Supplementary material S2: Analysis of free text comments made on the overall position

The summary of the author's analysis follows each italic comment.

"CDSS are important to ensure that patients' management is in line with best evidence based practice. My concerns however about CDSS include to whether the systems may inhibit junior clinicians' thought processes about individual cases particularly about looking at the bigger picture of the case, especially when a presentation might be atypical or complex or an alternative diagnosis should be considered. CDSS have the potential to alter training and the benefits of a comprehensive clinical experience."

- The aim of CDSS is to bring patient management in line with best evidence
- CDSS may inhibit junior doctor thought processes eg. with atypical case presentations
- CDSS may alter training needs and the benefits of comprehensive clinical experience

"We worry about (a) the lack of uniformity of systems, so that doctors working in one Trust need to be trained when they move to another Trust (i.e. the standards do not specify the user interface);

- Worry about the lack of uniformity of system interface / functions adding to the training burden [and thus raising safety concerns]

(b) regulation has tended to be 'hands-off,' so that there is a discontinuity between the rigour with which medicines are regulated and the laxity of regulation of the software that allows them to be prescribed;

- Regulation has been too hands off compared with the regulation of drugs – especially given that some of these systems are used for prescribing of high risk drugs

(c) all CDSS in the clinical environment is burdensome unless the hardware to run it is responsive and available."

- CDSS are burdensome in the clinical environment because responsive NHS hardware is in short supply

"The standards and testing metrics as well as test results should be open and peer reviewed, just like drug trials. Would also suggest that a register of such devices / systems should exist as for clinical trials, with easily accessible and understood explanations of the reliability / validity etc"

- Standards for testing and test results should be open and peer reviewed, just like drug trials
- The NHS should keep a register of tested CDSS and the test results with easily accessible & understood explanations of their reliability, validity etc.

"CDSS needs to be continuously reviewed and updated by a team of experts, including the EPR clinicians, pharmacists, nurses and medical informaticians,

- CDSS need to be continuously reviewed and updated by an expert team including EPR clinicians, pharmacists, nurses and medical informaticians.

The level of the alerts within a system need to be targeted to high-risk errors/problems, to minimise the risk of alert fatigue."

- To minimise alert fatigue, CDSS alert threshold levels need to be targeted to high risk errors

"Important for the user to be in contact with the provider so that the provider can update the software if problems are identified. "

- Important for user to be in contact with CDSS provider so provider can update software if necessary

"AI is many things and the regulation and testing of it is different in different scenarios. The patient held instrument with AI can be very helpful and difficult to regulate as it is downloadable on the web and does not have to pass a regulatory barrier of purchase by an institution (Hospital Trust or NHS). It is this group of AI that is likely to be the most disruptive and possibly most useful. IF half the population used an instrument that had a 95% sensitive, but very non-specific threshold for finding their melanoma we would be challenged to advise them against using it but also in meeting the demand for consultations to assess those alerted due to the low specificity. The risk of these diagnostic scenarios means that the value of an approved range of Apps and AI for public and institutions may be needed to help avert chaos. But it will carry its own challenges and costs."

- Feasibility and rigour of regulation and testing of AI depends on user and setting
- Patient-used devices with embedded AI could be disruptive to NHS if not sufficiently specific – eg. they could overload dermatologists with suspected melanoma
- Need for an NHS approved list of apps and AI for the public and professionals to avert chaos

"Risk factor analysis apps and AI for monitoring advice in hospitals is relatively low risk as long as the latter works. The problems will arise if the inputs are made incorrectly whereby it generates authoritative but misleading advice."

- Low quality and erroneous inputs will result in authoritative but misleading advice out

"As long as the CDSS is built incorporating regular monitoring by a responsible group of professionals, appraising developments in the field to ensure safe evidence based practice, there is potential for it to work for the benefit of patients. There also must be clarity on the governance around its use (likelihood of audit trail to assess the impact of CDSS on efficiency, effectiveness and improvement to patient care)."

- Need regular monitoring by responsible group of professionals or specialty society to ensure safe evidence based practice
- Need to apply clinical governance to CDSS eg. an audit trial will allow effectiveness and impact to be assessed