From: S47E

To: Ross, Victoria DR 1; Williams, Felicity DR; Kelaher, Cath DR

Subject: Clinical Advisory Group: Anti-malarial co-design workshop [SEC=UNCLASSIFIED]

Date: Wednesday, 11 December 2019 12:47:09 PM

Attachments: image001.png

Dear All.

Thank you for your involvement up until this point with DVA's efforts to address the issue of veterans concerned with having taken the anti-malarial drugs tafenoquine and mefloquine.

Work on this issue has now progressed and DVA has commenced working with BUPA to develop anti-malarial health assessments. As you will recall from the initial workshop in September where the project design was initially discussed, BUPA will be convening a co-design workshop of clinicians, namely a Clinical Advisory Group. The aim of the workshop will be to provide input and review BUPA developed materials and processes for the conduct of a medical assessment that a concerned veteran will present for. Once finalised, this workshop will complete an important step towards the launch of the health assessment program in early 2020. A Veterans and Families Stakeholder co-design workshop will also be conducted around the same time to supplement the design and delivery of the health assessment process.

The co-design workshop has been proposed to take place at the DVA offices in Canberra in the second half of January 2020. While these details are yet to be finalised, I wanted to touch base with you to ascertain your availabilities over the January period. Thus far, we have identified Thursday to be a preferable day with our Chief Health Officer and DVA Executive available to attend a half-day workshop on either the 16th, 23rd or 30th of January.

I am seeking your interest in being part of this clinician co-design group and confirm whether we can provide your name and contact email address as a potential participant. As per the Statement of Work, BUPA will then be in contact with you on the finer details.

If you have any further questions or would like to discuss any of the issues raised here, please feel free to contact me on the number below.



From: Smart, Tracy AVM 1

To: OCJ HLTH; Schramm, Craig BRIG; shanks, dennis PROF; Ross, Victoria DR 1; Brennan, Leonard BRIG

Subject: FW: MO advice re mefloquine announcement and govt response [DEM=Sensitive]

Date: Sunday, 10 March 2019 6:31:24 PM

Attachments: <u>image002.png</u>

070319 Minister TPs anti-malarial KP (002).docx 070319 VAXX Chester Release - Mefloquine.docx

O - - - : 11: - -

Folks

My gut feeling is that this is a good thing and should finally mean the issue is closed for us...I hope.

Cheers

Tracy

Tracy Smart

Air Vice-Marshal

Commander Joint Health/Surgeon General ADF

Joint Health Command

CP2-7-121

Department of Defence CANBERRA ACT 2600

ph: 02 6266 3919

mob: \$22

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From: Hancock, Veronica <xxxxxxxxxxxxxxxx@xxx.xxx.xx>

Sent: Friday, 8 March 2019 7:00 PM

Ccs47E@dva.gov.au>s47E@dva.gov.au>s47E@dva.gov.au>

Subject: MO advice re mefloquine announcement and govt response [DLM Sensitive]

Hi again Tracy,

Following on from my email earlier this week, please find attached the proposed media release and talking points which cover the tabling of the Government Response, the early announcement of the Budget measure and the publication of the UQ research.

We are currently awaiting a letter from the PM which will include the necessary approval for an early announcement and tabling of the Response. Minister Chester has expressed an intent to table the Response and announce (via media release) the measure at the same time. The President of the Senate must also sign off on the Government Response prior to it being tabled.

At this stage, it looks like this is all likely to occur mid-next week.

Will keep you posted.

Regards, Veronica



To support those who serve or have served in the defence of our nation and commemorate their service and sacrifice.



The Department acknowledges the Traditional Owners of the land throughout Australia and their continuing connection to country, sea and community. We pay our respect to all Aboriginal and Torres Strait Islander peoples, their cultures and to their elders past and present.

Sent: Tuesday, 5 March 2019 10:25 AM

Concitive

Thanks Veronica – appreciate the heads up. We sensed that the MO was looking for more ways to appease the concerns.

BTW we also got a media request yesterday re the Labor announcement but were still waiting on DVA input. I have attached what was cleared from us – pretty vanilla but its really difficult for us to respond to these requests when DVA has the lead and is the only area that the MO is really talking about re the issue. In future we will try to push these back in to your space rather than trying to answer in a vacuum. Hope this is ok.

Cheers

Tracy
Tracy Smart

Air Vice-Marshal
Commander Joint Health/Surgeon General ADF
Joint Health Command
CP2-7-121
Department of Defence
CANBERRA ACT 2600

ph: 02 6266 3919 mob: \$22

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Sent: Monday, 4 March 2019 5:42 PM

Cc: S47E @dva.gov.au>

Subject: MO advice re mefloquine announcement and govt response [DEM-Sensitive]

Hi Tracy,

For info. Dylan called from the Minister's office this afternoon to advise that following discussions with Minister and PMO, Minister is intending to make an early announcement of the mefloquine Budget measure, at the same time as tabling the Government response to the Senate mefloquine inquiry.

The Budget measure is a \$2.1 million commitment "Response to Senate Inquiry into antimalarials mefloquine and tafenoquine" that will support veterans who are concerned about having taken the anti-malarial drugs mefloquine or tafenoquine during their service. This initiative will deliver a national program of comprehensive health assessments for veterans, providing a whole-of-person assessment which will allow for identification of potential service related illness, disease or injury, and where appropriate referral for further specialist assessment, treatment and support. This measure will be implemented from 1 July 2019 through Open Arms.

We do not yet have confirmation as to when the announcement & tabling will take place (although note that the Government response was due to be tabled today). One possibility is next week during a visit to Brisbane.

We are presently working on adding a para to the introduction section of the draft response to announce the measure, and preparing a media release.

We will provide you a copy of the revised response once FAS cleared.

Thanks, Veronica



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Minister talking points

Anti-malarial funding and the Government's response to Senate Inquiry into the use of Quinolone anti-malarial drugs Mefloquine and Tafenoquine

Prepared by: Cleared by: Date:

Anti-malarial funding

- The Government is committing \$2.1 million to a new initiative to support veterans who are concerned about having taken the anti-malarial drugs mefloquine or tafenoquine.
- This initiative will deliver a national program that will provide concerned veterans with the option to receive a comprehensive health assessment to identify service-related illness, disease and injury.
- Where appropriate, the veteran will be referred for further specialist assessment, treatment and support.
- This initiative responds to concerns heard from veterans during both the recent Senate Inquiry and the Mefloquine and Tafenoquine Consultation Forums coordinated across Australia last year.
- This initiative will be implemented from 1 July 2019.
- The Department of Veterans' Affairs (DVA) provides help to veterans who are concerned about having taken the anti-malarial medications mefloquine and tafenoquine.
- DVA has a designated phone line —1800 633 567 for veterans with enquiries, including available support, non-liability health care and the claims process.
- DVA can also pay for treatment for any mental health condition without the need for the conditions to be accepted as related to service. This is known as non-liability health care, and it is available to anyone who has served a single day in the full-time ADF and some reservists.
- Open Arms Veterans and Families Counselling provides free, confidential, nationwide counselling and support for eligible current and former ADF members and their families and can be contacted 24/7 on 1800 011 046.

Government response to Senate Inquiry into the use of Quinoline anti-malarial drugs Mefloquine and Tafenoquine in the ADF

- The Government has presented to Parliament the Government response to the Senate Inquiry into the use of Quinoline anti-malarial drugs Mefloquine and Tafenoquine in the Australian Defence Force (ADF).
- The Government largely supports the view of the Senate Inquiry Committee and the recommendations.
- The Government response is available on the Senate Inquiry website <u>www.aph.gov.au/Parliamentary_Business/Committees/Senate/Foreign_Aff</u> <u>airs_Defence_and_Trade/Mefloquine</u>) and the DVA website <u>www.dva.gov.au/mefloquine</u>.
- The Senate Inquiry began in June last year, with both the Department of Veterans' Affairs and the Department of Defence having provided submissions to the Inquiry, and appearing at the public hearings in Canberra.
- The Government would like to thank the individuals and organisations who
 participated in the Inquiry for their contribution to this important issue.
- The evidence provided to the Inquiry adds to the Government's understanding of how we can further serve and support veterans and their families.
- The Government would like to acknowledge that for some it was a difficult process to provide details about their concerns. Should any of these individuals need support, or someone to talk to, Open Arms – Veterans and Families Counselling provides 24/7 free, confidential, national-wide counselling.

University of Queensland research

- The research was commissioned in 2017 by DVA and Defence in response to concerns about the use of anti-malarial medications during service.
- This is part of the Government's ongoing efforts to understand the effects of some of these medications used in the Australian Defence Force (ADF).

 DVA and Defence will consider the report as part of further work to provide support to veterans who are concerned about their use of anti-malarial medications during their service.

If asked

What does this measure do?

 This initiative will deliver a national program of comprehensive, wholeof-person health assessments for veterans. This will allow for early identification of service related illness, disease and injury. Veterans can be referred for specialist assessment, treatment and support as required.

What does this measure respond to?

• This initiative responds to health related concerns heard from veterans at both the recent Senate Inquiry and the Mefloquine and Tafenoquine Consultation Forums which were held across Australia last year.

When will I be able to have my health assessment?

• Health assessments will be available to veterans after July 2019.

How do I book a health assessment?

- DVA is working on the implementation of this initiative.
- To register your interest in accessing a Health Assessment, please contact 1800 MEFLOQUINE (1800 633 567) to provide your name and contact details.

Once I have had my health assessment, what will happen next?

• Where required, veterans will be referred for further specialist assessment, treatment and support.

What were the Mefloquine and Tafenoquine Consultation Forums?

- Between September and November 2018 DVA hosted seven Mefloquine and Tafenoquine Consultation Forums.
- The forums were held in Adelaide, Sydney, Brisbane, Townsville, Perth, Melbourne and Darwin.
- The purpose of the forums was to hear from current and former members of the ADF who are concerned about having taken mefloquine or tafenoquine, and outline the treatment, services and support available.
- A summary of the key themes discussed by forum attendees and the resources given to the attendees can be accessed via the DVA

Mefloquine and Tafenoquine Information webpage (www.dva.gov.au/mefloquine).

What about support for acquired brain injury or neurocognitive disorders?

• If you would like further information about support available to veterans who identify as having an acquired brain injury or neurocognitive disorder, please call 1800 MEFLOQUINE (1800 633 567).

What support is currently available?

 Information about support available to veterans who are concerned about having taken mefloquine or tafenoquine during their service is available at the Mefloquine and Tafenoquine Information webpage: www.dva.gov.au/health-and-wellbeing/health-services-andconditions/mefloquine-and-tafenoquine-information



The Hon Darren Chester MP

Minister for Veterans' Affairs
Minister for Defence Personnel
Minister Assisting the Prime Minister for the Centenary of ANZAC

MEDIA RELEASE

XX March 2019

GOVERNMENT COMMITS \$2.1 MILLION TO ANTI-MALARIAL INITIATIVE

FUNDING has today been announced for a new \$2.1 million initiative to support veterans who are concerned about having taken the anti-malarial drugs mefloquine or tafenoquine.

Minister for Veterans' Affairs Darren Chester said this initiative will be implemented from 1 July 2019, and deliver a national program to concerned veterans with the option to receive a comprehensive health assessment to identify service-related illness, disease and injury.

This initiative responds to concerns heard from veterans during both the recent Senate Inquiry and the mefloquine and tafenoquine consultation forums coordinated across Australia last year.

"The Government is pleased to present to Parliament its response to the *Senate Inquiry into the use* of Quinoline anti-malarial drugs mefloquine and tafenoquine in the Australian Defence Force (ADF)." Mr Chester said.

"We largely support the views of the Senate Inquiry Committee and its recommendations, and we acknowledge that some current and former ADF personnel have complex health concerns."

The evidence provided to the Inquiry adds to the Government's understanding of how it can further serve and support veterans and their families.

Mr Chester also thanked the individuals and organisations who participated in the Inquiry for their contribution to this important issue.

"I would also like to acknowledge everyone who put forward their views on what is an issue this Government takes very seriously," Mr Chester said.

"For some it was a difficult process to provide details about their concerns. Should any of these individuals need support, or someone to talk to, Open Arms — Veterans and Families Counselling provides 24/7 free, confidential, national-wide counselling.

"For those veterans who are who are concerned about having taken the anti-malarial medications mefloquine and tafenoquine or are seeking information about support available, please contact the Department of Veterans' Affairs (DVA)."

Additionally, the report by the University of Queensland on the *Self-reported health of Australian Defence Force personnel after use of anti-malarial drugs on deployment* has also been released today.

Open Arms – Veterans and Families Counselling, provides support for current and ex-serving ADF personnel and their families. Free and confidential help is available 24/7. Phone 1800 011 046 (international: +61 1800 011 046 or +61 8 8241 4546) or visit www.OpenArms.gov.au

"This is part of the Government's ongoing efforts to understand the effects of some of these medications used in the Australian Defence Force (ADF)," Mr Chester said.

A copy of the full Government response is available on the Senate Inquiry website.

A copy of the University of Queensland on the *Self-reported health of Australian Defence Force* personnel after use of anti-malarial drugs on deployment is available on the Department of Veterans' Affairs website.

DVA can be contacted on the designated 1800 MEFLOQUINE (1800 633 567) phone line for support.

ENDS

MEDIA CONTACTS: Rachel Tharratt: 02 6277 7820 DVA Media: 02 6289 6466

Office of the Hon. Darren Chester, Canberra ACT.

From: S47E on behalf of CCS.MENTAL.SOCIAL.HEALTH
To: Kelaher, Cath DR; Williams, Felicity DR; Ross, Victoria DR 1

Subject: Invitation to participate in Anti-malarial Health Assessment Co-design Workshop (23 January 2020) [SEC=UNCLASSIFIED]

Date: Friday, 20 December 2019 5:17:51 PM

Dear Cath, Vicki and Felicity,

I am emailing to invite you to participate in a clinical workshop next month to co-design a comprehensive health assessment tool and clinical guidance for those veterans who are concerned with having taken anti-malarial medications Mefloquine or Tafenoquine.

The workshop will be held on **23rd January 2020, 11am-2pm AEDT** at DVA's Canberra Office (21 Genge Street, Canberra City). A working lunch will be provided, as will any interstate travel to the workshop.

As you know, a number of veterans are of the view that they are suffering an acquired brain injury due to taking anti-malarial medications Mefloquine or Tafenoquine 20 years ago. There was a Senate inquiry into this very issue in 2018 which found there was no evidence to support this but noted that those who believed this have real symptoms (possibly related to many other factors) and should be offered care.

https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Foreign_Affairs_Defence_and_Trade/Mefloquine/Report

In response, DVA is now working to implement the Australian Government's initiative to deliver a national program that will provide concerned veterans with the opportunity to receive a comprehensive health assessment to identify service-related illness, disease and injury. In addition, Open Arms' neuropsychological screening pilot in Townsville will commence from February where a number of veterans who have taken Mefloquine live (and many thanks for your work in support of this in particular).

DVA has engaged the services of an external provider – BUPA Australia - to develop and deliver the health assessments. The health assessments will be conducted by a General Practitioner who has an understanding of the health concerns of those who have taken Mefloquine or Tafenoquine, the complex conditions with which some veterans may present and the veteran experience. Veterans will be referred for further specialist assessment, treatment and support as necessary.

A critical step in the program will be the development of the clinical health assessment tool and supporting materials and guidance and as part of this we have asked that there be a co-design workshop. This will not only ensure the clinical efficacy of the tools, but also ensure the assessment itself retains its clinical focus. As such, broader veteran/family stakeholders will be consulted separately on other assessment related materials, such as patient consent forms and information, the communications framework and advice on how this veteran cohort can best attain a positive experience from the assessment.

Please let us know if you are available to attend the clinicians workshop (RSVP to www by 10 January 2020 would be appreciated).

DVA has asked BUPA to make the travel arrangements for interstate participants. Please let us know if travel support is required.

I look forward to hearing from you and working with you again in the new year.

For now, I wish you all the best this holiday season.

Kind Regards,



To support those who serve or have served in the defence of our nation and commemorate their service and sacrifice.



From:

Ross. Victoria DR 1

Subject: Participation in workshop on delivery of meflgouine health assessment [SEC=UNCLASSIFIED]

Date: Friday, 16 August 2019 1:01:57 PM

Hi Vicki,

Cc:

As discussed, we are working to engage Bupa to deliver and design the mefloquine and tafenoquine health assessment budget measure through the new Defence health contract. As a starting point we are organising a scoping workshop which help define how the assessments will be delivered, the breadth of co-design activities and how we can utilise existing guidelines, services etc. We would like to have Defence represented at this workshop. At this stage we are looking to have the workshop in the week of 26 August, most likely Thursday 29 August, in Canberra.

Bupa will provide a draft agenda for the workshop by early next week.

Could you please let us know who from Defence should attend the workshop?

Let me know if you have any further questions.

Thanks,



s47E

Assistant Director | Mental and Social Health Policy

Department of Veterans' Affairs

P: S47E

E: 847E

<u>@dva.gov.au</u> | GPO Box 9998, CANBERRA

ACT 2601

To: S47E Tindall, Katherine CAPT - RAN; Ross, Victoria DR

1; Williams, Felicity DR; Kelaher, Cath DR; Lawson, Stephen CAPT - RAN 2; S47E

s47E s47F s47F

s47E

Subject: Planning Workshop - Health Assessments for veterans concerned about having taken mefloguine and

tafenoquine [SEC=UNCLASSIFIED]

Start:Wednesday, 4 September 2019 12:00:00 PMEnd:Wednesday, 4 September 2019 5:00:00 PM

Location: DVA Offices - Level 8 - Millen Room (Bridge Conference) - 21 Genge St Canberra

Attachments: image001.png

Final Agenda - DVA Bupa Health Assessment Scoping Workshop.docx

Update 3/9 – Attached is the agenda for the workshop tomorrow.

For Bupa and Defence attendees, please call on arrival and we will escort you to the meeting room

47E

Thanks

s47E

Good Morning

Confirming the Planning Workshop will be held tomorrow from 12pm-5pm in the Millen Room, DVA Canberra Offices (21 Genge St Canberra).

Lunch will be provided. An agenda will follow later today.

Kind Regards

s47E

Good Afternoon

This meeting invite is to replace the one cancelled by \$47E earlier today.

This invitation is a placeholder for an initial co-design/planning workshop with the initiative delivery partner, Bupa, for the Health Assessment for veterans concerned about having taken mefloquine and tafenoquine.

The intent of the workshop is to commence the co-design and define the scope of the initiative.

An agenda is being drafted. All papers will be shared with attendees ahead of the day.

It is anticipated that not all participants will be required for the entire duration of the workshop (12pm-5pm).

More details about the times particular participants will be required during the workshop will be available soon.

Thank you

If you have any questions, please do not hesitate to free to reach out.

Kind Regards

s47E

Policy Officer I Mental Health Policy

Wellbeing Policy Branch I Veterans' Services Design Division I Department of Veterans' Affairs

p: \$47E w: www.dva.gov.au w: www.dva.gov.au http://www.dva.gov.au/

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DVA anti-malarial scoping workshop



Date	Wednesday 4th September 2019
Time	12pm to 5pm
Location	Department of Veterans' Affairs, Canberra
Meeting	DVA anti-malarial scoping workshop
Attendees	Bupa: S47F Program coordinator / workshop facilitator DVA / ADF representatives

Introductions & setting the scene – 30 minutes

12:00PM

Round of introductions

Bupa – why are we here today?

- Initial scoping workshop
- Plan for initiation of health assessments
- Phase II planning design national program and network, codesign process
- Operations
- Today's outcomes Bupa will put together a detailed project plan and scope / proposal based on today's decisions
- Things not in scope for today (e.g. discussing in depth program documentation)

DVA - provide brief program context

- Brief history
- Description of veteran experience and needs
- Current context
- Program objectives and desired outcomes



DVA anti-malarial scoping workshop

Health assessment – 75 minutes

12:30pm

- Establish objectives and desired outcomes
- Plan initial program roll out: WHAT specifics, WHERE location, WHO number of clinicians, clinician attributes, number of veterans, HOW patient flow
- Communications, outreach and engagement plan (veteran and clinician)
- Timelines, draft action plan
- Evaluation metrics

Decisions/Action Items	Who	Timeframe

Break - 15 minutes

1:45PM

Working lunch

Comprehensive national program codesign – 90 minutes

2:00PM

- Establish objectives of codesign phase
- Decide on any items that should not be included in codesign (e.g. DVA non-negotiables)
- Stakeholders who should be involved in the codesign phase? Outreach plan.
- Deliverables (e.g. clinical guidelines/work instructions, process maps, clinical pathways, etc.)
- Timelines, including any workshops, draft action plan
- Approval processes

Decisions/Action Items	Who	Timeframe

DVA anti-malarial scoping workshop



Risk management – 45 minutes

3:30PM

• Discussion of project risks and management plan

Decisions/Action Items	Who	Timeframe

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4:15PM

- Timelines
- Early considerations

Decisions/Action Items	Who	Timeframe

Wrap up & next steps – 15 minutes

4:45PM

- Consider workshop round 2 if needed
- Decide on approval processes for deliverables stemming from today (proposal, scope of work)

Decisions/Action Items	Who	Timeframe

From: Ross, Victoria DR 1

To: Kelaher, Cath DR; Tindall, Katherine CAPT - RAN; Lawson, Stephen CAPT - RAN 2; Williams, Felicity DR

Subject: prep for DVA co-design workshop [SEC=UNCLASSIFIED]

Date: Monday, 2 September 2019 10:21:00 AM

Attachments: 20190322 GP Clinical management guidelines - veterans with complex health issues.pdf

UK GWS assessment.pdf

AFP Managing unexplained symptoms in GP 2015.pdf

UNCLASSIFIED

Hi everyone,

I think we're still meeting with DVA this Wednesday although it's a bit confusing. Attached is some background info, perhaps we could discuss our position on Tuesday so we're all

on the same page.

From my perspective the issues are

- It's not all about the mefloquine. The veterans at whom this assessment is aimed are those with complex symptomatology/conditions who aren't accessing health care or feel that they are not receiving the 'right' health care. The intent is to improve engagement with the health care system and appropriate care to optimise their health and wellbeing. It's about acknowledging their concerns, assessing their symptoms and finding a way forward. We are concerned that there is potential for the doctors doing the assessment to accept and/or reinforce that mefloquine/tafenoquine are the cause of the veteran's poor health etc.
- This health assessment appears to be in addition to the extant Veteran Health Check. Does it need to be?
- How does continuity of care factor in. If this assessment is done by a BUPA provider, will
 they continue on as the veteran's GP? The primary issue is that these veterans are not
 engaged with or don't trust the system. There is a risk that their care may become even
 more fragmented.

Cheers,

Vicki

Dr Victoria Ross

MBBS MPH FRACGP FAFPHM

Senior Medical Advisor, Military Population Health

CP3-7-091 Department of Defence

PO Box 7912

CANBERRA BC ACT 2610

Tel (02) 62663936 Fax (02) 62663933

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Clinical Guidelines for providing appropriate care to ADF members and veterans concerned about having been prescribed mefloquine or tafenoquine

Version 3, March 2019

PURPOSE

These clinical guidelines are primarily designed to assist clinicians manage patients who are concerned about having taken mefloquine or tafenoquine and specifically those that are suffering from neuropsychiatric symptoms which they attribute to historical use of these antimalarials (often from the 1999-2002 period). They may also be useful in managing patients with neuropsychiatric symptoms that they attribute to other antimalarials and other medications more generally, or symptoms of unknown cause.

BACKGROUND

In recent years, there has been much publicity in the civilian media and concerns raised by some serving and ex-serving Defence members relating to the use of mefloquine and tafenoquine for malaria chemoprophylaxis by the Australian Defence Force. The United Kingdom is experiencing similar concerns and the United States has experienced similar concerns in the past.

On 30 November 2015, Defence released a statement on the use of mefloquine in the ADF that advised if "any ADF member, past or present is concerned that they might be suffering side-effects from the use of mefloquine Defence encourages them to raise their concerns with a medical practitioner so they may receive a proper diagnosis and treatment."

http://news.defence.gov.au/2015/11/30/statement-on-the-use-of-mefloquine-in-the-adf/

It is anticipated that Defence medical officers will encounter ADF members who are concerned that they may be suffering side-effects from historical use of mefloquine or tafenoquine. Similarly, civilian GPs may encounter ex-serving members with these concerns.

Mefloquine side-effects

Mefloquine has been registered for malaria chemoprophylaxis in Australia since 1993, and has been prescribed to over 35 million people worldwide. The side-effect profile is well known. In chemoprophylaxis the safety profile of mefloquine is characterised by a predominance of neuropsychiatric adverse reactions. Most of the recent changes in product information relate to the duration that psychiatric or neurological side-effects may last. On occasions, these symptoms have been reported to continue long after mefloquine has been stopped.

$\frac{https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm\&t=PI\&q=Lariam\&r=/$

The neuropsychiatric side-effects of mefloquine have received the most attention and are best considered as psychiatric – disturbed sleep, anxiety, paranoia, depression, hallucinations and psychosis; and neurological – vertigo, loss of balance, tinnitus, sensorineural hearing loss and neuropathy.

Side-effects from mefloquine usually occur soon after commencing the medication. Side-effects usually resolve within days to weeks after ceasing the medication. Due to mefloquine's long half-life (21 days on average) it is possible for symptom onset to be weeks after cessation. In rare cases, side-effects may persist for months or longer.

Mefloquine and Post-traumatic Stress Disorder (PTSD) or mild traumatic brain injury (mTBI)

There is no evidence that mefloquine causes or triggers PTSD or mTBI. In the acute situation, there is potential for acute mefloquine-related psychiatric symptoms to confound a PTSD or mTBI diagnosis. There is no evidence to suggest that a PTSD diagnosis made months or years after ceasing mefloquine can be attributed to past mefloquine use.

Mefloquine toxicity - CNS toxicity syndrome - mefloquine toxidrome

Dr Remington Nevin, an ex-US Army medical officer, has published a number of opinion articles proposing the adoption of diagnoses to describe long term or permanent neurological symptoms related to mefloquine use. None of the terms have been officially accepted and there are no accepted diagnostic criteria, diagnostic tests nor any treatment. Clinicians should understand that members may present seeking one of these diagnoses.

It is important to acknowledge that mefloquine has been associated with long term or permanent neurological symptoms which can be diagnosed.

Chemically acquired brain injury

Several veterans and people active in the media have suggested that the quinoline class of antimalarials can cause brain injury. In 2017 the Repatriation Medical Authority (RMA) conducted a review of the medical and scientific literature to investigate whether mefloquine, tafenoquine and primaquine can cause chemically acquired brain injury. The RMA found that there is insufficient sound medical-scientific evidence that exposure to these pharmaceuticals causes chronic brain injury.

CYP2D6

CYP2D6 is one of the cytochrome P450 enzymes. It is necessary for the metabolism of primaquine to an active form against malaria. Its role in the metabolism of tafenoquine is less certain. It is not relevant to mefloquine metabolism. The gene that codes for this enzyme is highly polymorphic and individuals can be described as poor, intermediate or normal metabolisers. Several veterans and advocates have stated that people who are poor metabolisers can suffer from tafenoquine or mefloquine toxicity.

There is no evidence linking this enzyme to side effects from these medications. The genetic mutation (for poor or intermediate metabolism) is not predictive of primaquine efficacy. Primaquine may still be effective in someone who has reduced enzyme metabolism. It is reasonable to test individuals who have had a confirmed vivax malaria relapse despite having fully complied with a primaquine course (treatment failure). This testing could be done to inform future malaria treatment options, if this is relevant to their situation. There is no basis for pre-emptive or mass screening.

Tafenoquine

Tafenoquine is a relatively new anti-malarial medication which is chemically closely related to primaquine. As a quinine derivative, it falls into the same broad class of antimalarials as mefloquine however it acts quite differently in the body and its known side-effect profile more closely reflects those of primaquine (primarily gastro intestinal upset). It was registered in Australia in 2018 for both prophylaxis (Kodatef™) and radical cure (Kozenis™). It was trialled by the ADF between 1999 and 2001 as an option for prophylaxis, eradication and treatment of malaria.

There is no evidence that tafenoquine causes serious neuropsychiatric effects, either acute or chronic. In patients receiving Kodatef™ in clinical trials, adverse psychiatric reactions included sleep disturbances (2.5%), depression/depressed mood (0.3%), and anxiety (0.2%). Long term use has been associated with an eye condition, vortex keratopathy (small deposits in the cornea), also seen with long term use of chloroquine. The condition does not affect vision and has no symptoms. It is benign and resolves completely after tafenoquine is stopped.

The prescribing information for Kodatef™ advises that it should not be used in people with a history of serious psychosis or current psychotic symptoms, delusions or hallucinations. This is a precaution as there is no data on the safety of tafenoquine in people with a history of psychiatric disorder as these individuals were excluded from clinical trials of tafenoquine for prophylaxis. Serious psychiatric disorders such as psychosis and depression have been associated with some quinoline anti-malarial agents.

Prescribing information and consumer medicine information for tafenoquine is available on the TGA website at www.tga.gov.au and searching the Australian Register of Therapeutic Goods (ARTG).

CLINICAL APPROACH

Persons presenting with neurological or psychiatric symptoms with a history of previous mefloquine or tafenoquine use should be thoroughly assessed. It is important to accept that the member or veteran has concerns that their symptoms may be related to historical mefloquine or tafenoquine use and their concerns should not be summarily dismissed.

Members presenting who are concerned because they have taken mefloquine or tafenoquine in the past but have no symptoms (the worried well) also need to have their concerns noted and addressed.

What can the general practitioner do?

- Document any symptoms as part of a comprehensive history. Note the date of symptom onset in relation to mefloquine or tafenoquine use and the nature of symptoms after ceasing the medication. A comprehensive history is very important, as there are many factors which could be relevant to the presenting symptoms. These include developmental and family history, social history, injury, deployment experiences and other life events. In the ADF, most antimalarial use occurs in the context of deployment.
- 2. Perform a thorough examination and document any abnormal neurological or other signs as well as relevant negatives. All patients should receive an audiogram and a Sharpened Romberg test.
- 3. Assess the patient with readily available psychological screens, if relevant. For example, K-10, DASS-21, DAR or CAPS-5.
- 4. Arrange further diagnostic investigations or specialist referral as appropriate.
- 5. Those presenting with neurological symptoms will often require referral to one or more of the following to confirm a diagnosis, quantify symptoms and recommend treatment:
 - a. Neurologist; and /or
 - b. Neuropsychologist (including a request for a battery of tests to baseline neuropsychological function)
- 6. Those presenting with psychiatric symptoms should be referred to a psychiatrist, preferably a psychiatrist with experience in military populations, where available.
- 7. Assess and document risk.
- 8. **Explore useful treatments.** Treatment options will depend on the symptoms being experienced and whether a condition can be diagnosed.
 - a. Where a clinical diagnosis (including a provisional diagnosis) is made, evidence based treatment for the condition should be provided.
 - b. No specific treatment has been proposed for mefloquine related neuropsychiatric problems apart from ceasing the medication, which has already occurred.

- c. Generally, pharmacotherapy or psychotherapy should be withheld until a disorder is diagnosed, however treatment of specific symptoms causing significant distress should be considered even without a provisional or definitive diagnosis (e.g. prochlorperazine for dizziness).
- 9. Document the claims in the medical record. Include details of deployment location, operation and dates; the antimalarial taken or believed to have been taken and if relating to the 1998-2003 period whether they participated in an Army Malaria Institute trial. Be aware that some veterans will not accurately recall whether or not they participated in a trial. They can check if they were a trial participant by contacting adf.malaria@defence.gov.au.
- 10. Advise the member/veteran that there is additional information on antimalarial use in the ADF available on the Joint Health Command external web site: www.defence.gov.au/Health/HealthPortal/Malaria/default.asp and the DVA website www.dva.gov.au/health-and-wellbeing/health-services-and-conditions/mefloquine-and-tafenoquine-information.

In addition, clinicians may find this article from the September 2015 Australian Family Physician useful: *Managing medically unexplained illness in general practice* http://www.racgp.org.au/afp/2015/september/managing-medically-unexplained-illness-in-general-practice/

Risk Assessment and Mental Health Management

Defence members who present to a Defence medical officer with mental health symptoms, psychological distress or increased risk should be assessed and managed in accordance with Defence Health Manual Volume 2 Part 10 Chapter 2 – Assessing and managing Defence members at Risk of Suicide, Self-Harm or Harm-to-Others. Defence members who require mental health assessment and treatment are to be managed in accordance with Defence Health Manual Volume 2 Part 10 Chapter 1 - Coordinated care and management of Defence members receiving mental health services in garrison. The immediate assessment and management of risk, when identified, is the priority.

In the civilian sector, acute mental health presentations should be managed according to best practice and local arrangements.

DVA also provides non-liability health care for all mental health conditions and a wide variety of support services, including counselling through Open Arms. Non-liability health care means that the veteran doesn't have to prove that their mental health condition was caused by their military service.

DVA now has a single free call contact number for all enquiries: **1800 555 254**. The DVA website has more information (www.dva.gov.au).

Military Employment Classification and MEC Review Board

For those Defence members still in full time service or in the active Reserves, MEC considerations will depend on the health status, functional capacity and health support needs of the individual. If a member is not deployable, and the period of non-deployability extends beyond 12 months from onset of illness, MECRB consideration is required.

If the member has raised the possibility of mefloquine or tafenoquine being associated with their symptoms, this needs to be documented in the MEC Review.

In summary:

- 1. Be respectful and acknowledge the concerns
- 2. Treat when appropriate
- 3. Offer referral to appropriate specialists for testing/documentation of function and exclusion of other causes
- 4. Document the member's health record
- 5. Assess and manage risk



GULF HEALTH: INFORMATION GUIDE FOR HEALTH PROFESSIONALS

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Section 1

INTRODUCTION

Twice over the last decade and a half, large numbers of UK military personnel have been called to active service in the Gulf region. In health terms, this service presented considerable challenges, including those from: terrain; endemic infectious agents; climate; and the threat of chemical and biological warfare agents. In addition there was unprecedented media interest and speculation in relation to all aspects of the campaign, including health issues, before, during and after the conflicts. Already many participants, regular and reservists, have returned to civilian life and increasingly more will do so.

This guide is produced by the Veterans' Policy Unit (VPU) of the Ministry of Defence (MOD). It is intended to provide health professionals, both service and civilian, with information that they may find useful in dealing with the health concerns of veterans from these operations in the Gulf.

1990/1991 Gulf Conflict: Around 53,000 UK Servicemen and women served in the 1990/1991 Gulf Conflict. At least two thirds have now left the Armed Forces and responsibility for their health care falls to the National Health Service, in particular to their GPs. There are ex-Service Gulf veterans living in all parts of the UK, and many GPs will have veterans among their patients. Since returning from the Gulf, some veterans have become ill. In some cases this is due to disorders which are unrelated to service. Others have recognised medical conditions such as Post Traumatic Stress Disorder (PTSD) where service links are accepted. A third group reports the multi-system, multi-organ, non-specific, symptoms and illnesses which epidemiological evidence confirms are not specific to, but are more common in, those who served in the Gulf in 1990/1991.

2003 and subsequent operations in the Gulf: Over 80,000 UK Servicemen and women have served in operations in the Gulf since January 2003. It is too soon to know whether any health issues will emerge following these operations but learning from experience of the 1990/1991 Gulf Conflict, the MOD has put in place a range of measures to monitor the health of returning personnel and investigate any concerns quickly.

The Government and MOD considers its people its greatest resource and there is therefore considerable concern about the health and well-being of personnel both during and after service. The Government is committed to addressing the complex and difficult issue of why some veterans have fallen ill since returning from the 1990/1991 Gulf Conflict and has adopted three principles in its approach to the subject:

- First, that all Gulf veterans will have prompt access to medical advice.
- Second, there will be appropriate research into veterans' illnesses and factors which might have a bearing on these.
- Third, the MOD will make available to the public any information it possesses which is of potential relevance to this issue.

To oversee the Government's response to Gulf veterans' illnesses, in 1997 the MOD established a Gulf Veterans' Illnesses Unit. The unit, which is now part of the Veterans Policy Unit, acts as a focal point for Gulf veterans who are ill or worried about their health and is responsible for conducting relevant reviews, providing support to research teams and answering public correspondence on this subject.

Further information on Gulf veterans' illnesses, and copies of MOD publications on this subject, can be obtained by calling the VPU Gulf helpline on 0800 169 4495; by visiting the Gulf veterans' illnesses website at www.gulfwar.mod.uk; or by writing to:

VPU GVI 7th Floor Zone H Ministry of Defence Main Building Whitehall London SW1A 2HB

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KEY POINTS ABOUT GULF VETERANS' ILLNESSES

- The MOD accepts that since returning from the 1990/1991 Gulf Conflict, some personnel have become ill. The health of those who served in the Conflict remains a high priority.
- In some cases veterans' illnesses are due to disorders which are unrelated to service. Others have injuries or recognised medical conditions such as PTSD, where service links are accepted. A third group reports the multi-system, multiorgan, non-specific, medically unexplained symptoms and illnesses which epidemiological evidence shows are not specific to, but are more common in, those who served in the Gulf in 1990/1991.
- The consensus of the medical and scientific community is that the ill health reported by some veterans of the 1990/1991 Gulf Conflict cannot be characterised as a discrete syndrome because similar symptoms are seen in non-Gulf veterans. The difference is that in those who served in the 1990/1991 Gulf Conflict these symptoms are more common and more severe.
- This pattern of ill health is not unique to UK Gulf veterans, and is repeated amongst 1990/1991 Gulf veterans from the other coalition countries. This is regardless of the specific experiences and exposures of the personnel concerned, which were not the same for all participants. Similar symptoms and illness are also reported by some who did not actually deploy.
- Only a minority, albeit an important minority, are ill. We want to know why this is.
- Monitoring shows that there is no excess in overall mortality for veterans of the 1990/1991 Gulf Conflict in comparison to a similar control group of personnel that did not deploy.
- Veterans of either the 1990/1991 Gulf Conflict or of operations in the Gulf since January 2003 can be referred by their GPs or Service Medical Officers to the Gulf Veterans' Medical Assessment Programme (see section 3).
- The MOD has funded and continues to fund appropriate research into the ill health suffered by veterans of the 1990/1991 Gulf Conflict (see section 4).
- It is too soon to know whether any unusual health issues will emerge following the recent and continuing operations in the Gulf. The MOD takes the health of its people very seriously and has put in place a range of measures to monitor the health of returning personnel and investigate any concerns quickly (see section 4).
- The MOD is committed to providing information to Parliament and to veterans on matters relevant to the issue of Gulf veterans' illnesses (see section 5).

- Gulf veterans who are concerned about their health are invited to contact the MOD's Veterans Policy Unit on Freephone 0800 169 4495 for advice.
- A considerable amount of information about the Ministry of Defence's approach to Gulf veterans' illnesses is available on our website at:

For veterans of the 1990/1991 Gulf Conflict: www.gulfwar.mod.uk

For veterans of operations in the Gulf since 2003: www.mod.uk/issues/optelic_health

THE GULF VETERANS' MEDICAL ASSESSMENT PROGRAMME (GVMAP)

The GVMAP was established in July 1993 to examine UK Gulf veterans who were concerned that their health had been adversely affected by service in the 1990/1991 Gulf Conflict. The GVMAP is located at St Thomas' Hospital, London.

On 7 May 2003, MOD Ministers announced in Parliament that the GVMAP's remit would be extended to include those who had taken part in operations in Iraq since January 2003.

Who is the GVMAP for?

The GVMAP is open to all Servicemen and women, irrespective of whether they are still serving or not - as well as MOD civilians - who served in the Gulf at any time between August 1990 and July 1991, or who believe that their health has suffered as a direct result of the Gulf Conflict. Individuals who worked for contractors providing direct support to UK operations during the Gulf Conflict may also be seen. The programme is not intended to cover other UK citizens who may have been in the Gulf region at the time.

The GVMAP is also open to those who were deployed to operations in the Gulf on or after 20 January 2003 (Operations TELIC and RESINATE). The facility is also available to attached voluntary aid society personnel, contractors working in direct support of UK operations in theatre and embedded journalists. Contractors, some Voluntary Aid Society Personnel and embedded journalists will be asked to pay a fee to cover the cost of the assessment and tests carried out at the GVMAP.

What is the purpose of the GVMAP?

The GVMAP has two main purposes:

- First, to investigate patients' medical complaints and, so far as possible, to diagnose
 what they are suffering from and recommend appropriate management, or provide
 reassurance if no illness is found.
- Second, the GVMAP collates statistical information, which is available in an anonymised form as a resource for researchers who have obtained the appropriate ethical clearance. This has proved useful in helping to determine whether there are particular patterns of ill health associated with service in the Gulf. (No information about named individuals will be given to third parties without express written consent). A paper on the first 284 service and ex-service patients examined at the GVMAP was published in 1996¹, a paper on the first 1,000 service and ex-service patients was published in January 1999², a paper on the second 1,000 patients was published in June 2001³. Work analysing the third 1000 patients and an overview on all the first 3,000 patients was published in October 2002⁴. Analytical work continues.

Where is the GVMAP?

The GVMAP is based at St Thomas' Hospital in central London. The location provides access to a wide range of facilities and enables interdepartmental referrals and laboratory or medical tests to take place without undue delay, and the Capital is well served by rail and air links to all parts of the country. However, in order to improve our service to some Gulf veterans, who find travelling to London difficult or inconvenient, the GVMAP physician holds a clinic at Northallerton, North Yorkshire every two months for patients who might find that location more convenient.

Rarely, special arrangements can be made for individual veterans who are unable to travel either to London or to Northallerton.

Why should I refer my patient to the GVMAP?

How do I refer my patient to the GVMAP?

Veterans who are still serving in the Armed Forces can be referred to GVMAP by their Service Medical Officer. Personnel who have left service and civilians who have concerns about their health and possible links to Gulf service should contact their GP to access the GVMAP.

If the GP or Service Medical Officer thinks that referral to the GVMAP is appropriate, he or she should write to the Head of GVMAP at: The Baird Health Centre, Gassiot House, St Thomas' Hospital, Lambeth Palace Road, London, SE1 7EH. The referral letter should include details of past medical history, present health problems and any treatment that the patient is currently having, together with information (where applicable) on the branch of the Armed Forces in which the veteran served and the veterans' former service number if known.

Does the GVMAP see everyone referred?

In the case of a very small number of patients referred, there is nothing to be gained from them being seen at the GVMAP – for example, because it is clear that their condition is being appropriately managed or they have been seen before and nothing new would be gained by a further visit. The physician at the GVMAP therefore does not automatically see everyone referred. When a decision is taken not to see a patient, the referring doctor is told why and given a brief update about Gulf health issues. If the

physician at GVMAP decides not to see a veteran, this does not preclude him from seeing that veteran at a later date if circumstances change.

What happens at the GVMAP?

The GVMAP is currently staffed by a civilian consultant physician and supporting staff. Patients referred to the GVMAP are given a full interview and medical examination and a range of laboratory tests; investigations routinely undertaken for all patients include: urinalysis; haematological; biochemical; biological and serological tests; ultrasound scan of the abdomen and electrocardiography. These tests are carried out on the day of the appointment and take approximately four hours. Additional investigations will be carried out if they are clinically indicated. Referrals to other consultants/specialists may be required.

What about psychological assessments?

Amongst veterans of the 1990/1991 Gulf Conflict, there are some who suffer from psychological conditions. Of over 3,000 patients who have been to GVMAP, about 20% were diagnosed as psychiatrically unwell with a range of symptoms and illnesses. Since 1999, the GVMAP has utilised, where appropriate, a country-wide network of psychiatric assessment centres with staff with specialist knowledge of the psychological injury of conflict and PTSD. The GVMAP pays for this, including the patient's travel costs. As a result of such referrals, a study of outcomes has been carried out and, at the time of publication of this guide, is in press⁵.

Is there a long waiting list?

No. Our aim is that all patients referred to the GVMAP will be sent an appointment letter within 5 days; and that as far as possible the date of the appointment will be within 6 weeks of the patient's referral, provided that this is convenient for the patient. If the patient cannot attend on the date shown, every effort will be made to rearrange the appointment as soon as possible.

Funding arrangements?

The examination and clinical tests will be provided free of charge except in the case of contractors, some voluntary aid personnel and embedded journalists who accompanied deployments since January 2003. The MOD will also pay for further tests which the GVMAP physician believes are necessary to carry out the assessment.

With the exceptions detailed above, the cost of the patient's travel to the GVMAP from within the UK will be met by MOD (normally we will provide rail warrants in advance). The MOD will also reimburse up to £10 for a snack or light lunch. Where necessary (if the length of the journey precludes the possibility of a return trip within a single day) accommodation costs and the cost of breakfast and an evening meal at the hotel will also be met by MOD.

Accommodation will be booked by MOD. Veterans will not be able to claim reimbursement for accommodation they have booked themselves. Any special requirements resulting from the veteran's medical condition (for example, for a carer to

accompany him/her) must be notified to the GVMAP in advance and supported by a note from the patient's GP.

What happens after my patient is seen?

The GVMAP itself does not provide treatment. Its role is to assess patients and recommend treatment as appropriate. Implementation and follow-up, via the Defence Medical Services (for serving personnel) and the NHS for those who have left service, will be for the individual's own doctor.

The GVMAP consultant will write to the referring doctor after the consultation with a copy of the assessment report with test results following within six weeks. Patients who wish to see their report and who have signed a consent form are automatically sent a copy of the medical assessment report and test results at the same time as the results are sent to the referring doctor.

We ask doctors to co-operate in taking forward treatment recommendations and in responding to any enquiries about a patient's progress. GVMAP will send a standard follow up letter to all GPs who refer patients, asking for information on the patient's condition and subsequent treatment. This is usually done 6 months after the GVMAP appointment.

Section 4

GULF VETERANS' ILLNESSES RESEARCH IN THE UNITED KINGDOM

1990/1991 Gulf Veterans' Illnesses Research Programme

MOD's current 1990/1991 Gulf veterans' illnesses research programme, with the exception of the Vaccines Interactions Research Programme which is described on page 13 of this guide, is being carried out independently of MOD. The Vaccines Interactions Research Programme is being conducted partly at the Defence Scientific and Technology Laboratory at Porton Down. To ensure that this research is conducted in an objective and scientifically sound manner, it is being overseen by an Independent Panel (consisting of scientists and doctors, two of whom were nominated as representatives of the Gulf veterans).

Researchers are welcome to submit proposals for additional research to MOD at any time. These will be passed either to the Medical Research Council (MRC) who provide independent advice on the merit of proposals and the direction Gulf veterans' illnesses research should be taking, or, if appropriate, to the Independent Panel overseeing the vaccines interactions research, for independent scrutiny. Recommendations of the MRC or Independent Panel are normally considered favourably by MOD.

The MOD has funded or contributed to the funding of the following research studies:

Morbidity and Mortality

An epidemiological study by a team led by Professors Nicola Cherry and Gary Macfarlane at Manchester University aimed to determine whether Gulf veterans are experiencing greater ill-health than Service personnel who did not take part in the 1990/1991 Gulf Conflict and to identify possible exposures and predisposing factors associated with any distinctive pattern of symptoms which may be found. The randomly selected study group for this survey was composed of two groups of 4,800 Gulf veterans, plus a control group of 4,800 personnel who did not deploy to the Gulf. The research team also investigated whether service in the Gulf is associated with increased mortality, by looking at all deaths that occurred in the 8 year period from 1 April 1991 to 31 March 1999 in the total Gulf cohort of 53,462 and in a similar sized group, randomly selected from among those who did not deploy.

The results of the morbidity study were published as two papers in the May 2001 edition of *Occupational and Environmental Medicine*^{6 7}. The research found that, although the overall severity of symptoms was not high, Gulf veterans reported a greater severity of symptoms than those who were not deployed to the Gulf. There was no evidence of any illness unique to Gulf veterans and the various symptoms reported were ranked in generally the same order by both groups. The researchers found no evidence of a "Gulf War Syndrome". The research also found weak associations between some reported exposures (handling pesticides, vaccinations and exposure to oil fire smoke) and particular types of ill health.

The results of the mortality study were published in *The Lancet* on 1 July 2000⁸. The study found that the number of deaths and the causes of death in the comparison group who did not deploy to the Gulf were similar to those recorded amongst Gulf veterans.

There was however a small excess of deaths amongst Gulf veterans attributable to accidents, particularly road traffic accidents. Since the publication of the study, the MOD has monitored the mortality of both the Gulf and control groups and has published updated statistics every six months. The Defence Analytical Services Agency, who provide analytical and statistical services for the MOD, are responsible for this data and it can be viewed on their website: www.dasa.mod.uk/natstats/gulf/intro.html

Reproductive Health

A team led by Dr Patricia Doyle and Dr Noreen Maconochie at the London School of Hygiene and Tropical Medicine carried out a very large epidemiological study of the reproductive health of Gulf veterans and their partners, and the health of their children. Specific areas of interest were fertility, pregnancy outcomes and child health as well as information about specific occupational and environmental exposures. A paper entitled "The study of reproductive outcome and the health of offspring of UK veterans of the Gulf war: methods and description of the study population" was published in *BioMed Central* on 10 January 2003⁹. The paper describes in detail the method used for the study and provides information about response rates.

Papers reporting reproductive outcomes and male fertility were published in 2004. In "Miscarriage, stillbirth and congenital malformation in veterans of the first Gulf war" the researchers reported that for male veterans of the 1990/1991 Gulf Conflict, they found no evidence for increased risk of stillbirth, chromosomal malformations, or congenital syndromes. Some associations were reported between fathers' service and increased risk of miscarriage and other less well-defined malformations. For female veterans, the number of stillbirths and malformations were too small to allow meaningful analysis and there was no effect on miscarriage. In a paper published in the *British Medical Journal Online First*¹¹ the researchers examined whether male Gulf veterans suffer increased risk of infertility. The researchers found a small increased risk of reported infertility and that pregnancies fathered by Gulf veterans who did not report problems also took longer to conceive. They could not however conclude that this association was caused by service in the Gulf.

Although the study has primarily focussed on reproductive health, a member of the research team also published a paper in *BioMed Central*¹² which looked at the general health reported by veterans. The findings of this supported that of Cherry *et al* described above.

Study of UK Gulf Veterans

A further epidemiological study looking at whether service in the Gulf in 1990/1991 is associated with increased illness in UK veterans has been funded by the US Department of Defense and carried out by a team led by Professor Simon Wessely at the Institute of Psychiatry, King's College, London. Although this study was carried out independently of MOD, the Department co-operated with the research team by providing essential data to the researchers. This study involved 4,248 Gulf veterans and two control groups: one of 4,246 personnel who served during the Gulf Conflict but did not deploy there, and another of 4,250 personnel who have served in Bosnia. The results from phase one of the study, which involved the completion of a health questionnaire, were published as two papers in *The Lancet* in January 1999¹³ ¹⁴. The

papers said that UK Gulf veterans reported symptoms of ill-health up to three times more frequently than the other groups, although the symptoms did not appear to be unique to this group, and the authors concluded that these findings did not support a unique Gulf illness. The findings included a hypothesis that multiple immunisations are associated with later self-reported ill health in Gulf veterans. A further paper published in May 2000¹⁵ provided a more detailed analysis of that hypothesis. The research did not find an association between ill health and the individual vaccines given in the 1990/1991 programme. Nor did it link ill health to a particular combination of vaccines. Multiple immunisations before deployment to the Gulf do not seem to be associated with self reported ill health, whereas multiple immunisations given during the deployment do seem to be associated with ill health. The suggestion in the paper is that this different outcome is stress mediated. However, this is no more than a hypothesis.

Phase two of the study aimed to validate some of the findings of phase one by conducting clinical examinations and medical tests on a proportion of the study group in order to further define their conditions. The results of this work have been published as several papers in peer reviewed scientific journals. A paper on Antinuclear Autoantibodies (ANA) in Gulf War Related Illness and Chronic Fatigue Syndrome (CFS) patients was published in *Clinical and Experimental Immunology* in August 2002¹⁶. The authors noted that the most common symptoms of Gulf veterans overlap with those of CFS patients. The study tested the hypothesis that CFS and Gulf veterans' illnesses were associated with a particular type of ANA, (autoantibodies to nuclear envelope antigens) which have been associated, albeit rarely, with autoimmune disorders. The authors found no significant difference in the prevalence of ANA across the study groups and that none of the patients or veterans studied had ANA of the nuclear envelope type. A paper entitled: "The Mental Health of United Kingdom Gulf War Veterans: A Two-Phase Cohort Study" was published in the British Medical Journal in September 2002¹⁷. The paper's conclusion was that the majority of disabled Gulf veterans do not have a formal psychiatric disorder. PTSD is not increased in Gulf veterans and psychiatric disorders do not fully explain self-reported ill health in Gulf veterans. A paper on cognitive functioning and disturbances of mood in UK Gulf veterans was published in the November 2002 issue of *Psychological Medicine*¹⁸. The paper concluded that there was no evidence of major neuropsychological disturbance in Gulf veterans. Test performance in unwell veterans was impaired compared with well Gulf veterans, but was generally within the normal range.

A third phase of research consisting of a longitudinal study of the changing health of Gulf veterans over time, and a further analysis of the health of the Bosnia cohort examined in the earlier study, has been funded by MOD. The work is complete and a number of papers^{19 20 21} have been published as a result. They report that, at follow up:

- Gulf veterans continue to report poorer health than other military personnel, but the overall health gap has narrowed slightly;
- poorer health is associated with being older, having more severe symptoms at baseline, having psychological distress and believing that one is suffering from "Gulf War Syndrome";
- reporting of hazards is not static, and is associated with current health perception.

Neuromuscular Symptoms Study

MOD funded a clinical study which was carried out under Dr Michael Rose and Dr Mohammad Sharief at King's College, London. The study investigated the hypothesis that symptoms of fatigue, weakness, muscle pain and sensory disturbance which have been reported by some Gulf veterans might be due to disturbance of the nerve or muscle function. It focused on those veterans who have, according to their response to the epidemiological study carried out at King's under Professor Wessely, significant neuromuscular symptoms. Two papers have been published. The first, entitled "Neurophysiologic analysis of neuromuscular symptoms in UK Gulf war veterans"22 reported that there was no objective evidence for a specific neuromuscular junctional disorder that could be linked to service in the 1990/1991 Gulf Conflict. In the second, "Evaluation of Neuromuscular Symptoms in UK Gulf War Veterans. A Controlled Study"²³, the researchers report that there was no correlation between subjective complaints of weakness/fatique and statistical and dynamic quantitative strength and fatigue measures, and that muscle biopsies did not find abnormalities in any group of veterans tested. There was clinical evidence that symptomatic Gulf veterans did find an exercise bicycle test more effortful than other groups of veterans tested, reflecting some inefficiency in the muscle tissue. However, the cause of the inefficiency is unclear.

Systematic Literature Review

MOD has funded, through the MRC, an independent systematic literature review of world-wide published research relating to Gulf veterans' illnesses. The review was carried out by a team led by Professor Glyn Lewis. The first paper entitled "Psychiatric disorder in veterans of the Persian Gulf War of 1991" was published in the *British Journal of Psychiatry* in May 2003²⁴. The authors compared the prevalence of psychiatric disorder in Gulf veterans in 20 published papers which included data on psychiatric disorders to prevalence in the comparison groups used in those studies. They found an increased prevalence of Post Traumatic Stress Disorder and common mental disorders in Gulf veterans compared with the control groups. Publication of similar systematic reviews on reproductive health, mortality and hospitalisations, multisymptom conditions and pain are awaited.

Cancer Study

MOD has funded work led by the University of Manchester on the incidence of cancers in Gulf veterans as recorded on the NHS central registers for England and Wales and for Scotland. The researchers concluded in their paper "Incidence of cancer among UK Gulf war veterans: cohort study" that there is no current excess risk of cancer overall nor of site specific cancers in veterans of the 1990/1999 Gulf Conflict. Specific exposures during deployment do not appear to have resulted in a subsequent increased risk of cancer. The long latent period for cancer however necessitates continued follow up.

Paraoxanase work

Findings on the levels of paraoxanase (PON1) (an enzyme that metabolises organophosphates) in Gulf veterans undertaken by a team at Manchester Royal Infirmary (MRI) were published in September 2000²⁶. The MRI researchers found that a self-selected group of 152 ill Gulf veterans had paraoxonase activity levels 50% less

than those of healthy civilians in a control group. MOD felt that the results were sufficiently important to warrant further study and made arrangements for MRI to analyse blood samples collected by King's during their Phase 2 clinical studies (described above) to see if the original MRI results would be replicated in a blinded study. The MOD contributed towards the cost of the work. In a paper published in the *Journal of Occupational and Environmental Medicine* in July 2003²⁷, the researchers report that they found that PON1 activity in Gulf veterans was lower than in the control groups used. The study however found no statistically significant differences between PON1 activity in ill Gulf veterans and in healthy Gulf veterans.

Study of the Social Construction of "Gulf War Syndrome"

The MOD has part-funded, with the Economic and Social Research Council, a study by a PhD student in Medical Anthropology at the University of London into the Social Construction of "Gulf War Syndrome".

The study is based on interviews with Service and ex-Service Personnel and their families about "Gulf War Syndrome". The first in a proposed series of papers was published in the August 2004 edition of *Anthropology & Medicine*²⁸. This paper discusses the way in which individual veterans may look to "Gulf War Syndrome" to make sense of life events and illness, and the part that dialogue with others can play in the veteran's view of "Gulf War Syndrome".

Vaccines Interactions Research Programme

MOD has also funded a programme of research at the Defence Science and Technology Laboratory (Dstl) Porton Down to investigate the possible adverse health effects of the combination of vaccines and tablets which were given to troops in the 1990/1991 Gulf Conflict to protect them against biological and chemical warfare agents.

The first phase of this investigation, involving guinea pigs, did not identify any remarkable findings with the combination of ten vaccines and pyridostigmine bromide (PB) (the active ingredient in Nerve Agent Pretreatment Sets tablets) examined, but helped to determine the appropriate vaccine doses for use in the subsequent phases. Results from the study were published in the *Journal of Applied Toxicology* on 21 January 2001^{29.}

The next phase of this study was conducted in a small primate, the marmoset, using a complex experimental design. A number of sensitive indices, including cognitive performance, electroencephalogram, sleep, endocrinology, biochemistry and immune responsiveness, were monitored for eighteen months following the co-administration of the ten vaccines and PB. Preliminary results from the first 3 months of the study were presented by means of posters at two scientific conferences in April 2003. These preliminary findings indicated no apparent adverse health consequences 3 months following the administration of vaccine and/or pyridostigmine bromide. The main programme is complete and it is expected that final findings will begin to be submitted for publication in early 2005.

Work has also been undertaken at the National Institute for Biological Standards and Control to validate a 1990 study which reported that the combination of anthrax and

pertussis vaccines produced an adverse response in one strain of mouse. This study was undertaken in the light of a decision taken during the Gulf Conflict to offer immunisation against anthrax and to use pertussis vaccine as an adjuvant to enhance the immunisation effect. The new study included a range of genetically diverse strains of mouse to examine whether genetic factors may have a role to play in such a complex interaction. An outline of the findings of the first phase of this work was presented at the "Conference on Dangerous Pathogens" in September 2002. The study is now complete and the full results were submitted for publication in 2004.

Research on Organophosphate Pesticides

In addition to MOD's Gulf veterans' illnesses research programme, research funded jointly by the Department of Health, the Department for the Environment, Food and Rural Affairs and the Health and Safety Executive is studying the long-term health effects of low level exposure to organophosphate (OP) pesticides in the context of the health concerns of some farm workers. This may help us to understand the possible effects of potential OP exposures during the Gulf Conflict, although in general the military and agriculture settings provide different usage and dose levels.

MRC Review of Gulf Veterans' Illnesses Research

Following a request from MOD, the MRC undertook a review of Gulf veterans' illnesses research. The MRC's report was published in May 2003 and is available on the MRC's website at: www.mrc.ac.uk

Key points of the report are;

- There is no unique "Gulf War Syndrome".
- The same symptoms seen in Gulf veterans are also seen in personnel who did not deploy, but around twice as many Gulf as non-Gulf veterans (24% compared to 10%) report having them, and suffer more severely.
- Thorough medical examinations and physical, psychological and psychiatric testing
 of ill veterans have detected no abnormalities. There is no correlation between how
 badly people think their memory and concentration has been affected and how well
 they do in tests.
- Gulf veterans who report more severe symptoms are more likely to recall having had more inoculations and exposure to pesticides, but their perception of their health is known to influence recall.
- There is little evidence that vaccination was a cause of veterans' illnesses. No commonly accepted mechanism could account for immune system related symptoms more than 10 years on.
- Symptoms do not fit the expected pattern for damage to peripheral nerves of nerve/muscle junctions caused by exposure to organophosphates.

The MOD has taken note of the Review's conclusions and recommendations and is

working with the MRC to take these forward:

- The University of Manchester has been commissioned to carry out a short study looking at the relationship between mortality & reported exposures.
- In July 2004, the MRC issued a call for proposals for rehabilitative studies and related work. The MOD hopes to commission work in early 2005.
- On neuro-imaging, the MRC has carried out a further review of the international literature and other available information, especially from the US, to decide the way forward.
- It is also anticipated that a workshop on paraoxonase studies will be held in early 2005.

Research and Monitoring of service personnel returning from Operations in the Gulf since 2003

It is too soon to know whether any unusual health issues will emerge following operations in the Gulf since 2003. The MOD has however put in place a range of measures to monitor the health of personnel returning from the Gulf and investigate any concerns quickly.

Recognising the need for prompt action as a lesson learnt from the 1990/1991 Gulf Conflict, MOD commissioned a package of research into the health of veterans of the recent operations, which is being overseen by an independent Review Board. The largest piece of research in this package is a study of the physical and psychological health of personnel, which is being conducted by the King's Centre for Military Health Research under Professor Wessely. Around 19,000 personnel will be assessed by questionnaire, including regulars, reserves, civilians and journalists, both deployed and non-deployed. Questionnaires are being mailed out and base visits are underway. Initial findings should be available in late 2005.

Qualitative research on personnel is underway as part of the work being done by King's College, led by Professor Christopher Dandeker. Around 250 personnel deploying in November 04 will be interviewed before, during (by postal questionnaire in theatre) and after deployment to examine the sociological issues. Additional work will be undertaken looking at the effect on wives and families, with funding for this being provided by the Economic and Social Research Council. A further non-MOD funded study on alcohol use in personnel has been funded by the Joseph Rowntree Foundation.

The research package also includes a study of exposure to Depleted Uranium (DU) across the battlefield. A sample of 700 personnel including clean-up personnel, medics and support staff from the main Health study will be asked to give urine samples, to assess the possible exposure to DU across the various theatre roles. Sample collection began in the Autumn of 2004 and the sub-study is expected to report in 2005. Personnel are also eligible for biological monitoring for urinary DU. More information on this can be found in section 5.

A major difficulty with scientific study of the Gulf 1990/1991 cohort is the poor

contemporary records, with much based on individual recall which has been shown to vary with time. For veterans of the recent operations, a project is underway with the MRC's Institute of Environment and Health at Leicester University, to record a database of exposures and locations.

When the initial results of these studies have been examined, further clinical studies may be commissioned on the advice of the Health Review Board. This may include research into reproductive health where appropriate.

The MOD also plans to monitor the mortality of veterans compared with a control group and publish figures every 6 months on the Defence Analytical Services Agency website.

Section 5

POTENTIAL EXPOSURES

Introduction

In addition to the stresses associated with preparation for, and participation in, armed conflict, UK troops in the 1990/1991 Gulf Conflict may potentially have experienced a number of exposures which have been suggested by some as possible causes of illness among Gulf veterans. Whilst there is currently no consensus among the scientific and medical communities on the aetiology of Gulf veterans' illnesses, the MOD is aware that veterans have health concerns about a number of possible exposures.

The MOD is committed to providing information to Parliament and to the public on matters of potential relevance to the issue of Gulf veterans' illnesses and a series of reports have been published, listed at Annex A to this document. The research programme following operations in the Gulf in 2003 includes work on exposures.

The current state of knowledge relating to the potential exposures that may have taken place is as follows:

Medical countermeasures/other vaccinations

In the 1990/1991 Gulf Conflict, British troops were offered vaccination against anthrax and plague, as protection against the possible use of these agents for biological warfare purposes by Iraq. Pertussis vaccine was also given as an adjuvant to the anthrax vaccine. In addition, where troops did not have a current immunisation, they were likely to have received routine vaccinations against yellow fever, tetanus, typhoid, poliomyelitis and cholera at about the same time. Particular categories of Service personnel e.g. health staffs will have received Hepatitis B vaccine. There is evidence that some troops also received meningitis vaccine; additionally, Hepatitis A immunoglobulin may have been given to some individuals. MOD is aware of one individual who was vaccinated against smallpox by private arrangement and another who was vaccinated against Japanese Equine Encephalitis for a possible deployment to the Far East.

British troops were given Nerve Agent Pretreatment Sets (NAPS), consisting of tablets containing 30mg pyridostigmine bromide. One tablet was to be taken orally every eight hours. Pyridostigmine reversibly blocks the enzyme acetylcholinesterase to which many nerve agents irreversibly bind. Many individuals would have taken anti-malarial prophylactics, namely Paludrine (proguanil hydrochloride) and chloroquine, for a short period, although the available evidence suggests that most individuals would have stopped taking them shortly after arriving in the Gulf. Further information on the origin and implementation of the medical countermeasures programme is contained in MOD publications C & I at Annex A.

Personal medical records were generally not taken to the Gulf, and were therefore unavailable for the recording of vaccination details. In many cases, this means that the vaccination records of Gulf veterans are incomplete. A paper has been produced which gives details of the Service medical documentation system, how it is designed

to operate in the three services and explains why a number of problems arose with medical record keeping during the 1990/1991 Gulf Conflict. The paper also explains how Gulf veterans or their representatives can gain access to their medical records, why there may be delays in gaining access, and from where assistance may be obtained. (See publication M at Annex A).

Service personnel, including those deployed to the Gulf in 2003, are currently offered a range of immunisations to protect against disease as appropriate. These include standard service immunisations, immunisations for deployment to areas with specific health hazards, immunisations to help protect personnel against the effects of biological weapons, and immunisations for personnel in specific occupational or "at risk" groups. The anthrax vaccine is offered to UK personnel. Poliomyelitis, tuberculosis, meningococcal meningitis, typhoid, tetanus, diphtheria, hepatitis A, yellow fever, rabies, hepatitis B, rubella and smallpox are also offered as appropriate. As in the 1990/1991 Gulf Conflict, UK service personnel were given NAPS tablets. All immunisations are offered in accordance with General Medical Council guidelines on consent.

Chemical and biological warfare (CBW) agents

There is no confirmed evidence of the offensive use of CBW agents by Iraq during the 1990/1991 Gulf Conflict. A number of chemical agent alarms did occur, but were followed up at the time and were not substantiated. However, MOD has reviewed incidents where CBW exposure is alleged to have occurred, and the results of such reviews are reported in MOD Publications D, E, H, J - L and O at Annex A.

Further information about how Chemical Warfare Defence was organised in the UK during the Gulf Conflict is given in MOD publication G at Annex A.

Oil well fire pollution

No evidence has emerged to suggest that pollution caused by oil well fires in Kuwait during the 1990/1991 Gulf Conflict could be responsible for ill-health among Gulf veterans. Pollutant levels from the fires appear to have been relatively low. The health of individuals working in the proximity of oil well fires in the Gulf was closely monitored and a number of reports were produced detailing the findings of this monitoring. The US Presidential Advisory Committee on Gulf War Veterans' Illnesses reached similar conclusions in a report published in December 1996. A report published in the United States by the RAND corporation³⁰ reported the results of a review of the health effects of the oil well fires. It concluded that the cumulative doses of relevant pollutants would fall below doses known to cause adverse health effects. It also concluded that there are no data to suggest that the symptoms of some veterans of the 1990/91 Gulf Conflict are associated with oil fire exposure.

Organophosphate (OP) pesticides

An investigation into the use of OP pesticides by UK forces during the 1990/1991 Gulf Conflict was carried out in 1996, and is reported in MOD Publication A (see Annex A). This found that Fenitrothion (C₉H₁₂NO₅PS) - based pesticide was used routinely for residual insecticide spraying in the Gulf during late 1990 and early 1991.

There was also extensive use of two insecticides based on Azamethiphos $(C_9H_{10}CIN_2O_5PS)$ as fly bait. Malathion $(C_{10}H_{19}O_6PS_2)$ -based dusting powder was used to treat some hundreds of Iraqi prisoners of war (for lice). There was also evidence of local purchase of unidentified residual insecticides. One of the latter pesticides, which may have been based on Diazinon $(C_{12}H_{21}N_2O_3PS)$, was used for a limited period by some environmental, and possibly unit hygiene, personnel although the total quantity involved was probably small.

Pesticides would have been used by Service personnel who had been trained in the safe use of these products. When considering possible exposures to pesticides during the Gulf Conflict it is important to distinguish between spraying surfaces with a residual insecticide and space, or swing, fogging using direct contact insecticide with a knockdown effect in a thermal fog to clear areas out of doors or whole buildings. OP pesticides are used for the former, but not the latter purpose.

Depleted uranium (DU)

There have been a number of claims about the health effects of DU, many of which are exaggerated or groundless. During the 1990/1991 Gulf Conflict, a 120mm DU-based round was used in the UK's Challenger 1 tanks. MOD's assessment is that UK tanks fired fewer than 100 rounds against Iraqi military forces during hostilities, although additional rounds were fired during earlier work-up training in Saudi Arabia. MOD is not aware of any UK personnel who sustained shrapnel injuries from DU-based ammunition in the 1990/1991 Gulf Conflict. There is no evidence to suggest that the illnesses being experienced by some UK Gulf veterans are linked to exposure to DU. Further information on DU is available on the MOD website: www.mod.uk/issues/depleted_uranium/index.htm.

Following a consultation exercise, and recognising that veterans of the 1990/1991 Gulf Conflict and Balkans are concerned about their possible exposures to DU in theatre, MOD has funded the development of a retrospective test for DU in urine, which is being implemented by the independent DU Oversight Board (DUOB). A pilot exercise commenced in March 2004 and the main testing programme was launched in September 2004. Progress of the programme can be viewed on the DUOB website at: www.duob.org.uk. Those interested in the test receive factsheets on DU and the test with their application form. Results of the tests with general advice on interpretation will be issued to participants by appropriate health professionals and a copy sent to the participant's GP, where consent is given. A telephone helpline (01527 532198) is available for those requiring further advice on the implications of their test result.

British Forces deployed to the Gulf in 2003 had DU munitions available as part of their armoury, and used them as necessary. 1.9 tonnes of DU were expended by British Challenger tanks. Since January 2003, all regular and reservist Service personnel and MOD civilians who are deployed to a theatre of war where DU is used are entitled to receive a urine test for DU if they have any concerns. The small numbers who may have received relatively high exposures are positively encouraged to do so. Contractors' personnel, aid workers and embedded journalists will also be able to receive the test. To provide a baseline for comparison, we have commissioned the Institute of Occupational Medicine in Edinburgh to carry out a

study to establish normal values in a military population who did not deploy.

How do I request a urinary DU test for my patient?

If your patient served in the **1990/91 Gulf conflict**, they may apply directly and without referral for the DUOB developed retrospective test. Details including an application form are available on the DUOB website: www.duob.org.uk. Alternatively, they can write for an application form to:

DUOB Secretariat Floor 7, Zone H Main Building Whitehall London SW1A 2HB

If your patient served in the **2003 Iraq conflict (Op TELIC)**, you can request a urinary uranium test from the Defence Radiological Protection Service (DRPS). The point of contact at DRPS, to whom requests for urine sampling are to be directed, is given below. Request forms, containers and instructions on the collection of urine samples will be issued by DRPS as required. Results of tests carried out will be returned with appropriate comment. Where results are considered to require specialist interpretation, additional comment on the medical aspects will be included from the Institute of Naval Medicine's Radiation Medicine specialist.

For urine sample bottles and information	For advice on results (GPs or
on testing	Occupational Health only)
DRPS Dosimetry Section	Duty Radiation Medicine Specialist
Institute of Naval Medicine	Institute of Naval Medicine
GOSPORT	GOSPORT
Hampshire	Hampshire
PO12 2DL	PO12 2DL
Mil: 9380 Ext 68162 or 68267	Mil: 9380 68026
Tel: 02392 768162 or 768267	Tel: 02392 768026
Fax: Ext 68150	Fax: 02392 504823

MOD PUBLICATIONS ON GULF VETERANS' ILLNESSES

- A. Organophosphate Pesticide Investigation Team (OPPIT): Substantive Report. 6 December 1996. Investigates the circumstances in which organophosphate (OP) pesticides were used during the 1990/1991 Gulf Conflict.
- B. **Gulf Veterans' Illnesses: A New Beginning.** 14 July 1997. Set out the how MOD intended to address the Gulf veterans' illnesses issues and underpins our approach today.
- C. Background to the use of Medical Countermeasures to protect British Forces against biological and chemical warfare agents during the Gulf Conflict (Operation GRANBY). 28 October 1997. Explains the basis on which various medical countermeasures, principally vaccines and nerve agent pre-treatment tablets, were used to protect British troops during the 1990/1991 Gulf Conflict.
- D. **Kuwaiti Girls' School Case Narrative.** 19 March 1998. Joint UK/US review of what has become known as the "Sabahiyah" incident, in which a large tank of liquid, initially thought to contain Iraqi mustard agent, was found in Kuwait after the end of the 1990/1991 Gulf Conflict.
- E. Dead animals during the Gulf Conflict: A review of the circumstances in which UK forces reported the presence of groups of dead animals in theatre during Operation GRANBY in 1990/91. 6 April 1998.
- F. Testing for the presence of depleted uranium in UK veterans of the Gulf conflict, the current position. 19 March 1999.
- G. British Chemical Warfare Defence During the Gulf Conflict. December 1999. A background paper detailing how Chemical Warfare Defence was organised in the UK at the time of the 1990/1991 Gulf Conflict.
- H. Review of Events Concerning 32 Field Hospital and the Release of Nerve Agent Arising from US Demolition of Iraqi Munitions at the Khamisiyah Depot in March 1991. December 1999. A review of the possible effects on UK units, in particular 32 Field Hospital, of possible exposure to very low levels of nerve agent which may have been released as a result of US demolition activity at the Khamisiyah depot in Iraq. See also publication O.
- I. Implementation of the Immunisation Programme against Biological Warfare Agents for UK Forces during the Gulf Conflict 1990/91. 20 January 2000. A detailed overview of the UK's anti-biological warfare immunisation during the 1990/1991 Gulf Conflict.
- J. A Review of the Suggested Exposure of UK Forces to Chemical Warfare Agents in Al Jubayl on 19 January 1991. 20 January 2000, a review of events in Al Jubayl on 19 January 1991 during the Gulf Conflict, where veterans have suggested that they were exposed to chemical warfare agents.

- K. A Review of the Activities of the 1 Field Laboratory Unit and Suggested Biological Warfare Agent Detections during Operation GRANBY. 18 May 2000. A review of events during the Gulf Conflict where veterans have suggested that they were exposed to biological warfare agents.
- L. A Review of UK Chemical Warfare Agent Alerts during the 1990/1991 Gulf Conflict. 20 July 2000. A review of UK chemical warfare agent alerts from August 1990 to March 1991.
- M. **Medical Records in the Gulf.** October 2001. An explanation of the relevant parts of the Service medical documentation system which describes how it operated in the Gulf Conflict, how veterans may obtain copies of their records, and why there may be difficulty in accessing records.
- N. The 1990/1991 Gulf Conflict: Health and Personnel Related Lessons Identified. 4 November 2004. This paper focuses on the health and personnel related issues resulting from the 1990/1991 Gulf Conflict, with the aim of learning from the problems identified. The paper identifies what the Ministry of Defence has already done to improve procedures and assesses how these have been applied to the current Iraq deployment (Operation TELIC). It also indicates where improvements are still required.
- O. Review of Modelling of the Demolitions at Khamisiyah in March 1991 and Implications for UK Personnel. 27 January 2005. The only known release of nerve agent during the 1990/91 Gulf conflict was following the demolition of Iraqi rockets at Khamisiyah in March 1991. A substantial amount of work has been done in the US to model this incident, with the latest results published in 2002. This paper details the MOD's assessment of the US model.

Copies of all the documents listed above and further information on Gulf veterans' illnesses can be obtained by calling the VPU Gulf helpline on 0800 169 4495; fax 020 7218 1482, or by writing to VPU, 7th Floor Zone H, Ministry of Defence, Main Building, Whitehall, London SW1A 2HB. They are also available at: www.gulfwar.mod.uk

ANNEX B

REFERENCES

¹ W J Coker. A Review of Gulf War Illness. Journal of the Royal Naval Medical Service 1996; 82: 141-146

² Coker WJ, Bhatt BM, Blatchley NF, and Graham JT. Clinical Findings for the first 1000 Gulf War veterans in the Ministry of Defence's medical assessment programme. BMJ 318:290-4, 1999.

³ Lee HA, Gabriel R, Bale AJ, Bolton P, Blatchley NF. Clinical Findings of the second 1000 UK Gulf War Veterans who attended the Ministry of Defence's Medical Assessment Programme. J R Army Med Corps 2001; 147: 153-160.

⁴ Lee HA, Gabriel R, Bolton JPG, Bale AJ, Jackson M. Health Status and clinical diagnosis of 3000 UK Gulf War Veterans. J R Soc Med 2002; 95: 491-497.

⁵ Lee HA, Gabriel R, Bale AJ. Clinical outcomes of Gulf Veterans' Medical Assessment Programme (GVMAP) referrals for Gulf veterans with post traumatic stress disorder to specialised centres. In Press.

⁶ Cherry N, Creed F, Silman A, Dunn G, Baxter D, Smedley J, Taylor S, Macfarlane GJ. Health and exposures of United Kingdom Gulf war veterans. Part 1: The pattern and extent of ill health. Occupational and Environmental Medicine May 2001, Vol 58, No 5, p291-298.

⁷ Cherry N, Creed F, Silman A, Dunn G, Baxter D, Smedley J, Taylor S, Macfarlane GJ. Health and exposures of United Kingdom Gulf war veterans. Part 2. The relation of health to exposure. Occupational and Environmental Medicine May 2001, Vol 58, p299-306.

⁸ Macfarlane G J, Thomas E, Cherry N. Mortality among UK Gulf War veterans, Lancet; 356: 17 – 21 2000.

⁹ Maconochie N, Doyle P, Davies G, Lewis S, Pelerin M, Prior S, Sampson P. The study of reproductive outcome and the health of offspring of UK veterans of the Gulf war: methods and description of the study population. BMC Public Health 2003,3:4.

Doyle P, Maconochie N, Davies G, Maconochie I, Pelerin M, Prior S, Lewis S. Miscarriage, stillbirth and congenital malformation in the offspring of veterans of the first Gulf war. International Journal of Epidemiology 2004: 33: 74-86.

¹¹ Maconochie N, Doyle P, Carson C. Infertility among male UK veterans of the 1990-1 Gulf war: reproductive cohort study. BMJ, doi: 10.1136/bmj.38163.620972.AE (published 14 July 2004)

¹² Simmons R, Maconochie N, Doyle P. Self-reported ill health in male UK Gulf War veterans: a retrospective cohort study. BMC Public Health 2004, 4:27 doi: 10.1186/1471-2458-4-27

¹³ Unwin C, Blatchley N, Coker W, Ferry S, Hotopf M, Hull L, Ismail K, Palmer I, David A, and Wessely S. Health of UK servicemen who served in the Persian Gulf War. Lancet 353:169-78, 1999.

¹⁴ Ismail K, Everitt B, Blatchley N, Hull L, Unwin C, David A, and Wessley S. Is there a Gulf War syndrome? Lancet 353:179-82, 1999.

¹⁵ Hotopf M, David A, Hull L, Ismail K, Unwin C, Wessely S. Role of vaccinations as risk factor for ill health in veterans of the Gulf war: cross sectional study. BMJ,320: 1363-1367, 2000.

¹⁶ Skowera A, Stewart E, Davis E T, Cleare AJ, Unwin C, Hull L, Ismail K, Hossain G, Wessely S C, Peakman M. Antinuclear autoantibodies (ANA) in Gulf War-related illness and chronic fatigue syndrome (CFS) patients. Clinical and Experimental immunology, volume 129, issue 2, August 2002.

¹⁷ Ismail K, Kent K, Brugha T, Hotopf M, Hull L, Seed P, Palmer I, Reid S, Unwin C, David A S, Wessely S. The mental health of UK Gulf war veterans: phase 2 of a two phase cohort study. BJJ 2002;325:576.

- ²¹ Wessely S, Unwin C, Hotopf M, Hull L, Ismail K, Nikalaou V, David A. Stability of recall of military hazards over time. Evidence from the Persian Gulf War of 1991. British Journal of Psychiatry 2003, 183, 314-322.
- ²² Sharief M , Priddin J, Dalamont R S, Unwin C, Rose MR, David A, Wessely S. Neurophysiologic analysis of neuromuscular symptoms in UK Gulf War veterans. Neurology volume 59, Number 10, November 26, 2002.
- ²³ Rose MR, Sharief M, Priddin J, Nikolaou V, Hull L, Unwin C, Ajmal-Ali R, Sherwood R, Spellman A, David A, Wessely S. Evaluation of neuromuscular symptoms in UK Gulf War veterans. Neurology volume 63, Number 9, November 9, 2004.
- ²⁴ Stimpson NJ, Thomas HV, Weightman AL, Dunstan F, Lewis G, Psychiatric disorder in veterans of the Persian Gulf War of 1991 systematic review. British Journal of psychiatry 2003, 182,391-403.
- ²⁵ Macfarlane G, Biggs A-M, Maconochie N, Hotopf M, Doyle P, Lunt M. Incidence of cancer among UK Gulf war veterans: cohort study. BMJ 13 December 2003, Vol 327, p1373.
- Mackness B, Durrington PN, Mackness MI. Low paraoxanase in Persian Gulf War Veterans self reporting Gulf War Syndrome. Biochem Biophys Res Commun 2000 Sep 24; 276(2): 729-.33.
- ²⁷ Hotopf M, Mackness MI, Nikolaou V, Collier D, Curtis C, David A, Durrington P, Hull L, Ismail K, Peakman M, Unwin C, Wessely S, Mackness B. Paraoxonase in Persian Gulf War Veterans. Journal of Occupational and Environmental Medicine 2003: 45(7):668-675.
- ²⁸ Kilshaw S. Friendly Fire The construction of Gulf War Syndrome narratives. Anthropolgy & Medicine Vol 11, No.2 August 2004, pp. 149-160.
- ²⁹ Griffiths GD, Hornby RJ, Stevens DJ, Scott LAM, Upshall DG. Biological Consequences of Multiple Vaccine and Pyridostigmine Pretreatment in the Guinea Pig. J. Appl. Toxicol, 21, 59-68 (2001).
- ³⁰ Spektor D.M., A Review of the Scientific Literature as it pertains to Gulf Veterans Illnesses, Volume 6, Oil Well Fires, RAND 1998.

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¹⁸ David AS, Farrin L, Hull L, Unwin C, Wessely S, Wykes T. Cognitive functioning and disturbance of mood in UK veterans of the Persian Gulf War: a comparative study. Psychological Medicine 2002 32:1327-1370.

¹⁹ Hotopf M, Anthony DS, Hull L, Nikalaou V, Unwin C, Wessely S. Gulf war illness – better, worse or just the same? A cohort study. BMJ 13 December 2003, Vol 327, p1370

²⁰ Hotopf M, David A, Hull L, Nikalaou V, Unwin C, Wessely S. Risk factors for continued illness among Gulf War veterans: a cohort study. Psychological Medicine 2004: 34: 1-8

Managing medically unexplained illness in general practice



Louise Stone





Background

Patients with medically unexplained symptoms commonly present to general practice and experience significant disability. Many have a history of trauma, which complicates the therapeutic relationship between doctor and patient. Because diagnosis is an expected outcome of a medical interaction, doctors and patients can feel frustrated and lost without one.

Objectives

This article provides practical management strategies that general practitioners (GPs) can use when patients present with medically unexplained symptoms.

Discussion

Three types of common presentations are discussed. Enigmatic illnesses occur when the doctor and patient believe that a biomedical disease is likely, but a diagnosis is not forthcoming. Contested illnesses occur when a patient is committed to a diagnosis the doctor does not accept. Chaotic illnesses occur when symptoms are over-determined; there are many possible diagnoses, but none fully explain the complex web of distress the patient experiences. Common strategies for managing medically unexplained symptoms are discussed, and specific approaches to each presentation are outlined.

atients with medically unexplained symptoms commonly present to general practice, 1,2 and their symptoms can be severe and disabling.^{3,4} The challenge for the general practitioner (GP) involves managing individual symptoms, but also crafting a framework for the chronic care of patients with significant ongoing illness.^{5,6} For many patients, this includes management of comorbid depression and anxiety, 2,78 and ongoing psychosocial stress.9

This article provides an approach to the management of patients with medically unexplained symptoms. Three ways these patients may present are outlined, and some of the strategies that may be utilised to alleviate their suffering are discussed. The article does not address the care of patients who are malingering, patients with individual syndromes (eq. irritable bowel syndrome) or patients with hypochondriasis.

Why is diagnosis so important? The importance of validation and explanation

Diagnosis is not just a tool to guide management. It is an expected part of a medical interaction. To be left without a diagnosis is to be left without a story, with no way to make sense of distressing symptoms, 10,11 or explain the disability to friends, family and workplace colleagues. 12,13 No diagnosis means no prognosis, so patients live with perpetual uncertainty. 14-16 Diagnosis also 'authorises' suffering, establishing illness as legitimate and socially acceptable. 17 It is difficult to access health and disability services or peer support without a diagnosis.18

For the doctor, a lack of diagnosis means a lack of guidelines and evidence-based treatments. Doctors often describe a sense of helplessness in the face of undiagnosable suffering. 17,19 Therefore, doctors and patients can share feelings of anxiety, anger and frustration.20,21

Patients may have no diagnosis that fully explains their illness experience, but there are often fragments of explanation that contribute to our understanding of their symptoms. 1722 Different explanatory fragments can reflect different perspectives, and may include biomedical, psychiatric and psychosocial elements. 23 The challenge for the GP lies in weaving these fragments together and crafting a shared understanding of the problem that the patient and doctor can work with and accept because this leads to better clinical outcomes. 22 For the GP, this means creating an explanation that will 'do for now', while accepting that a more satisfactory diagnosis may emerge over time. This issue is explored further in the case presented at the end of this paper. This can be a difficult and frustrating task for all concerned. 22,24

The role of psychiatric and psychosocial precipitants: 'Are you saying this is all in my head, doctor?'

One of the most difficult dilemmas in the management of medically unexplained symptoms involves understanding the role of psychiatric illness and psychosocial stress. In contemporary culture, these illnesses are often seen as less real and legitimate than physical illness; they are 'all in the head'. ¹⁷ Unfortunately, accepting a psychiatric label also means accepting a deep and unpleasant social stigma. ⁵ It is not surprising that patients resist the idea of being diagnosed with a psychiatric illness. Nevertheless, comorbidity of medically unexplained symptoms and psychiatric illness is high. ^{2,78} This is not to say that all medically unexplained symptoms have a psychiatric cause, or that psychiatric treatment can cure physical symptoms, but concurrent management can be very helpful. ²⁵

It is important to help patients understand that the mind and body are interconnected in complex ways, and that holistic care is often essential to improve health. The technique of shifting the focus away from just physical symptoms and biomedical diagnoses, to a more holistic understanding of illness is known as reattribution: a useful technique in primary care.²⁶

Types of medically unexplained illness

There are three distinct types of medically unexplained symptoms, which present differently and require different management approaches. While these categories can overlap, it is helpful to consider them individually because they profoundly affect the way the consultation occurs. However, there are also common strategies for managing all medically unexplained illness (*Box 1*).

Elusive illness: Where a significant biomedical diagnosis seems to be 'just around the corner'

In elusive illnesses, symptoms seem to suggest there is a diagnosis, but it cannot be determined at this time. These consultations are characterised by frustration, and fear of 'missing something'. General practice is immersed in uncertainty. At least 5% of patients in general practice have rare

Box 1. Common approaches to managing medically unexplained symptoms

Validation

- · Acknowledge that the symptoms are real and distressing
- Acknowledge that medicine has limits and the uncertainty is frustrating

Explanation

- Consider and record physical, psychiatric and psychosocial diagnoses and symptoms
- · Craft explanations that include the body and the mind
- Always consider the role of past or current trauma, psychosocial stress and personal vulnerabilities

Coordination of care and advocacy

 Coordinate care to avoid duplication of investigations and exacerbation of iatrogenic harm

Symptom management

- Offer symptom relief and practical support to address disability (eg home help, workplace assessment)
- Encourage physical therapies (eg massage, physiotherapy, hydrotherapy)
- Manage comorbidities as effectively as possible

Broadening the agenda beyond physical symptom management

- Encourage psychological care to address the impact of illness and underlying issues that may exacerbate symptoms
- · Address healthy lifestyle goals

Harm minimisation

 Check for new diagnoses when the illnesses changes significantly (eg the emergence of a new symptom) or during a yearly health check

Empathy

 Manage the therapeutic relationship carefully and seek support if it becomes unhelpful

diseases,²⁷ and many people present early, when symptoms are difficult to detect or characterise. We are often in a position to see a patient with significant illness that we are unable to diagnose. We are also unable to 'exclude disease'. Almost any symptom can herald a prodrome of autoimmune disease or an early carcinoma that is undetectable. Patients often find this uncertainty difficult to understand²⁸ and commonly request 'a blood test to check for everything'.

The challenge for GPs lies in balancing the iatrogenic risk of investigation with the therapeutic risk of missing something important. Statistically, increasing the number of investigations increases the risk of false positives and a cascade of further investigation and treatment that are unnecessary and potentially harmful.²⁹ By investigating, we also entrench the idea that there is something seriously wrong.¹⁷ Patients can develop a career of medical investigation and treatment.³⁰

Strategies for managing elusive illnesses are listed in *Box 2*. Essentially, the goal is harm minimisation and supportive care. Harm minimisation includes regular monitoring for changes

FOCUS MEDICALLY UNEXPLAINED ILLNESS

in symptoms, or the emergence of possible diagnoses, while preventing unhelpful cycles of referrals and re-referrals.31

Contested illnesses: When every consultation becomes a battleground

Contested illnesses occur when a patient is committed to a particular diagnosis, but the doctor does not agree. These consultations are characterised by conflict,22 and can become a battleground, 17 described as a 'duet of escalating antagonism'. 32 Patients arrive with a diagnosis they wish to have 'authorised' – an 'illness you have to fight to get'. 18 Common contemporary examples include Lyme disease and multiple chemical sensitivity.

Contested illnesses are more common now that diagnosis has become more democratic. Easy access to online information and support networks have made it easy for people with medically unexplained symptoms to find their preferred

Box 2. Specific approaches to the management of elusive illnesses

Validation

- · Acknowledge that rare and early diseases can be difficult to diagnose and may take time
- · Acknowledge that many tests will exclude diseases but will not diagnose it
- Acknowledge that many patients have diseases within a discipline. but are without a diagnosis (eg cancer of unknown primary)

Harm minimisation

- · Revisit diagnosis regularly. Over time, there will be multiple pieces of information from multiple sources. It may be helpful to have a medical student or registrar take a full, formal history and examination, and present the case
- · Monitor mental health. The despair associated with severe, medically unexplained illness is significant, pervasive and risky

Therapeutic relationship

- Acknowledge your own frustration and reiterate your commitment to care for the patient and their family
- · Focus on coordinating care to relieve the patient of as much of the burden of managing their disability as possible. It may require some advocacy as agencies may not accept disability without diagnosis

Clinical reasoning

- Pattern recognition is more accurate when patterns are retrieved the same way they are laid down. Describe the case using medical language when writing referrals or notes (eg acute, severe, burning chest pain not associated with exertion or inhalation). If the problem is represented in the notes in the same way it is stored in your memory, the diagnosis is more likely to be triggered and recalled. 38,39
- · 'A clever head trumps a clever test': In the absence of a clear diagnostic hypothesis, consider referral before expensive or potentially harmful investigations
- · Patterns exist in different forms in different disciplines. Rare genetic diseases may be recognised by dentists, dermatologists, physiotherapists or general paediatricians on the basis of patterns familiar to them in their own discipline. Therefore, referral to a multidisciplinary team can be critical

diagnosis on the internet.33 These patients often present with a list of requests for investigations, referrals and treatments, and may have well-developed strategies to obtain these.

Strategies for managing contested illnesses are outlined in Box 3. The goal is to maintain the therapeutic relationship between doctor and patient, and develop trust, while holding clear boundaries. This includes ensuring the patient receives good general practice care - it is easy to focus on Lyme disease and miss essential hypertension or generalised anxiety disorder. Contested illnesses are managed best when doctors and patients are able to define some common ground. It is important to clarify areas of agreement and disagreement.²²

Box 3. Specific approaches to the management of contested illnesses

Validation

- · Acknowledge what you can accept (eg that the symptoms are real and distressing, that medicine has its limits)
- Acknowledge what you cannot agree on (eg that as a GP, you have no evidence for a particular treatment, that you cannot find sufficient evidence to justify a particular diagnosis)
- Acknowledge that the patient is doing the best they can to manage their illness

Harm minimisation

- · Acknowledge that at this time, the medical community has not accumulated sufficient evidence to justify the diagnosis, investigation or treatment the patient is proposing. This may mean that proposed investigations or treatments are unhelpful or unsafe
- Where possible, acknowledge the limitations of self-report and anecdote, and encourage the patient to think critically of treatments that have no objective evidence. This may involving searching the literature to find evidence on behalf of your patient, particularly when they are considering risky or expensive treatments
- Encourage patients to consider the potential for harm, particularly with complementary medicines in those with comorbidities. Health professional and consumer information can be found on websites such as the National Center for Complementary and Integrative Health⁴⁰ or the National Prescribing Service (NPS MedicineWise)⁴¹
- Continue to encourage 'normal' general practice care, including preventive screening, management of comorbidities and lifestyle advice

Therapeutic relationship

- Be prepared to offer support 'within the limits of my discipline'. Do not be reluctant to let patients know when they are exploring options outside your range of expertise
- Recognise when the consultation is degenerating into unhelpful conflict and find a way to break the cycle. Some therapeutic relationships may become unworkable and need to be terminated. Others may require discussion with colleagues

Clinical reasoning

• It may be helpful to think of the illness as a type: 'I do not know that this is Lyme disease, but it is certainly behaving like an infectious disease'. This will help you design appropriate support strategies (encouraging general health, managing fatigue) and referring appropriately in case a different infectious disease is being missed

We should also advocate for our patients and, where possible, protect them from harm. This includes informing them of the risks of expensive and potentially harmful interventions, particularly from specialised clinics overseas that are not subject to Australian regulations.

Chaotic illnesses: Where problems 'go way down to the bottomless depths'

Chaotic illnesses have symptoms that are 'over-explained'; there are many problems and managing one exposes another.

Box 4. Specific approaches to the management of chaotic illnesses

Validation

- · Acknowledge that life is overwhelming and often lonely
- · Acknowledge that the patient has survived a difficult life
- Ask about, recognise and empathise with childhood trauma issues, and encourage patients to seek support
- Explain how childhood trauma can 'upregulate' the nervous system, and change the structure and function of the brain so that many physical symptoms, including pain, are worsened in adult life. 42,43 Explain clearly and explicitly that this means the pain is 'in the body' as well as 'in the head'
- · Explain that you understand there are no simple solutions, but offer what you can

Harm minimisation

- Do not forget preventive care strategies
- Attend to physical and psychological issues separately so that neither are likely to be overlooked. Sometimes, splitting care with another GP can be helpful. This is particularly the case where you are discussing sexual trauma and need to perform an intimate examination like a Pap smear
- Be prepared to acknowledge when a consultation did not go well, and reiterate your commitment to continue to do the best you can
- Protect your patient as much as you can from health professionals who are dismissive or judgemental. Choose 'generalist specialists' like geriatricians or general physicians where possible to minimise the number of therapeutic relationships that need to be managed

Therapeutic relationship

- Find a point of empathy: Many of these patients are frustrating and difficult to help. Understanding their trauma history can help you manage intractable issues that are difficult to address, and manage your own feelings of helplessness
- Accept that regular, scheduled visits can reduce crisis consultations
- · Try to keep as few doctors as possible involved in care: It is easy for management to become confused
- Spread the load with a small team: Involve other health professionals (including the practice nurse) and agencies as appropriate.
- Seek your own support if the therapeutic relationship becomes troubled

Clinical reasoning

· Make a clear list of current symptoms, ongoing issues and unresolved problems. Revisit this list if a new symptom occurs to see whether a new disease is emerging

These consultations are characterised by despair and hopelessness in the doctor and patient.

Patients with chaotic illness have troubles that are 'too complex in both medical and social terms for fixing'.14 Consultations can feel like a whirlpool; it is easy to become caught in a spiral of suffering with no solutions available. Many of these patients are victims of childhood trauma,34-36 and have complex social needs. Trauma complicates the therapeutic relationship. These patients often find it difficult to trust, and have difficulty establishing and maintaining positive interpersonal relationships.³⁶ It is therefore not surprising that the consultation dynamics can be challenging.

Strategies for managing chaotic consultations include ensuring there are regular opportunities to conduct an overview of clinical care, documenting all the agencies and health professionals involved in treatment, and ensuring that important preventive activities are performed. A yearly health assessment can help avoid focusing on the cascade of presenting symptoms alone. It is important to record, for each consultation, issues in ongoing care (eg following up results, or monitoring treatment) and presenting symptoms requiring attention before negotiating what can be attempted in a single consultation. Setting a clear agenda minimises the risk of drowning in symptoms without managing the illness effectively. Other strategies for managing chaotic illness are listed in Box 4.

Case – Explanatory 'fragments' that may help address the diagnostic dilemma of fatique

Mia, a university student aged 19 years, presents with fatigue. She lives away from home in a shared house. Her accommodation is unstable and she has spent some time in refuges when her housing has 'fallen through'. Mia has a boyfriend who is verbally abusive, and admits he can become physically violent after alcohol consumption and drug use. Mia has a background of childhood trauma due to sexual and physical abuse from her stepfather. She describes herself as lacking confidence and says she 'attracts one loser after another'. This has become obvious at work, where she describes bullying and harassment from her boss. Her medical history includes glandular fever 5 years ago, irritable bowel syndrome and migraine. She smokes, binge drinks on the weekends and has a poor diet.

Case discussion

The following diagnoses are all possible in this case and all provide potentially helpful directions for care. Note that no one diagnosis explains the whole picture, and it is difficult to prove which diagnosis (if any) accounts for the fatigue. Treatment will require a framework incorporating fragments that are relevant to the patient and helpful to the doctor. The outcome depends on the way such an explanation can help guide treatment and prioritise treatment approaches.

FOCUS MEDICALLY UNEXPLAINED ILLNESS

Potential biomedical diagnoses

- Postviral fatique
- Iron deficiency anaemia secondary to poor nutrition
- Murtagh's 'serious disorders not to be missed' and common masquerades' (eg diabetes, malignancy, thyroid disease, anaemia, etc)37
- Poor physical fitness
- Drug and alcohol misuse

Potential psychiatric diagnoses

- Depression
- Anxiety disorder
- Borderline personality disorder

Possible psychosocial formulation

Mia is a survivor of childhood trauma but has continued to replicate unhelpful interpersonal patterns. This has led to poor choices in partners and poor self-esteem, and has exacerbated bullying and harassment at work. She is struggling financially and has poor problem-solving skills, leading to considerable stress and unstable housing. Mia's stress management strategies are often unhealthy and include binge drinking.

Conclusion

Patients with medically unexplained symptoms are often very unwell and require complex care. Strategies include establishing and maintaining a healthy therapeutic relationship, explicitly validating the patient's experience, establishing a common ground explanation, and maximising general health. Harm minimisation strategies include balancing the risks and benefits of investigations and procedures, and advocating for patients at risk of harm from untried investigations or therapies. All patients need support to manage distressing symptoms and the disability that accompanies them. GPs are in a unique position to provide tenacious care for illness in the absence of disease, and for monitoring potential red flags that herald the emergence of a known diagnosis.

Author

Louise Stone MBBS, BA, MPH, MQHR, PhD, FRACGP, FACRRM, Clinical Senior Lecturer, Australian National University - Academic Unit of General Practice, The Canberra Hospital, ACT. dr.xxxxxx.xxxx@xxxxx.xxx

Competing interests: None.

Provenance and peer review: Commissioned, externally peer reviewed.

References

- Morriss R, Lindson N, Coupland C, Dex G, Avery A. Estimating the prevalence of medically unexplained symptoms from primary care records. Public Health 2012;126:846-54.
- 2. Steinbrecher N, Koerber S, Frieser D, Hiller W. The prevalence of medically unexplained symptoms in primary care. Psychosomatics 2011;52:263-71.
- 3. Koch H, van Bokhoven MA, ter Riet G, van der Weijden T, Dinant GJ, Bindels PJ. Demographic characteristics and quality of life of patients with unexplained complaints: A descriptive study in general practice. Qual Life Res 2007:16:1483-89.

- 4. de Waal MW, Arnold IA, Eekhof JA, van Hemert AM. Somatoform disorders in general practice prevalence, functional impairment and comorbidity with anxiety and depressive disorders. Br J Psychiatry 2004;184:470-76
- 5. Sadler JZ. Diagnosis/antidiagnosis. In: Radden J, editor. The philosophy of psychiatry: A companion. New York: Oxford University Press, 2004;163-79.
- 6. Stone L. Being a botanist and a gardener: using diagnostic frameworks in general practice patients with medically unexplained symptoms. Aust J Prim Health 2013;19:90-97.
- 7. Smith BJ, McGorm KJ, Weller D, Burton C, Sharpe M. The identification in primary care of patients who have been repeatedly referred to hospital for medically unexplained symptoms: A pilot study. J Psychosom Res 2009:67:207-11.
- 8. Löwe B, Spitzer RL, Williams JB, Mussell M, Schellberg D, Kroenke K. Depression, anxiety and somatization in primary care: Syndrome overlap and functional impairment. Gen Hosp Psychiatry 2008;30:191-99
- 9. Hanel G, Henningsen P, Herzog W, et al. Depression, anxiety, and somatoform disorders: Vague or distinct categories in primary care? Results from a large cross-sectional study. Journal Psychosom Res 2009;67:189-97.
- 10. Nettleton S, O'Malley L, Watt I, Duffey P. Enigmatic illness: Narratives of patients who live with medically unexplained symptoms. Soc Theory Health 2004;2:47-66.
- 11. Kirmayer LJ, Groleau D, Looper KJ, Dao MD. Explaining medically unexplained symptoms. Can J Psychiatry 2004;49:663-72.
- 12. Nettleton S. 'I just want permission to be ill': Towards a sociology of medically unexplained symptoms. Soc Sci Med 2006;62:1167-78.
- 13. Mik-Meyer N, Obling AR. The negotiation of the sick role: General practitioners' classification of patients with medically unexplained symptoms. Sociol Health Illn 2012;34:1025-38.
- 14. Frank AW. The wounded storyteller: Body, illness, and ethics. Chicago: University of Chicago Press, 2013.
- 15. Charmaz K. Good days, bad days: The self in chronic illness and time. Chapel Hill, NC: Rutgers University Press, 1993.
- 16. Charmaz K. Loss of self: a fundamental form of suffering in the chronically ill. Sociol Health Illn 1983;5:168-95.
- 17. Werner A, Isaksen LW, Malterud K. 'I am not the kind of woman who complains of everything': Illness stories on self and shame in women with chronic pain. Social Sci Med 2004;59:1035-45.
- 18. Dumit J. Illnesses you have to fight to get: facts as forces in uncertain, emergent illnesses. Soc Sci Med 2006;62:577-90.
- 19. Stone L. Blame, shame and hopelessness: Medically unexplained symptoms and the 'heartsink' experience. Aust Fam Physician 2014;43:191-
- 20. Woivalin T, Krantz G, Mäntyranta T, Ringsberg KC. Medically unexplained symptoms: Perceptions of physicians in primary health care. Fam Pract 2004;21:199-203.
- 21. Hahn SR. Physical symptoms and physician-experienced difficulty in the physician-patient relationship. Ann Intern Med 2001;134(9 Pt 2):897-904.
- 22. Salmon P. Conflict, collusion or collaboration in consultations about medically unexplained symptoms: The need for a curriculum of medical explanation. Patient Educ Couns 2007;67:246-54.
- 23. Van Ravenzwaaij J, Olde Hartman T, Van Ravesteijn H, Eveleigh R, Van Rijswijk E, Lucassen P. Explanatory models of medically unexplained symptoms: a qualitative analysis of the literature. Ment Health Fam Med 2010;7:223-31.
- 24. Salmon P, Peters S, Stanley I. Patients' perceptions of medical explanations for somatisation disorders: qualitative analysis. BMJ 1999;318:372-76.
- 25. Röhricht F, Elanjithara T. Management of medically unexplained symptoms: outcomes of a specialist liaison clinic. Psychiatr Bull 2014;38:102-07.
- 26. Morriss R, Gask L. Assessment and management of patients with medically unexplained symptoms in primary care. Psychiatry 2006;5:65-69.
- Senior T, Knight A. Rare diseases: A role for primary care. Lancet 2008:372:890.
- 28. Frostholm L, Fink P, Oernboel E, et al. The uncertain consultation and patient satisfaction: The impact of patients' illness perceptions and a randomized controlled trial on the training of physicians' communication skills. Psychosom Med 2005;67:897-905.
- 29. Hatcher S, Arroll B. Assessment and management of medically unexplained symptoms. BMJ 2008:336:1124-28.
- 30. Page LA, Wessely S. Medically unexplained symptoms: Exacerbating factors in the doctor-patient encounter. J R Soc Med 2003;96:223-27.

MEDICALLY UNEXPLAINED ILLNESS FOCUS

- 31. Balint M. The Doctor His Patient and the Illness. New York: International Universities Press, 1959.
- 32. Kleinman A. The illness narratives: Suffering, healing, and the human condition. New York: Basic Books, 1988.
- 33. Fair B. Morgellons: Contested illness, diagnostic compromise and medicalisation. Sociol Health Illness 2010;32:597-612.
- 34. Fiddler M, Jackson J, Kapur N, Wells A, Creed F. Childhood adversity and frequent medical consultations. Gen Hosp Psychiatry 2004;26:367-77.
- 35. Arnold R, Rogers D, Cook D. Medical problems of adults who were sexually abused in childhood. BMJ 1990;300:705-08.
- 36. Waldinger RJ, Schulz MS, Barsky AJ, Ahern DK. Mapping the Road From Childhood Trauma to Adult Somatization: The Role of Attachment. Psychosom Med 2006;68:129-35.
- 37. Murtagh J. Fatigue a general diagnostic approach. Aust Fam Physician 2003;32:873.
- 38. Stone L. Reasoning for registrars: an overview for supervisors and medical educators. Aust Fam Physician 2008;37:650.
- 39. Elstein AS, Schwarz A. Clinical problem solving and diagnostic decision making: Selective review of the cognitive literature. BMJ 2002;324:729-32.
- 40. National Center for Complementary and Integrative Health. Webpage. Bethesda: NCCIH, 2015. Available at https://nccih.nih.gov [Accessed 28 April 20151
- 41. NPS MedicineWise. Using complementary medicines. Sydney: National Prescribing Service Ltd, 2015. Available at www.nps.org.au/topics/how-tobe-medicinewise/using-complementary-medicines [Accessed 28 April 2015].

- 42. Wegman HL, Stetler C. A meta-analytic review of the effects of childhood abuse on medical outcomes in adulthood. Psychosomatic Medicine 2009:71:805-12.
- 43. Dube SR, Felitti VJ, Dong M, Giles WH, Anda RF. The impact of adverse childhood experiences on health problems: Evidence from four birth cohorts dating back to 1900. Prev Med 2003;37:268-77

correspondence afp@racgp.org.au

 From:
 Morton, David MR 3

 To:
 Hancock, Veronica

Cc: S47E DCJ HLTH; S47E

Re: Mefloguine Health Assessment Budget measure - Legislative Instrument [SEC=UNCLASSIFIED]

Date: Tuesday, 2 July 2019 2:53:40 PM

Attachments: image002.png

Veronica, what if you just do not refer to current serving in the Explanatory statement.

Sent from my iPad

Hi David,

The intent is not to specifically include current serving, but rather not to exclude any particular category of concerned persons. If we specifically exclude current serving, this will potentially provoke further concerns. We do not want to be in the situation where an allegation could be made that we are forcing people to quit before they can have a health assessment. As discussed, we could handle this via processes once a person has come forward, noting the service provider will be Bupa. For info, of the 15 who have currently come forward, as far as we can tell none are currently serving.

Happy to discuss.

Thanks, Veronica

<image001.jpg>

<image003.jpg>

To support those who serve or have served in the defence of our nation and commemorate their service and sacrifice.

<image002.png>The Department acknowledges the Traditional Owners of the land throughout Australia and their continuing connection to country, sea and community. We pay our respect to all Aboriginal and Torres Strait Islander peoples, their cultures and to their elders past and present.

Sent: Tuesday, 2 July 2019 11:59 AM

To:s47E @dva.gov.au>

<<u>xxxxxxxxxxxxxxxx@xxx.xxx.xx</u>>; s47E dva.gov.au>; 447E dva.gov.au>;

s47E <u>dva.gov.au</u>>; Ross, Victoria DR 1

Subject: RE: Mefloquine Health Assessment Budget measure - Legislative Instrument [SEC=UNCLASSIFIED]

UNCLASSIFIED



We appreciate the consideration of current serving members in relation to the eligibility provision of the instrument being drafted. However, The JHC advice on this matter is that reference to current serving members in the eligibility provisions is not necessary as such assessment are available to serving ADF members through the defence health system. If appropriate may choose to access the package of assessment that DVA are putting in place but we would purchase that through our existing arrangements.

Regards

David

P: +61 2 6266 3897 M: \$22 E: xxxxx.xxxxxxx@xxxxxxxxxxxxxx

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From: \$47E dva.gov.au>

Sent: Tuesday, 2 July 2019 10:40 AM

s47E <u>@dva.gov.au</u>>

Subject: Mefloquine Health Assessment Budget measure - Legislative Instrument [SEC=UNCLASSIFIED]

Good morning David and team,

As you would be aware, we are currently working to implement the Mefloquine health Assessment budget measure. This includes the development of a legislative instrument to establish eligibility for these assessments. The draft legislative

instrument and explanatory statement are attached for your oversight and comment.

Unfortunately, we are working to a very tight timeframe as we are seeking agreement to this legislative instrument from the Repatriation Commission on 11 July. If you have any comments on this instrument could you please send them trhough by COB today?

Apologies for the timeframe.

Kind regards,



s47E

Assistant Director | Mental and Social Health Policy

Department of Veterans' Affairs

P: \$47E

CANBERRA ACT 2601

From: <u>Hancock, Veronica</u>

To: Morton, David MR 3; Ross, Victoria DR 1

Cc: OCJ HLTH; S47E

Subject: RE: Mefloquine Health Assessment Budget measure - Legislative Instrument [SEC=UNCLASSIFIED]

Date: Thursday, 4 July 2019 9:46:03 AM

Attachments: image001.png

Hi David and Vicki, apologies, I did not get to this in time to incorporate these suggested changes to the wording – although we did manage to cover off your earlier point David, and have replaced the references in the ES to current and former serving with references to eligible persons.

We will send you through the final versions of the instrument and ES.

Kind regards, Veronica

Veronica Hancock
Assistant Secretary
Wellbeing Policy Branch
Veterans' Services Design Division
Department of Veterans' Affairs
t 02 6289 6712 m \$22

To support those who serve or have served in the defence of our nation and commemorate their service and sacrifice.



The Department acknowledges the Traditional Owners of the land throughout Australia and their continuing connection to country, sea and community. We pay our respect to all Aboriginal and Torres Strait Islander peoples, their cultures and to their elders past and present.

Sent: Tuesday, 2 July 2019 4:47 PM

To: Ross, Victoria DR 1 <xxxxxxxxxxxxxxx@xxxxxxxxxxxx; Hancock, Veronica

<xxxxxxxxxxx@xxx.xxx.xx>

Cc: OCJ HLTH <xxxxxxxx@xxxxxxxx.xxx.xx>

Subject: RE: Mefloquine Health Assessment Budget measure - Legislative Instrument

[SEC=UNCLASSIFIED]

UNCLASSIFIED

Veronica, I realise it is late in the day but Vicki Ross had some further observations and suggested changes to wording . Please see her email below.

Regards

David

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Sent: Tuesday, 2 July 2019 2:58 PM

Subject: RE: Mefloquine Health Assessment Budget measure - Legislative Instrument

[SEC=UNCLASSIFIED]

UNCLASSIFIED

Thanks David.

My only concerns are to do with the explanatory note

Under purpose, third para says

As acknowledged in the Committee's report, many of the individuals who have taken these medications are unwell and have complex health needs.

This statement is erroneous, we don't know how many people who have taken these meds in the past are unwell etc, so to say 'many' is misleading, it also implies that they are unwell because they took the meds. It would be preferable if it said something like

There are a number of veterans who are unwell and have complex health needs who are concerned about their past use of mefloquine and/or tafenoquine.

Also, under Overview, it says

There has been ongoing public concern in sections of the ADF community about the use of the anti-malarial medications mefloquine and tafenoquine in the ADF, in particular relating to the anti-malarial trials conducted by the ADF.

Most of the concern has actually been in the veteran community, not the ADF community, so this statement should reflect that.

Regards

Vicki

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jurisdiction of section 70 of the Crimes Act 1914. If you have received this email in error, you are requested to contact the sender and delete the email.

From: Morton, David MR 3 < <u>xxxxx.xxxxxxx@xxxxxxxxxxxxxxxxx</u> >

Sent: Tuesday, 2 July 2019 11:38 AM

Subject: FW: Mefloquine Health Assessment Budget measure - Legislative Instrument

[SEC=UNCLASSIFIED]

UNCLASSIFIED

Vicki, I have reviewed this but would welcome your review. DVA want to include current serving ADF members as part fo eligibility. I can't see a problem here can you. We need to respond to DVA by COB today and I will need to run it by CJHLTH.

Regards

David

<u>P: +61 2 6266 3897 M:.</u>s22 <u>E: xxxxx.xxxxxxx@xxxxxxxxxxxxxxxxx</u>

IMPORTANT: This email remains the property of the Department of Defence and is subject to the jurisdiction of section 70 of the Crimes Act 1914. If you have received this email in error, you are requested to contact the sender and delete the email.

Subject: Mefloquine Health Assessment Budget measure - Legislative Instrument [SEC=UNCLASSIFIED]

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Apologies for the timeframe.

Kind regards,



s47E

Assistant Director | Mental and Social Health Policy

Department of Veterans' Affairs s47E

<u>@dva.gov.au</u> | GPO Box 9998, CANBERRA

ACT 2601

From: Ross, Victoria DR 1
To: \$47E

Cc: Williams, Felicity DR; Mooney, Helen DR 1; Kelaher, Cath DR

Subject: RE: Mefloquine Health Assessments - potential attendees for co-design process [SEC=UNCLASSIFIED]

Date: Wednesday, 11 September 2019 11:21:00 AM

UNCLASSIFIED

Hi Annie.

From DVA I think we had also suggested \$47E . If he can't attend then Dr Cath Kelaher from IHC could.

From our end please include Dr Felicity Williams and Dr Helen Mooney As far as local GPs go we suggest

one or more of the GPs from Holt Medical Practice \$47F 7F

s47F Jerrabombera Medical Centre s47F

Also s47F in Brisbane s47F .

Timing of the workshop will be important as GPs work fee for service, absence from their practice means no income for that period and having to juggle patient bookings etc.

Regards,

Vicki

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From: s47E @dva.gov.au>

Sent: Tuesday, 10 September 2019 3:34 PM

Subject: Mefloquine Health Assessments - potential attendees for co-design process

[SEC=UNCLASSIFIED]

Good Afternoon Vicki

Thank you for attending the workshop last Wednesday. The input of yourself, Felicity and Cath helped to guide the design of the health assessments and was much appreciated.

At the workshop, we agreed to provide Bupa with a list of contacts who could be included as part of the co-design process. Below are some potential names, would you have any additional suggestions?

Clinical

Name	Role
Dr Gordon Wing	Military GP s47F s47F

s47F	s47F
Dr Francisco Paco Munoz	Military GP s47F s47F
Dr Jenny Firman	Chief Health Officer, DVA
Dr Victoria Ross	Senior Medical Advisor, Military Population Health Department of Defence
RACGP representatives	
ACRRM representatives	

Lived Experience

Name	Role
Stuart McCarthy	Lived Experience Military /
	Mefloquine
s47F	Lived experience family
s47F	Lived Experience Family

If you could respond by COB tomorrow that would be appreciated.

Kind Regards

s47E

s47E Policy Officer I Mental Health Policy

Wellbeing Policy Branch I Veterans' Services Design Division I Department of Veterans' Affairs p s47E w: www.dva.gov.au

From: Ross, Victoria DR 1

To

 $\frac{2347}{8}$ RE: Planning Workshop - Health Assessments for veterans concerned about having taken mefloquine and tafenoquine (SEC=UNCLASSIFIED)

Subjects Tuesday, 3 September 2019 1:48:00 PM Date:

Attachments image001.png

AFP Managing unexplained symptoms in GP 2015.pdf 20190322 GP Clinical management guidelines - veterans with complex health issues.pdf

UNCLASSIFIED

Thank you s47E

I wonder if we could have a few minutes pencilled in to the agenda please to give some background and context from the Defence perspective?

Also, I've attached a couple of relevant documents, just in case you haven't already seen them,

And the Senate Inquiry report

https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Foreign_Affairs_Defence_and_Trade/Mefloquine/Report Regards,

Vicki

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Original	Appointment
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From: S47E dva.gov.au> On Behalf Of MENTAL.SOCIAL.HEALTH.POLICY dva.gov.au

Sent: Tuesday, 3 September 2019 12:18 PM

To: \$47E

s47E Tindall, Katherine CAPT - RAN; Ross, Victoria DR 1; Williams, Felicity DR; Kelaher, Cath

DR; Lawson, Stephen CAPT - RAN 2; S47E

Subject: Planning Workshop - Health Assessments for veterans concerned about having taken mefloquine and tafenoquine [SEC=UNCLASSIFIED]

When: Wednesday, 4 September 2019 12:00 PM-5:00 PM (UTC+10:00) Canberra, Melbourne, Sydney.

Where: DVA Offices - Level 8 - Millen Room (Bridge Conference) - 21 Genge St Canberra

Update 3/9 – Attached is the agenda for the workshop tomorrow.

For Bupa and Defence attendees, please call on arrival and we will escort you to the meeting room 547E

Thanks

s47F

Good Morning

Confirming the Planning Workshop will be held tomorrow from 12pm-5pm in the Millen Room, DVA Canberra Offices (21 Genge St Canberra).

Lunch will be provided. An agenda will follow later today.

Kind Regards



Good Afternoon

This meeting invite is to replace the one cancelled by Jane Le earlier today.

This invitation is a placeholder for an initial co-design/planning workshop with the initiative delivery partner, Bupa, for the

Health Assessment for veterans concerned about having taken mefloquine and tafenoquine.

The intent of the workshop is to commence the co-design and define the scope of the initiative.

An agenda is being drafted. All papers will be shared with attendees ahead of the day.

It is anticipated that not all participants will be required for the entire duration of the workshop (12pm-5pm).

More details about the times particular participants will be required during the workshop will be available soon.

Thank you

If you have any questions, please do not hesitate to free to reach out.

Kind Regards



s47E I Policy Officer I Mental Health Policy

Wellbeing Policy Branch I Veterans' Services Design Division | Department of Veterans' Affairs

p: S47E w: www.dva.gov.au

The Department acknowledges the Traditional Owners of the land throughout Australia and their continuing connection to country, sea and community. We pay our respect to all Aboriginal and Torres Strait Islander peoples, their cultures and to their elders past and present.

From: Oneill, Kim MRS on behalf of OCJ HLTH

To: Ross, Victoria DR 1

Cc: Morton, David MR 3; Clarke, Jay GPCAPT 2

Subject: URGENT REVIEW: Mefloquine Health Assessment Budget measure - Legislative Instrument

[SEC=UNCLASSIFIED]

Date: Tuesday, 2 July 2019 11:14:25 AM
Attachments: 020719 - explanatary statement.docx

020719 Instrument.docx

Importance: High

UNCLASSIFIED

Hey Vicki,

Can you have a look at this one prior to David reviewing it please, noting they have requested a response/comments back by COB today.

Thanks

Kind Regards

Kim O'Neill

Executive Officer Coordination, Joint Health Command CP2-7-33 Campbell Park Offices, PO Box 7911, Canberra BC ACT 2610

Phone: (02) 6127 0187 Mobile \$47F

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From: s47E @dva.gov.au>

Sent: Tuesday, 2 July 2019 10:40 AM

To: Morton, David MR 3 <xxxxx.xxxxxx@xxxxxxxxxxxxxxxxxx

Cc: OCJ HLTH <xxxxxxx@xxxxxxx.xxx; Hancock, Veronica <Veronica.Hancock@dva.gov.au>;

s47E @dva.gov.au>; s47E @dva.gov.au>; s47E @dva.gov.au>;

Subject: Mefloquine Health Assessment Budget measure - Legislative Instrument [SEC=UNCLASSIFIED]

Good morning David and team,

As you would be aware, we are currently working to implement the Mefloquine health Assessment budget measure. This includes the development of a legislative instrument to establish eligibility for these assessments. The draft legislative instrument and explanatory statement are attached for your oversight and comment.

Unfortunately, we are working to a very tight timeframe as we are seeking agreement to this legislative instrument from the Repatriation Commission on 11 July. If you have any comments on this instrument could you please send them trhough by COB today?

Apologies for the timeframe.

Kind regards, s47E

Assistant Director | Mental and Social Health Policy

Department of Veterans' Affairs

ACT 2601

EXPLANATORY STATEMENT

Veterans' Entitlements (Anti-Malarial Medications Health Assessment) Determination 2019

(Instrument 2019 No. R36)

EMPOWERING PROVISIONS

Paragraphs 88A(1)(a) and (d) of the Veterans' Entitlements Act 1986 (VEA).

PURPOSE

The attached instrument (Instrument 2019 No. R36) implements the Government's 2019-20 Budget measure to provide assistance to former and current members of the Australian Defence Force (ADF) who were prescribed mefloquine or tafenoquine, both of which are prescribed anti-malarial medications, during their service with the ADF. The Government is committing \$2.1 million to this measure which will deliver a national program of comprehensive health assessments for eligible former and current ADF members.

This Budget initiative responds to the Foreign Affairs, Defence and Trade References Committee's Report, *The use of the Quinoline anti-malarial drugs Mefloquine and Tafenoquine in the Australian Defence Force*. The Committee's Report and Government Response can be accessed at the Australian Parliament House website: https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Foreign_Affairs_Defence_and_Trade/Mefloquine.

As acknowledged in the Committee's report, many of the individuals who have taken these medications are unwell and have complex health needs. The health assessments will provide eligible former and current ADF members with an opportunity to discuss their concerns with a general practitioner with an understanding of health issues related to mefloquine or tafenoquine, the complex conditions with which some former and current ADF members may present and the ADF experience. This will allow for identification of service related illness, disease and injury. Where appropriate, the former or current ADF member will be referred for further specialist assessment, treatment and support, including potential referral to the Open Arms – Veterans and Families Counselling Neurocognitive Health Pilot.

The attached instrument is made under section 88A of the VEA. The instrument specifies the class of person who is eligible for specified treatment under Part V of the VEA. To be eligible, a person must:

- have rendered at least one day of continuous full-time service since 1 January 1989 (the year which mefloquine was first prescribed to members of the ADF); and
- have taken mefloquine or tafenoquine during their service or believe on reasonable grounds that they have taken mefloquine or tafenoquine during their service.

whether or not the person has ceased to be a member of the ADF.

This means the instrument applies to both former and current members of the ADF who meet the above eligibility criteria.

The specified treatment consists of one comprehensive health assessment by an authorised general practitioner. An authorised general practitioner is a general practitioner engaged by an organisation that has entered into a contract with the Commonwealth or the Repatriation Commission, or both, to provide health assessments for the purposes of this instrument. Only an authorised general practitioner can provide a health assessment under this instrument. The term 'general practitioner' has its ordinary meaning. A general practitioner refers to someone who is trained in a wide range of medicine and medical procedures, but excludes medical specialists who have undergone speciality training in a specific field of medicine after completing the same training as a general practitioner.

An external service provider will be contracted to deliver the national program of health assessments. A former or current ADF member seeking to access a health assessment will only need to contact the contracted service provider to schedule the assessment (rather than needing to contact or seek approval from DVA first). The service provider will be required to ensure the former or current ADF member meets eligibility criteria. Access to these health checks is in addition to any existing entitlements eligible former and current ADF members have to health assessments.

This instrument commences on the day after it is registered on the Federal Register of Legislation.

CONSULTATION

Section 17 of the *Legislation Act 2003* requires the rule-maker to be satisfied that any consultation that is considered appropriate and reasonably practicable to undertake, has been undertaken.

External consultation has been undertaken with the Department of Defence. DVA hosted Mefloquine and Tafenoquine Consultation Forums across Australia in late 2018. Consultation within DVA has been undertaken with the Wellbeing Policy Branch.

Further consultation was not considered necessary as the proposal is beneficial in nature in terms of its impact on clients and does not have regulatory impacts on businesses, community organisations or individuals. In these circumstances it is considered that the requirements of section 17 of the *Legislation Act 2003* have been met.

RETROSPECTIVITY

None.

DOCUMENTS INCORPORATED BY REFERENCE

None.

REGULATORY IMPACT

Nil.

HUMAN RIGHTS STATEMENT

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Human rights implications

The attached legislative instrument engages and promotes the Right to Health. The Right to Health is contained in article 12(1) of the International Covenant on Economic Social and Cultural Rights. The Right to Health is the right to the enjoyment of the highest attainable standard of physical and mental health. The UN Committee on Economic Social and Cultural Rights has stated that health is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity.

Overview

There has been ongoing public concern in sections of the ADF community about the use of the anti-malarial medications mefloquine and tafenoquine in the ADF, in particular relating to the anti-malarial trials conducted by the ADF. Although there is limited medical scientific evidence underpinning the causal effect of taking mefloquine and tafenoquine, the Government acknowledges that there is a cohort of former and current ADF members in need of additional assistance and seeks to provide them with appropriate treatment and support.

The measure will allow any former or current ADF member who has concerns about having taken the anti-malarial medications mefloquine or tafenoquine during service to access a comprehensive health check by an authorised general practitioner.

Conclusion

The attached instrument promotes the Right to Health by enabling eligible former and current ADF members to access treatment by way of a comprehensive health assessment by an authorised general practitioner.

Accordingly, the attached instrument is considered to be "human rights compatible"

Repatriation Commission Rule-Maker

FURTHER EXPLANATION OF PROVISIONS

See: Attachment A

Attachment A

FURTHER EXPLANATION OF PROVISIONS

Section 1

This section provides the name of the instrument is the *Veterans' Entitlements (Anti-Malarial Medications Health Assessment) Determination 2019.*

Section 2

This section provides the instrument is to commence on the day after it is registered on the Federal Register of Legislation.

Section 3

This section sets out the primary legislation that authorises the making of the instrument, namely paragraphs 88A(1)(a) and (d) of the VEA.

Section 4

This section is a purpose provision. The purpose of this instrument is to enable persons within a class specified in section 6 to receive treatment consisting of one health assessment by a general practitioner.

The note to this section informs the reader that a person's health assessment by a general practitioner is in addition to any other health assessment available to the person as a client of the Department of Veterans' Affairs.

Section 5

This is the interpretation section.

The term 'Australian Defence Force' has the same meaning as in the *Defence Act 1903*.

The term 'authorised general practitioner' is defined as a general practitioner engaged by an organisation that has entered into a contract with the Commonwealth or the Repatriation Commission, or both, to provide health assessments for the purposes of this instrument.

The note to section 5 provides that 'continuous full-time service' is defined in section 5C(1) of the VEA.

Section 6

Paragraph 88A(1)(a) of the VEA empowers the Repatriation Commission to make a written determination stating "that a veteran included in a specified class is eligible to be provided with treatment of a specified kind".

Paragraph 88A(1)(d) of the VEA empowers the Repatriation Commission to make a written determination stating "that a person who is not covered by paragraph (a), (b) or (c) and who is in a specified class is eligible to be provided with treatment of a specified kind".

Using these powers, section 6 specifies the class of person who will be eligible for the treatment specified in section 7 of the instrument.

The class of person specified in section 6 is a person who:

- has taken, or reasonably believes that he or she has taken, mefloquine or tafenoquine as part of his or her service in the Australian Defence Force; and
- has rendered at least one day of continuous full-time service on or after 1 January 1989;

whether or not they have ceased to be a member of the Australian Defence Force.

The Note to section 6 provides that mefloquine and tafenoquine are prescribed anti-malarial medications.

Section 7

Section 7 sets out the kind of treatment under Part V of the VEA that a person who is in the specified class in section 6 is eligible to be provided with. The treatment is one health assessment by an authorised general practitioner. Only an authorised general practitioner can provide a health assessment under this instrument.

The note to section 7 confirms that the Treatment Principles under section 90 of the VEA, the Repatriation Private Patient Principles under section 90A of the VEA and the Repatriation Pharmaceutical Benefits Scheme under section 91 of the VEA apply to any treatment provided, if they are relevant to the treatment.

Section 8

This section provides that the instrument is revoked on 30 June 2023.



Repatriation Commission

Veterans' Entitlements (Anti-Malarial Medications Health Assessment) Determination 2019

Instrument 2019 No. R36

		under paragraphs he following instr		d (d) of the Veterans'
Dated this	of	2019		
The Seal of the Repatriation Co was affixed here presence of:))))	
	ABETH COSSON AM CSC PRESIDENT	I		CRAIG ORME DSC AM CSC UTY PRESIDENT
	NALD SPINKS AM MMISSIONER			

1 Name

This instrument is the *Veterans' Entitlements (Anti-Malarial Medications Health Assessment) Determination 2019.*

2 Commencement

This instrument commences on the day after it is registered on the Federal Register of Legislation.

3 Authority

This instrument is made under paragraphs 88A (1)(a) and (d) of the *Veterans' Entitlements Act 1986*.

4 Purpose

The purpose of this instrument is to enable persons within a class specified in section 6 to receive treatment consisting of one health assessment by a general practitioner.

Note: A person's health assessment under this instrument is in addition to any other health assessment available to the person as a client of the Department of Veterans' Affairs.

5 Definitions

In this instrument:

Act means the Veterans' Entitlements Act 1986.

Australian Defence Force has the same meaning as in the Defence Act 1903.

authorised general practitioner means a general practitioner engaged by an organisation that has entered into a contract with the Commonwealth or the Repatriation Commission, or both, to provide health assessments for the purposes of this instrument.

Note: The term 'continuous full-time service' is defined in section 5C(1) of the Act.

6 Specified class

For paragraphs 88A(1)(a) and (d) of the Act, the specified class is a person who:

- (a) has taken, or reasonably believes that he or she has taken, mefloquine or tafenoquine as part of his or her service in the Australian Defence Force; and
- (b) has rendered at least one day of continuous full-time service on or after 1 January 1989;

whether or not the person has ceased to be a member of the Australian Defence Force.

Note: Mefloquine and tafenoquine are prescribed anti-malarial medications.

7 Specified kind of treatment

A person who is a member of the specified class in section 6 is eligible to be provided with treatment under Part V of the Act consisting of one health assessment by an authorised general practitioner.

Note: The Treatment Principles under section 90 of the Act, the Repatriation Private Patient Principles under section 90A of the Act and the Repatriation Pharmaceutical Benefits Scheme under section 91 of the Act apply to any treatment provided.

8 Revocation

This instrument is revoked on 30 June 2023.

From: Ross, Victoria DR 1

To: \$47E @dva.gov.au)

Cc: Tindall, Katherine CAPT - RAN; Lawson, Stephen CAPT - RAN 2; Williams, Felicity DR; Kelaher, Cath DR

Subject: Veterans health assessment planning workshop 4 Sep [SEC=UNCLASSIFIED]

Date: Friday, 30 August 2019 12:45:00 PM

UNCLASSIFIED



Just touching base before the workshop next week, you're on the invitation list so hoping you'll be there.

From our perspective there are several issues that we need to be cognisant of.

- It's not all about the mefloquine. The veterans at whom this assessment is aimed are those with complex symptomatology/conditions who aren't accessing health care or feel that they are not receiving the 'right' health care. The intent is to improve engagement with the health care system and appropriate care to optimise their health and wellbeing. It's about acknowledging their concerns, assessing their symptoms and finding a way forward. We are concerned that there is potential for the doctors doing the assessment to accept and/or reinforce that mefloquine/tafenoquine are the cause of the veteran's poor health etc.
- This health assessment appears to be in addition to the extant Veteran Health Check. Does it need to be?
- How does continuity of care factor in. If this assessment is done by a BUPA provider, will they continue on as the veteran's GP? The primary issue is that these veterans are not engaged with or don't trust the system. There is a risk that their care may become even more fragmented.

Looking forward to the workshop, no doubt all these, and other, issues will be explored then.

Regards, Vicki

Dr Victoria Ross

MBBS MPH FRACGP FAFPHM
Senior Medical Advisor, Military Population Health
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NOTING BRIEF FOR CJC

Document 13

DEPARTMENTAL RESPONSE TO MR STUART MCCARTHY

– TAFENOQUINE STUDIES AND USE

Branch: Joint Health Command	Reference: MC19-001019
For Information: N/A	Due Date: 02 May 19
1 of information. 14/14	Routine

Purpose

1. The purpose of this brief is to seek your clearance and signature on a response to Mr Stuart McCarthy's correspondence of 25 March 2019 to the Minister for Defence Personnel, the Hon Darren Chester MP, about the antimalarial medication tafenoquine (Enclosure 1). The Minister has asked for the Department of Defence to respond to Mr McCarthy.

Recommendations

- 2. That you:
- a. Sign the draft response letter to Mr Stuart McCarthy at Enclosure 2.

Key Issues

- 3. On 25 March 2019, Mr McCarthy emailed the office of the Minister for Defence Personnel, the Hon Darren Chester MP, about his concerns regarding tafenoquine (Enclosure 1).
- 4. A draft response to Mr McCarthy is at <u>Enclosure 2</u> for your consideration and signature.
- 5. The Therapeutic Goods Administration (TGA) approved the importation and use of tafenoquine for the ADF antimalarial studies in the early 2000's. The TGA visited the ADF Malaria and Infectious Diseases Institute with the United States Food and Drug Administration to review the study paperwork and processes as part of the two organisation's registration and approval processes.

	a. Signed / Please Discuss
TL Smart	WG McDonald
Air-Vice Marshal	AIRMSHL
CJHLTH	CJC
Apr 19	Apr 19
	r
Contact Officer: Mr David Morton	Tel: 02 6266 3897
Clearance Officer: Mr David Morton	Tel: 02 6266 3897

- 6. The TGA thoroughly assessed the applications from 60 Degrees Pharmaceuticals and Biocelect to register tafenoquine in Australia. The TGA approved tafenoquine for registration in Australia on 13 September 2018 under the brand names Kodatef® for malaria prophylaxis and Kozenis® for radical cure (malaria treatment). JHC has revised the Defence malaria policy to include tafenoquine as an option for antimalarial prophylaxis.
- 7. On 15 March 2019, the Minister for Defence Personnel announced a new \$2.1 million initiative to support veterans who are concerned about their use of mefloquine and tafenoquine. The initiative will deliver a national program that will provide veterans with the option to receive a comprehensive health assessment to identify service-related illness, disease and injury. Where appropriate, the veteran will be referred for further specialist assessment, treatment and support.
- 8. The initiative responds to concerns raised by veterans during the 2018 Senate inquiry, as well as during the mefloquine and tafenoquine consultation forums conducted by the Department of Veterans' Affairs across Australia last year.
- 9. The initiative will be implemented from 1 July 2019. Veterans seeking to register their interest in accessing a health assessment should contact 1800 MEFLOQUINE (1800 633 567), the Department of Veterans' Affairs' designated phone line for concerned veterans.

Background

10. Nil.

Way ahead

11. Nil.

Conclusion

12. Tafenoquine is now a registered medicine in Australia and is available for use in Defence and the wider Australian community. Defence has revised its health policy regarding the prevention and management of malaria to include tafenoquine. This is still in the formal policy review process and will be considered by the Defence Health Policy Steering Group shortly for endorsement and progression to Surgeon General ADF for approval to publish.

Consultation

13. Nil.

Enclosures:

- 1. Enclosure 1: Correspondence from Mr Stuart McCarthy, dated 25 March 2019.
- 2. Enclosure 2: Draft response letter to Mr McCarthy.