Dear colleague,

Since our last communication regarding our campaign on the issue of informed consent in Irish maternity services, much has happened. We have met with the HSE, received correspondence from Minister Harney, and a meeting is arranged between AIMSI and HIQA for July 6th, 2010.

Please see the following links and summaries for more details.

AIMSI meets with Dr Barry White, National Director for Quality and Clinical Care, HSE - June 16 2010

http://www.aimsireland.com/news/?topic=newsBulletin#_nbItem10

Whilst AIMSI was given the opportunity to raise the issue of consent in maternity services, the meeting necessarily centred on the miscarriage misdiagnoses controversy and the development of National Guidelines in maternity care. AIMSI will be meeting with Professor Michael Turner and Sheila Sugrue (National Leads in Obstetrics and Midwifery) who will oversee the HSE National Clinical Programme for Obstetric Care, and we intend to raise consent issues again at this forum and expect that a more comprehensive discussion will be had on the issue.

****

Also, the new *Practice Standards for Midwives (July 2010)* have just been launched by An Bord Analtrais and will replace the *Guidelines for Midwives (3rd Edition)* which came into force in September 2001. In this new publication, Practice Standard 1 'Practices in Accordance with Legislation and Professional Guidelines' includes the issue of 'Consent' in it's *Guidance for Practice.*

'Women should have the opportunity to make an informed decision about their care and treatment throughout the maternity experience. The woman is respected as the primary decision-maker and midwives assist her in this process by providing her with accurate and unbiased information on which she can base informed choices. An Bord Altranais supports the development of local policies and guidelines to guide practice in relation to consent. These should provide the midwife with guidance in instances where a woman does not have the capacity to make an informed decision. Local policies and guidelines should also be developed collaboratively by the health care team to guide practice where a woman may refuse treatment for herself and/or her baby. (pg 13) see link http://www.nursingboard.ie/en/publications_current.aspx

AIMSI is pleased to see the inclusion of patient consent and informed choice in this recent publication but again we reiterate the need for national guidelines to facilitate consistency and transparency in this area. Further, whilst the gap between theory and practice in the area of consent remains, AIMSI will continue to campaign for the rights of women to informed decision making and consent in their maternity care.

**********.

DAIL QUESTIONS – June 22nd 2010

Thank you to Caoimhghín Ó Caoláin and Aengus Ó Snodaigh who raised the issue of consent, national guidelines and the recent miscarriage misdiagnoses scandal with Minister Mary Harney in Dail Questions, June 22nd 2010.

QUESTION NO: 120
DÁIL QUESTION addressed to the Minister for Health and Children (Ms. Harney (Dublin Mid-West))
for **ORAL ANSWER** on **22/06/2010**

To ask the Minister for Health and Children if she will order a full review of consent policies within the maternity system here and initiate national guidelines for clinical practice in maternity care; and if she will make a statement on the matter.

- Aengus Ó Snodaigh

(nominated by Caoimhghín Ó Caoláin)

REPLY.
The HSE has recently established a clinical programme for Obstetric care led by Professor Michael Turner of the Coombe Women's and Infants University Hospital. An important priority in the programme will be the development and implementation of National Guidelines for clinical practice. I expect that, in relation to matters of consent, the provision of obstetric services in accordance with these guidelines, as is the case in all other health services, will meet with ethical guidelines set by the Medical Council in 2009.

In addition the Miscarriage Misdiagnosis Review announced by the HSE this week will inform the development of the proposed National Guidelines.

Questions to the Minister for Health
22nd June 2010
Deputy Martin Ferris (nominated by Caoimhghín Ó Caoláin) asked the Minister for Health and Children the measures she will take to help prevent misdiagnosis of miscarriages; and if she will make a statement on the matter.

Deputy Caoimhghín Ó Caoláin asked the Minister for Health and Children the action she is taking in response to the widespread incidents of miscarriage misdiagnosis which have come to light; the date on which she was first made aware of this problem; and if she will make a statement on the matter.

Deputy Mary Harney: Incidents of this kind are distressing to the women and families involved and I again express my sincerest sympathies to all of those who were affected. They are serious incidents and are treated as such.

The initial case which was the subject of media coverage over the past two weeks, was brought to my attention by way of letter received in my office on 12 August 2009. The solicitors for the couple concerned wrote to Our Lady of Lourdes Hospital, Drogheda, on 7 August 2009, seeking certain assurances about the care of, and other actions to be carried out by the hospital for, the woman concerned. On the same day, the solicitors wrote a short letter to me enclosing a copy of that letter. This was also copied to the CEO of the HSE, Professor Brendan Drumm and to the State Claims Agency.

The case was handled by my Department in line with the patient safety protocol which I put into place in the Department in September 2008. The protocol deals with correspondence relating to issues of patient safety from patients, doctors, health service staff and solicitors. It is managed by the chief medical officer on my behalf given that a medical assessment of any potential patient safety issue is required. Within one week the HSE responded to the solicitors and a further letter was sent on 24 August. I was copied on both these letters. The case was placed on the patient safety register and was reviewed regularly.

In line with the protocol, my Department followed up by telephone and by letter with the HSE to determine if there were risk issues arising from its investigation of the case. Following these contacts, the hospital's risk management unit advised the Department in January that a number of measures had been put in place to ensure that the chances of making an error of this kind again were minimised. My Department requested further detail which was subsequently received in April 2010.

My Department's patient safety protocol meeting of 6 May 2010, reviewed the hospital's action in the case and was satisfied that it had been dealt with appropriately and did not pose a patient safety risk for other users of that service. It was assessed that the review and follow-up actions for patient safety had been put in place at the hospital. The chief medical officer was satisfied that the case had been dealt with appropriately at all times.

I wish to point out that there was no other case of this type on the patient safety protocol register since its inception in October 2008 and neither was it indicated to my Department that any other such cases had been identified. As a result of media coverage in recent days, a number of other cases were brought to my attention. A number of actions were agreed by the HSE in conjunction with my Department to ensure the safe management of early pregnancy loss across the country.

The chief medical officer of my Department and the director of quality and clinical care in the HSE recently wrote to all obstetric units advising them to ensure that the decision to use drugs or surgical intervention in these circumstances must be approved by a consultant obstetrician.

The HSE has now announced details of a miscarriage misdiagnosis review team and its terms of reference. The review team is being chaired by an independent expert in obstetrics and gynaecology, Professor William Ledger, vice president of the Royal College of Obstetrics in the UK, who will be joined by Professor Michael Turner, national clinical lead of the HSE's obstetrics programme and a former master of the Coombe hospital; Ms. Sheila Sugrue, HSE national lead for midwifery. Service-user

representation will be provided by Cathriona Molloy from Patient Focus. It is expected that the review will be completed within six months and the report will be published.

In addition, a clinical programme for obstetric care has been established by the HSE's national director of quality and clinical care which will define standardised care for early pregnancy loss and other aspects of obstetric care. It is important to understand that the use of scans and other technology must be guided by expert clinical opinion based on careful clinical history and examination. Scans will not always be necessary or appropriate.

The HSE has advised it has been working with all maternity facilities nation-wide to ensure that women with concerns about their care or treatment have access to information, support and reassurance. The number of calls to these facilities between Wednesday 9 June 2010 and midday on Friday last, has totalled 295. Of these calls, 95 were made to the maternity unit at Our Lady of Lourdes Hospital, Drogheda.

The HSE advised my Department that it has consulted HIQA in relation to the terms of reference of the miscarriage misdiagnosis review. I am satisfied with the course of action being taken by the HSE on this issue to date and I consider it appropriate to await the outcome of the HSE review. I see no necessity at this time to ask HIQA to conduct a parallel review.

It is important to put this case in context. Ireland has, by international standards, a very high-quality maternity service. Maternal mortality, perinatal mortality and infant mortality are all low by comparison to other jurisdictions. Women can be satisfied and confident as they come to use this service.

Deputy Caoimhghín Ó Caoláin: I welcome the terms of reference and the establishment of the review team in this case. However, a number of very serious questions remain. Why did the Minister, the Department and the HSE have to wait until after Melissa Redmond's story went into the public arena, when it was known from last August 2009? Did not the Minister, the Department or the HSE consider the implications of what was brought to their attention then, not only with regard to Melissa Redmond's story but for other women presenting at Our Lady of Lourdes Hospital, Drogheda and for women who would present, perhaps in similar circumstances, at other maternity units across the State? Why is it always that the Minister can only respond when the spotlight of public attention is placed on an issue? Has the Minister or the HSE taken the opportunity to try to establish from the records of maternity units across the State, the noted and acknowledged numbers of misdiagnoses that resulted in the loss of a child unnecessarily?

Deputy Mary Harney: It is not the case that we waited until this case came into the public domain. From the time this came to the attention of the HSE, of my Department and, in fairness, of the hospital, action was taken swiftly to establish what had happened in this case.

Deputy Caoimhghín Ó Caoláin: What about the implications?

Deputy Mary Harney: Furthermore, this case was seen by the chief medical officer

and his team as an isolated case. It was not regarded as something that affected other areas. To put this in context, I refer to the Port Laoise issue in September 2008.

As a result of the patient safety implications that arose, I set up new protocols in the Department for dealing with patient safety issues, because I frequently get letters from Members, doctors, health care professionals, patients and lawyers suggesting patient safety is at risk. I am not competent to deal with those issues and neither are the administrative people in the Department. The people competent to deal with the issue are medics and that is why this is being overseen by the chief medical officer. The protocols are working very well. At any one time, there could be a significant number of issues and currently there are up to 120. Many of these are resource issues, but others are situations where misdiagnosis has been alleged. These must all be properly investigated.

In May 2010, prior to any of this coming into the public domain, it was decided that an elite clinician in the field of obstetrics would be appointed by the HSE to have appropriate clinical pathways, just as we are doing with heart failure and stroke -----

Deputy Caoimhghín Ó Caoláin: The Minister has already told us that. This was not an isolated case.

Deputy Mary Harney: This relates to all these issues. We now have new clinical leadership emerging where clinicians will be involved in rolling out clinical pathways in this and other areas. It is only when we have this standardised approach from the college of obstetrics and gynaecology that we can be assured, whether in the public or private sector, of a standardised approach throughout the country.

Deputy Caoimhghín Ó Caoláin: Has the number of cases in question been established?

Deputy Mary Harney: There is no way of establishing that. The review will do that. As I mentioned, up to last Friday approximately 295 calls had been made since the helpline was opened. I understand that 95% of those calls were made to Our Lady of Lourdes Hospital. I do not suggest all of those calls are cases, but obviously they were from people who had a miscarriage. To put the numbers in context, we have 14,000 miscarriages a year and 70,000 births. We do not suggest that all the calls relate to cases similar to the unfortunate Redmond case, but 295 is the number of calls made.

Deputy Caoimhghín Ó Caoláin: I warrant there is information to confirm misdiagnosis in some cases.

****

Once again, thank you for your support and as ever we will update you with any further developments.

Kind Regards

Caitriona D'Arcy
Jene Kelly