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Multiple Technology Appraisal (MTA)

Prasugrel with percutaneous coronary intervention for treating acute coronary syndrome (review of TA182)

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

About you

Your name: Nick Hartshorne-Evans

Name of your organisation: The Pumping Marvellous Foundation

Are you (tick all that apply):

- a patient with the condition for which NICE is considering this technology?
- a carer of a patient with the condition for which NICE is considering this technology?
- an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology? If so, give your position in the organisation where appropriate (e.g. policy officer, trustee, member, etc) [redacted]
- other? (please specify)

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What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

1. **Advantages**
(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

It needs to be understood that the intervention is more important for the patient than the individual components.

As a patient it is not clear what the difference is between Prasugrel and other anti-platelets unless studied. As Prasugrel combined with Aspirin is used mainly in PCI and only 4 weeks after the intervention then patient opinion would be more concerned with the after effects of the intervention. It does not seem to have any long term condition management concerns as this is transposed to other anti-platelets after 4 weeks. It seems that Prasugrel needs a loading dose where other anti-platelets like Clopidogrel don't. I am not suggesting this is a negative or a positive for the patient but is just an observation and there is only one instance of loading to expedite efficacy. Is there a potential for the patient to not take the loading dose due to unclear and qualified clinical instruction therefore making Prasugrel not as effective. This doesn't seem to be the case either as the loading dose would be administered by specialist teams in an emergency situation?

As an observation Prasugrel is likely to be more effective in the PCI environment than Clopidogrel as it induces platelet aggregation more rapidly and consistently against standard to high doses of Clopidigrel which for a patient is a good outcome. Also where Clopidogrel requires CYP2C19 which is a liver enzyme then this is historically lower in the South Asian community therefore it would suggest for patient safety Prasugrel is safer in this group than Clopidogrel.

As a patient whether you're aware or not of any of the complications whilst suffering from ACS and having a stent, all you want is the procedure to be safe and successful with no issues after the procedure.

It could be deduced that patients ideally would like to walk away from their treatment and forget about the procedure and symptoms pre and post procedure. Therefore if Prasugrel could help to achieve this then this would be a positive outcome surrounding their condition.

Combining NICE clinical guidance 48 and the publication in the New England Journal of Medicine the TRITON-TIMI 38 study seems to indicate consistent outcomes as Prasugrel was associated with lower incidence of ischemic events and seemed to be more effective with people with Diabetes. However

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there was a higher incidence of bleeding than Clopidogrel which is not a good point for the patient.

As Prasugrel gets to a point where platelet aggregation is at 80% within 2 hours with a loading dose then patients receiving PCI, which you could argue the vast majority is unplanned, then time is a key factor.

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (lifestyle, work, social functioning etc.)
- other quality of life issues not listed above
- other people (for example family, friends, employers)
- other issues not listed above.

The course or outcome of the condition
Short Term – quicker effectiveness, reduction in thrombotic events
Long Term – better quality of life without an event as long as primary care understand dosing

Physical Symptoms
Short Term – Can't see any effect as patient will be given an anti-platelet irrespective whether Prasugrel
Long Term – Can't see any effect as patient will be given an anti-platelet irrespective whether Prasugrel

Pain – N/A

Level of Disability – N/A

Mental Health – N/A

Quality of Life
Short Term – N/A
Long Term – Negative effect if needs monitoring like Warfarin

Other people
Short Term – N/A
Long Term – No impact unless needs monitoring like warfarin

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What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition? (continued)

2. **Disadvantages**
Please list any problems with or concerns you have about the technology. Disadvantages might include:

- aspects of the condition that the technology cannot help with or might make worse.
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or their family (for example cost of travel needed to access the technology, or the cost of paying a carer).

Can't see any issues with Prasugrel around making the condition worse or difficult however with the increased incidence in bleeding like all anti platelets and anti-coagulation therapies it would be advisable to accompany the drug with better patient education.

I am always concerned that when patients are released from ACUTE situations and they have any mild to moderate reaction eg Skin Rash then the primary care clinician will look for an alternative where maybe their decision is based around patient feelings and pressure rather than what is clinically more effective due to their knowledge and generality of their practice and primary care costs. NICE clinical guidance 48 suggests 4wks of Prasugrel in combination with Aspirin and then moving over to Clopidogrel and Aspirin which would reduce this risk.

Can't see any issues around impact on others apart from what has been mentioned.

I am always concerned about patient accessibility to the latest technology in all settings so my comments would be consistent like any new technology. It has to be an option and available.

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

Patients know they are taking drugs. Due to an unplanned PCI I would suggest they would only care after the treatment and only then if they were interested.

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4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

More

Sufferers of Diabetes Mellitus

South Asian Communities where the incidence of CVD is higher than the population average as a group. Based around Diabetes Mellitus prevalence in South Asian Communities and reduced levels of CYP2C19 liver enzyme where Clopidogrel has been proved to be less effective then this would be a benefit.

Less Benefit
Having researched the groups who need to be aware before taking anti-platelets then Prasugrel seems no different than other anti-platelets.

Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

Clopidogrel
Aspirin
Tirofabin
Abciximab
Ticragelor

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:

- improvement in the condition overall
- improvement in certain aspects of the condition
- ease of use (for example tablets rather than injection)
- where the technology has to be used (for example at home rather than in hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc.)

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The two areas as discussed previously would be – the faster time to efficacy and the more effectiveness in certain population groups (Diabetes Mellitus and South Asian Community)

(iii) If you think that the new technology has any disadvantages for patients compared with current standard practice, please describe them. Disadvantages might include:

- worsening of the condition overall
- worsening of specific aspects of the condition
- difficulty in use (for example injection rather than tablets)
- where the technology has to be used (for example in hospital rather than at home)
- side effects (for example nature or number of problems, how often, for how long, how severe).

The TRITON-TIMI38 study indicated that there was a reduction in the combined rate of death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke (12.1% for Clopidogrel vs. 9.9% for Prasugrel) when combined with Aspirin at the primary end point which reduced mortality so this seems to be an obvious benefit. However the study did indicate a higher risk of fatal bleeds, more than Clopidigrel which is obviously not in the interests of patients.

Equality and Diversity

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that this appraisal:

- Could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;
- Could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- Could lead to recommendations that have any adverse impact on people with a particular disability or disabilities

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NO exclusions

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts

Unless this is appraisal is any different than others then I have no opinion therefore use the same diligence.

I would say that cost implications should not be considered in the face of a new technology having a significant benefit to a minority population group.

Research evidence on patient or carer views of the technology

If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

N/A

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Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

N/A

Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

No

Availability of this technology to patients in the NHS

What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

If current thinking is based on the TRITON-TIMI38 then it looks like if taken with Aspirin then the efficacy is more rapid therefore more effective quicker therefore reducing thrombotic events.

Diabetic Mellitus sufferers and the South Asian Community would seem to benefit as well.

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Therefore I would recommend its pervasive availability

What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

A missed opportunity to reduce life changing thrombotic events especially in the two sub groups that are mentioned above.

Are there groups of patients that have difficulties using the technology?

These are the researched groups

If you are pregnant or breast-feeding.
If you have liver or kidney problems.
If you have ever had a stroke, or a transient ischaemic attack (sometimes called a TIA or 'mini-stroke').
If you have a condition which causes bleeding, such as a recent wound or a stomach ulcer.
If you have ever had an allergic reaction to a medicine, particularly if you have had a bad reaction to any other antiplatelet medicine.

Other Issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.

Not that I haven't mentioned.