MRSA Action UK response to:
"Changes to arrangements for regulating NHS bodies in relation to healthcare associated infections for 2009/10 – A consultation for the NHS"

Consultation questions
1. Do the registration requirements, set out in the draft regulations at Annex A, describe clearly what NHS organisations must do to comply with the law?

The inspection programme against the Code of Practice for the Prevention and Control of Healthcare Associated Infections by the Healthcare Commission, was designed to provide reassurance to the public and patients that the required standards are being met in relation to infection control. It was also designed to reassure organisations that they are taking the necessary measures to prevent and control infections, highlighting any steps that need to be taken to improve their services and patient care.

These requirements of the Code of Practice for the Prevention and Control of Healthcare Associated Infections are to ensure:

> "Health organisations keep patients, staff and visitors safe by having systems to ensure that the risk of healthcare acquired infection to patients is reduced, with particular emphasis on high standards of hygiene and cleanliness, achieving year-on-year reductions in MRSA,"
>
> "Health care organisations keep patients, staff and visitors safe by having systems to ensure all re-usable medical devices are properly decontaminated prior to use and that the risk associated with decontamination facilities and processes are well managed" and
>
> "Health care services are provided in environments which promote effective care and optimise health outcomes by being well designed and well maintained with cleanliness levels in clinical and non clinical areas that meet the national specification for clean NHS premises".

Although providers would be expected to comply with all duties of the code, non compliance with these factors were believed to be the best current measure of whether the duty in the regulation has been complied with.

General practice and general dental services will not fall within the scope of the new registration process in 2009/10. Whilst it is intended that from 2010/11 the full registration system will roll out across the NHS, and to private and voluntary healthcare and social care providers, we are concerned at the delay in the registration process as tackling healthcare associated infections must apply across the whole healthcare economy for effective prevention and control strategies to be effective.

The draft regulations require registered service providers to protect patients, workers and others who may be at risk from identifiable risks of acquiring healthcare associated infections. The regulations have been drawn from the existing Code of Practice, and the Code of Practice has been drawn up using knowledge from evidence based interventions that work, including looking across the patient journey and at the information that follows the patient throughout their healthcare experience.

We believe it is not therefore possible to look in isolation at General Practice and private and voluntary healthcare providers to ensure effective strategies are in place

to protect the patient, visitors and healthcare workers from the risks of healthcare associated infections.

As patients move between hospital and the primary care setting the risk of acquisition of healthcare infections is recognised by the infection prevention and control professionals who devised the Code of Practice. Screening, and judicious antibiotic prescribing should be considered in the primary care setting, particularly in relation to General Practice, community pharmacy and in dentistry where the use of broad spectrum antibiotics can be common place, therefore any delay in the registration process and the measures that need to be in place to become registered has the potential to undermine the provision of safe care between these healthcare providers.

The guidance provided in the Code of Practice for the Prevention and Control of Healthcare Associated Infections is explicit in showing that systems to prevent healthcare associated infections are in place, stating
"Good management and organisation are crucial to establishing high standards of infection control. The systems for the prevention and control of Healthcare Associated Infections are expected to address:

- management arrangements to include access to accredited microbiology services;
- clinical leadership;
- application of evidence based protocols and practices for both patients and staff;
- design and maintenance of the environment and medical devices; and
- education, information and communication."

Duty 5 states:
An NHS body must ensure that it makes suitable and sufficient information available to:
a. patients and the public about the organisation's general systems and arrangements for preventing and controlling HCAIs; and
b. each patient concerning:
• any particular considerations regarding the risks and nature of any HCAI relevant to their care; and
• any preventive measures relating to HCAIs that a patient ought to take after discharge.

Duty 6 states:
An NHS body must ensure that it provides suitable and sufficient information on a patient's infection status whenever it arranges for that patient to be moved from the care of one organisation to another, so that any risks to the patient and others from infection may be minimised.

This explicit reference to precautions being in place for all healthcare providers reinforces the need for registration across the healthcare economy and we believe the delay in the process will have implications for proper enactment of the measures set out in the Code of Practice.

The requirements of Duty 5 and Duty 6 remain in the draft Code of Practice and we welcome this, however any delays in registration must not impinge on regulators being called in where there are serious issues of concern where there may be evidence of breaches identified against the Draft Code of Guidance.

2. Does the revised Code of Practice enable the Care Quality Commission to fairly judge whether an organisation is complying with the regulations?

We welcome the revised Code of Practice and supporting guidance, and believe this has been strengthened with the new requirement for screening and more explicit use across organisational boundaries.

We believe the supporting guidance that accompanies the revised Code of Practice must be mandatory, regulators and inspectors may not be adequately skilled to be able to interpret what may be a reasonable additional or alternative strategy to mitigate risks from healthcare associated infections. The Code of Practice and guidance is well written, simple and easy to follow. It must therefore be adhered to, we believe that measures needed to mitigate risks set out in the Code of Practice are reasonable and should not open to subjective unqualified judgement where there would be margin for error.

Assurance Framework

We believe the assurance framework should include the provision of information to patients and the public. Reports to Trust Boards and monitoring reports on incidence of infection rates should be made available on Primary and Acute Trust websites, and should be available on the pages on infection control for each hospital on the NHS Choices and Doctor Foster websites. We would welcome reports outlining the key activities listed under the Assurance Framework heading being made available in this way. For patients who may not have internet access, infection prevention and control policy and infection rates should be on public display at hospital entrances.

Consultation question
3. Do you agree with the proposals to make regulations relating to enforcement?

Whilst we welcome powers of enforcement it is unclear as to how fines or prosecution would be applied. The consultation document is not explicit.

In relation to the reference stating "These new powers include issuing warning letters, issuing penalty notices in lieu of prosecution, and suspending a provider's registration for a period of time. In addition, the court fines that can follow from the offences of failing to comply with requirements or conditions of registration, or of providing care while being unregistered or after registration has been cancelled or suspended, have been increased to a maximum of £50,000." We would wish to see some more specific guidance giving examples of what would constitute a breach and the severity of the penalty.

Similarly we would wish to see examples of when this penalty would be applicable: "Section 10 provides that any person who carries on a regulated activity without being registered with the Care Quality Commission is guilty of an offence, and is liable on summary conviction to a fine of up to £50,000 or up to 12 months' imprisonment, or both, and on indictment to an unlimited fine or up to 12 months' imprisonment, or both."

Would fines come from Trust budgets, or are there occasions for fines to be applicable to individuals? Maidstone and Tunbridge Wells is an example where patient and public perception may have engendered a sense of responsibility on individuals for the numbers of failings that caused the deaths of 90 people, would such circumstances constitute imprisonment or fines for individuals?

MRSA Action UK believe that there was considerable evidence to suggest this level of penalty may have been applicable, yet no prosecution followed, despite the Healthcare Commission report alleging a series of failings by the Trust and individuals. From the information available, it was not possible to establish with certainty a causal link between failings to manage infection and the death of any particular person. This landmark case would therefore appear to set the scene for future failings and harm to patients, we believe therefore that the Code of Guidance must be explicit in terms of when such extreme measures would be necessary.

In terms of the Regulatory Impact Assessment the table below is extracted from the consultation document.

Compliance with core standards – Trusts' self declaration 2008	**No. of trusts**	**Ongoing not met**	**Ongoing insufficient assurance**	**Ongoing concern**
Acute trusts	169	10	1	11
Ambulance trust	12	0	0	0
Care Trust/MH	7	0	0	0
Care Trust/PCT	6	1	1	2
Community Trust	1	0	0	0
Learning Disability	2	0	0	0
Mental Health	50	2	0	2
Primary Care Trust	134	12	6	17
Primary Care Trust/MH	13	0	2	2
Total	394	34		

Whilst the impact assessment states Option 2 and the preferred option, the benefits to patients are listed as being higher is Option 3 is taken. Using the information on the compliance with core standards as listed above, a risk based approach would enable the effective use of resources to target those Trusts that are presenting the greatest risk to patients, the public and healthcare workers.

We do not believe therefore that requiring all the duties of the Code to be met will cause resources to be diverted inefficiently. We do not believe that there will be any circumstances where it is not appropriate for any healthcare provider not to comply with the Code of Practice if good clinical governance and a culture of safety pervades in each organisation. The consultation document is explicit where it recognises that compliance with the duties of the Code is the best way of ensuring that patients, staff and visitors are protected from the risk of healthcare associated infections.

We do not accept that innovations in patient care or new research about healthcare associated infections would be complex and costly to make in enshrining the enforcement of the Code of Practice into law in its entirety. This will be the third time the Code of Practice has been updated since its inception, it is therefore open to revision and we would expect it to be kept up-to-date as new knowledge and policy changes become necessary. The bacteria that cause healthcare associated infections evolve all the time, the Code of Practice will need to do the same.

Frequent enforcement action for minor issues is not likely undermine the credibility of the regime and reduce its deterrence effect, not taking action is more likely to undermine the regime, particularly from the patient perspective.