who else could help you get your message across. These may include:

- Other patient organisations
- Local key opinion formers
- Government affairs consultancies
- Local experts
- Local lawyers

MODULE FIVE

Spotlight on migraine services and access to appropriate medicines

Evaluation

Evaluation of your Toolkit

1.0 Introduction

Your Toolkit is a comprehensive resource that has been developed to support patient organisations throughout the world to optimise patient involvement to improve migraine outcomes. The focus of your Toolkit is the role of patient involvement in improving migraine services and access to appropriate medicines.

However, your Toolkit is just the start. Over the coming months and years, we hope to build on this Toolkit and its contents with a range of initiatives and programmes that further advance organisations' capacity and capability in this important area.

We Would Value Your Feedback!

To ensure that future activities meet your needs, and to understand what how useful you found your Toolkit and its contents, where it can be improved and to identify additional information we can incorporate into future updates, we would very much value your feedback.

We have tried to keep this as simple as possible.

Download the attached word document and return this to us via email

Thank you for your support!

A Word copy of the evaluation form can be downloaded **here**

Toolkit Evaluation

Your feedback is important to us. Please complete the questions below and return this to info@EMHA.com. We anticipate that this will take no more than ten minutes.

General questions

1. How useful do you think the Toolkit will be to your overall patient involvement work and activities?

Not at all useful	**Somewhat useful**	**Useful**	**Very useful**	**Extremely useful**
☐	☐	☐	☐	☐

Additional comments:..

....

2. How useful do you think the Toolkit will be in advancing the role of patient involvement in improving migraine services?

Not at all useful	**Somewhat useful**	**Useful**	**Very useful**	**Extremely useful**
☐	☐	☐	☐	☐

Additional comments:..

....

3. As a result of reviewing your Toolkit, did your overall expertise/ knowledge increase in the topic of advancing the role of patient involvement in improving migraine services?

☐ **YES**

☐ **NO**

If no please explain why: ....

....

4. As a result of reviewing your Toolkit, will you be doing anything differently in terms of patient involvement in improving migraine services?

☐ **YES**

☐ **NO**

If yes, please list the top three things you will be doing differently: ....

....

If no, please explain why: ....

....

5. How useful do you think the Toolkit will be in advancing the role of patient involvement in access to appropriate medicines?

Not at all useful	**Somewhat useful**	**Useful**	**Very useful**	**Extremely useful**
☐	☐	☐	☐	☐

Additional comments: ....

....

6. As a result of reviewing your Toolkit, did your overall expertise/ knowledge increase in the topic of advancing the role of patient involvement in access to appropriate medicines?

☐ **YES**

☐ **NO**

If no please explain why: ....

....

7. As a result of reviewing your Toolkit, will you be doing anything differently in terms of patient involvement in access to appropriate medicines?

☐ **YES**

☐ **NO**

If yes, please list the top three things you will be doing differently: ....

....

If no, please explain why: ....

....

8. Would you recommend the Toolkit to your colleagues or other organisations you work with?

☐ **YES**

☐ **NO**

If no please explain why: ....

....

Toolkit contents and layout

9. How good do you think the content of your Toolkit is?

Not at all good	Somewhat good	Good	Very good	Extremely good
☐	☐	☐	☐	☐

Additional comments:..

....

10. How relevant is the content of your Toolkit to your organisation’s work?

Not at all relevant	Somewhat relevant	Relevant	Very relevant	Extremely relevant
☐	☐	☐	☐	☐

Additional comments:..

....

11. How easy was the content of your Toolkit to understand?

Not at all easy	Somewhat easy	Easy	Very easy	Extremely easy
☐	☐	☐	☐	☐

Additional comments:..

....

12. How easy was the content of your Toolkit to navigate?

Not at all easy	**Somewhat easy**	**Easy**	**Very easy**	**Extremely easy**
☐	☐	☐	☐	☐

Additional comments:..

....

13. Do you have suggestions for other areas and content that could have been included in your Toolkit.

☐ **YES**

☐ **NO**

If yes, please list these below: ....

....

....

14. Any other comments?

Finally, we would like to undertake more in-depth research into the Toolkit through 30 minute structured interviews. Would you be happy to support us in this? If yes, we will send you more details in due course

☐ **YES**

☐ **NO**

Please return your completed form to: (tbc)

Thank you for taking time to complete this evaluation of your Toolkit.

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**As of June 2018, Migraine Action has closed.*