PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	NICE guidance: a comparative study of the introduction of the single technology appraisal process, and comparison with guidance from Scottish Medicines Consortium
AUTHORS	John Ford, Norman Waugh, Pawana Sharma, Mark Sculpher and Andrew Walker

This paper was submitted to the BMJ but declined for publication following peer review. The authors addressed the reviewer's comments and submitted the revised paper to BMJ Open. The paper was subsequently reviewed by a BMJ Open reviewer with access to the BMJ reviews.

VERSION 1 - REVIEW

REVIEWER	Claudia Wild Ludwig Boltzman Institut

GENERAL COMMENTS	The manuscript „Nice guidance on new drugs……" is: • analysing the effects of the introduction of the STA-process on timeliness • analysing the effects of the introduction of the STA-process on different types of drugs (cancer) • comparing the outcomes of the NICE appraisals with those of SMC. The conclusion is, that: • STA accelerated the process (a bit), • STA accelerated the process, only for other than cancer drugs • SMC is appraising more and faster • There are differences in the outcomes of the appraisals between NICE and SMC, but – taking a closer look - they are marginal. In general: The manuscript „Nice guidance on new drugs……" is highly relevant and could be of interest for the readers of the BMJ. But – at present – a thread or a coherent course of arguments/elements in the analysis/discussion part is lacking. This can easily be overcome by rearranging the elements and – possibly - the introduction of more subheadings. In detail: • The first 1,5 pages describe in words and show in 2 flow charts the processes in NICE and SMC. BUT: it is written (p 1): „there is no independent systematic review or modelling".....in the disscusion, it is said, that NICE decisions are

	based on QALYs. So who calculates the QALYs ?? I assume NICE not industry ?? • It is mentioned twice, that the fact, that NICE as well as SMC base their decisions on industry submissions (more than the EPARs ??), is critiqued (p 1 by assessment groups: NICE, p 2 by staff: SMC). I can imagine, why there is critricism, but to make this transparent, I propose to write a sentence on the arguments of the criticism. Page 4 of 33 For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml For peer review only • p 2 Methods: the inclusion dates for medications should have not only the „until Aug 2010“, but also the starting date (2005 ?), the period… • p 2 Methods: the terms/words „approval“ and „non-approval“ are used. In my language use „approval equals EMA-market authorisation“ and can not be used for national decisions or „recommendation“ or „acceptance“. Please consider the wording here. • p 3 timelines of NICE: 18.3 (non-cancer drugs) or 24.2 (cancer drugs). This is really very long. There should be a few more words on where the time is spent in the NICE process compared to the SMC-process (there is 1 sentence on DAD for SMC, but nothing on NICE). • p 4: discussion should be re-structured/ better readable and should include some more informations • Begin: The NICE STA process has been introduced in 2005, with the intention of….. Our analysis shows that this became true for…..but not for…..While the SMC needs XY months for average appraisal, NICE needs.. • Now analysis of the (lack) of timeliness (paragraphs on p 5) of NICE, because of….. • Then: Differences in recommendations: 10-20% rejections, mor in cancer. • Now analysis of differences of recommendation. There must be some kind of explanation for additional elements to support decisions (QALY), new reimbursement schemes, „evolution of evidence base“ (expand on that) • Then: comparison to other studies + analysis: OK • Then: NICE and SMC in the context of further (European) appraisals. UK appraisal groups, but also European. Maybe 1 sentence on RE/ relative effectiveness „ambitions“ within EUnetHTA. Conclusion: high amount of redundancy ! • Commas and periods marks are missing, etc. (blanks) throughout the text. Recommendation: the manuscript should be published with certain

	changes, esp in the discussion part. I would be happy the review/read it again before publication

REVIEWER	Craig Currie, Cardiff University

GENERAL COMMENTS	Very helpful, informative, and I have no doubt that the study will be of widespread interest. My only minor issue is that the structure of the report is a little unusual; it's neither a formal study structure, nor that of a more informal editorial/commentary.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Recommendation:

Comments:

The manuscript „Nice guidance on new drugs……" is

- analysing the effects of the introduction of the STA-process on timeliness
- analysing the effects of the introduction of the STA-process on different types of drugs (cancer)
- comparing the outcomes of the NICE appraisals with those of SMC.

The conclusion is, that

- STA accelerated the process (a bit),
- STA accelerated the process, only for other than cancer drugs
- SMC is appraising more and faster
- There are differences in the outcomes of the appraisals between NICE and SMC, but – taking a closer look - they are marginal.

Comments:

In general:

The manuscript „Nice guidance on new drugs……" is highly relevant and could be of interest for the readers of the BMJ. But – at present – a thread or a coherent course of arguments/elements in the analysis/discussion part is lacking. This can easily be overcome by rearranging the elements and – possibly - the introduction of more subheadings.

In detail:

• The first 1,5 pages describe in words and show in 2 flow charts the processes in NICE and SMC. BUT: it is written (p 1): „there is no independent systematic review or modelling“…..in the disscusion, it is said, that NICE decisions are based on QALYs. So who calculates the QALYs ?? I assume NICE not industry ??

Text has been amended to improve the clarity.

• It is mentioned twice, that the fact, that NICE as well as SMC base their decisions on industry submissions (more than the EPARs ??), is critiqued (p 1 by assessment groups: NICE, p 2 by staff: SMC). I can imagine, why there is critricism, but to make this transparent, I propose to write a sentence on the arguments of the criticism.

Text has been amended to improve the clarity.

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• p 2 Methods: the inclusion dates for medications should have not only the „until Aug 2010“, but also the starting date (2005 ?), the period…

Text has been amended to improve the clarity. It should be noted that we have included all medications since both organisations were established and therefore presented the complete ‘population’.

• p 2 Methods: the terms/words „approval“ and „non-approval“ are used. In my language use „approval equals EMA-market authorisation“ and can not be used for national decisions or „recommendation“ or „acceptance“. Please consider the wording here.

This terminology reflects that which is used by NICE and SMC. The authors do not think it is appropriate to combine terminology.

• p 3 timelines of NICE: 18.3 (non-cancer drugs) or 24.2 (cancer drugs). This is really very long. There should be a few more words on where the time is spent in the NICE process compared to the SMC-process (there is 1 sentence on DAD for SMC, but nothing on NICE).

This has been discussed at length in the discussion

• p 4: discussion should be re-structured/ better readable and should include some more informations

The discussion has been restructured for readability and clarity

- Begin: The NICE STA process has been introduced in 2005, with the intention of….. Our analysis

shows that this became true for…..but not for…..While the SMC needs XY months for average appraisal, NICE needs..

- Now analysis of the (lack) of timeliness (paragraphs on p 5) of NICE, because of…..
- Then: Differences in recommendations: 10-20% rejections, mor in cancer.
- Now analysis of differences of recommendation. There must be some kind of explanation for additional elements to support decisions (QALY), new reimbursement schemes, „evolution of evidence base“ (expand on that)
- Then: comparison to other studies + analysis: OK
- Then: NICE and SMC in the context of further (European) appraisals. UK appraisal groups, but also European. Maybe 1 sentence on RE/ relative effectiveness „ambitions“ within EUnetHTA.

Conclusion: high amount of redundancy !

- Commas and periods marks are missing, etc. (blanks) throughout the text.

Recommendation: the manuscript should be published with certain changes, esp in the discussion part.

VERSION 2 – REVIEW

REVIEWER	Claudia Wild Ludwig Boltzman Institut
REVIEW RETURNED	03/12/2011

GENERAL COMMENTS	The authors have respected my previous comments in a peer review. The manuscript ist highely relevant: it should be published.