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Editorial

How to safeguard competency and training in invasive prenatal diagnosis: 'the elephant in the room'

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Introduction – impact of new technology in prenatal screening

Cell-free DNA (cfDNA) screening for Down syndrome (and other common autosomal aneuploidies) represents a major advance in the field of prenatal care. The unprecedented accuracy of this new technology and its rapid uptake have forced a complete re-evaluation of traditional screening programs over the past 3 years[1]. One of the major benefits of this technology is that it reduces the requirement for couples to consider invasive prenatal testing, with its attendant risks of miscarriage. Obstetric healthcare systems that have introduced such testing have noted a significant reduction in numbers of chorionic villus sampling (CVS) procedures and amniocenteses carried out, with potentially significant effects upon service organization and training. Population-based datasets[2–4] and institution-based studies[5–8] around the globe now confirm the predicted decline in the numbers of invasive prenatal tests undertaken due to the uptake of cfDNA screening (Figure 1).

Importantly, this decline in diagnostic testing has not come at the expense of detection, but rather in association with historic rises in diagnostic yield. Today, one in every six invasive procedures performed detects a major chromosomal abnormality, in contrast to four decades ago when only 1 in 100 procedures yielded a clinically significant diagnosis[2]. Invasive testing will certainly continue to have a key role in prenatal diagnosis for the foreseeable future, particularly for the genomic assessment of fetuses with structural abnormalities[9,10], as well as for diagnostic confirmation of high-risk cfDNA test results. In Australia, a plateau in invasive diagnostic testing rates is appearing, suggesting the arrival of a new steady state in prenatal testing after the initial impact of cfDNA screening (Figure 2).

What is the true rate of procedure-attributable pregnancy loss from invasive diagnostic testing?

One of the expected benefits of fewer invasive procedures is a reduction in the number of procedure-related miscarriages. However, the actual number of miscarriages averted by the use of cfDNA screening is difficult to calculate owing to the uncertainties in determining the true procedure-related risk of miscarriage. For a 'high-risk' woman to be able to choose between a 'safe' advanced screening test or an 'invasive' diagnostic test, she and her partner need up-to-date comprehensive information on both the accuracy of cfDNA and the risks of procedure-related pregnancy loss.

A recent systematic review of cfDNA screening calculated a sensitivity and specificity for trisomy 21 of 99.4% (95% CI, 98.3–99.8%) and 99.9% (95% CI, 99.9–100.0%), respectively, based on data from 148 145 tests. The corresponding figures for trisomy 18 were 97.7% (95% CI, 95.2–98.9%) and 99.9% (95% CI, 99.7–100.0%)[11]. Thus cfDNA testing is well established as the most accurate screening test for common autosomal aneuploidies, although poor reporting of false and inconclusive results remains a significant limitation of the existing literature.

Traditionally quoted figures from a Cochrane systematic review suggest that, in low-risk populations, second-trimester amniocentesis imposes an additional ~1% risk of miscarriage (2.1% *vs* 1.3%; relative risk (RR), 1.02–2.52), with similar risks for CVS[12]. However, there is substantial variation in the literature surrounding procedure-attributable fetal loss rates, partly due to differing definitions of pregnancy loss and completeness of follow-up, and few studies are randomized[13]. The problem with most controlled studies is that women who undergo amniocentesis or CVS are not comparable with those who do not have an invasive procedure. They may differ by maternal or pregnancy characteristics, which is why some are offered an invasive test and others are not. A recent meta-analysis of large controlled studies published in the last 10 years has challenged conventional figures for the risk of miscarriage by reporting substantially lower procedure-related risks of only 0.11% (95% CI, −0.04 to 0.26%) for amniocentesis and 0.22% (95% CI, −0.71 to 1.16%) for CVS[14]. This has led to calls for 'women to be provided with accurate and up-to-date information on both invasive and non-invasive prenatal diagnostic testing so that they can make evidence-based choices'[15].

While the procedure-attributable miscarriage risk may be lower than previously thought, it is uncertain if

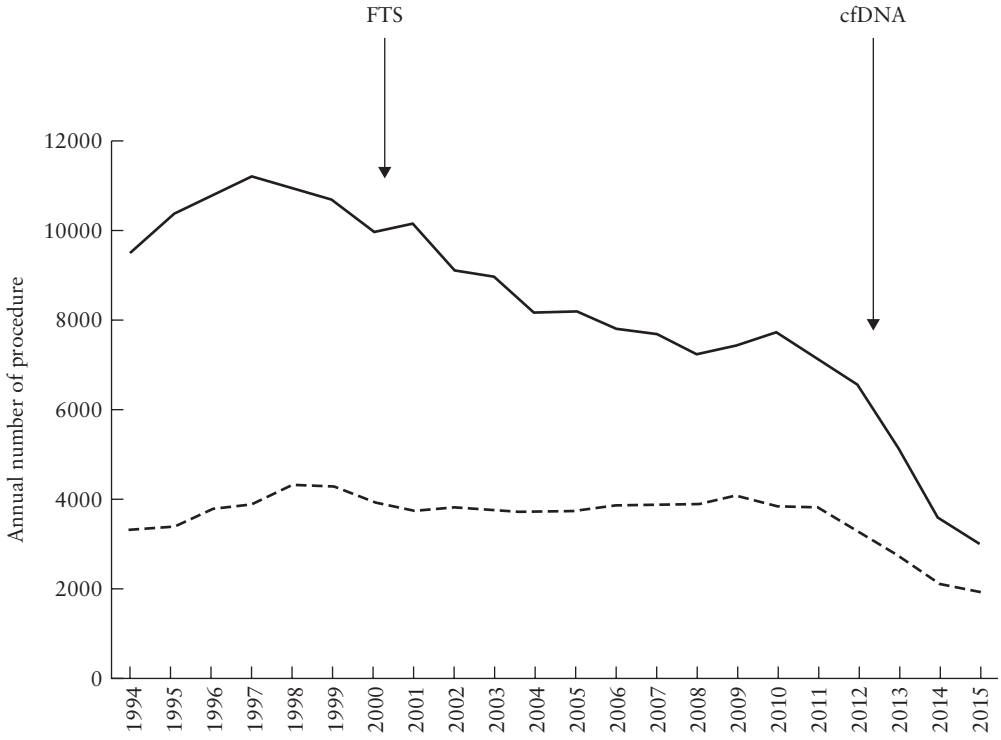

Figure 1 Australian Medical Benefits Scheme billing numbers of amniocenteses (——) and chorionic villus sampling procedures (- - - -) performed between January 1994 and June 2015[48], in relation to introduction of combined first-trimester screening (FTS) and cell-free DNA (cfDNA) screening. Annual numbers for 2015 are projected from first 6 months only.

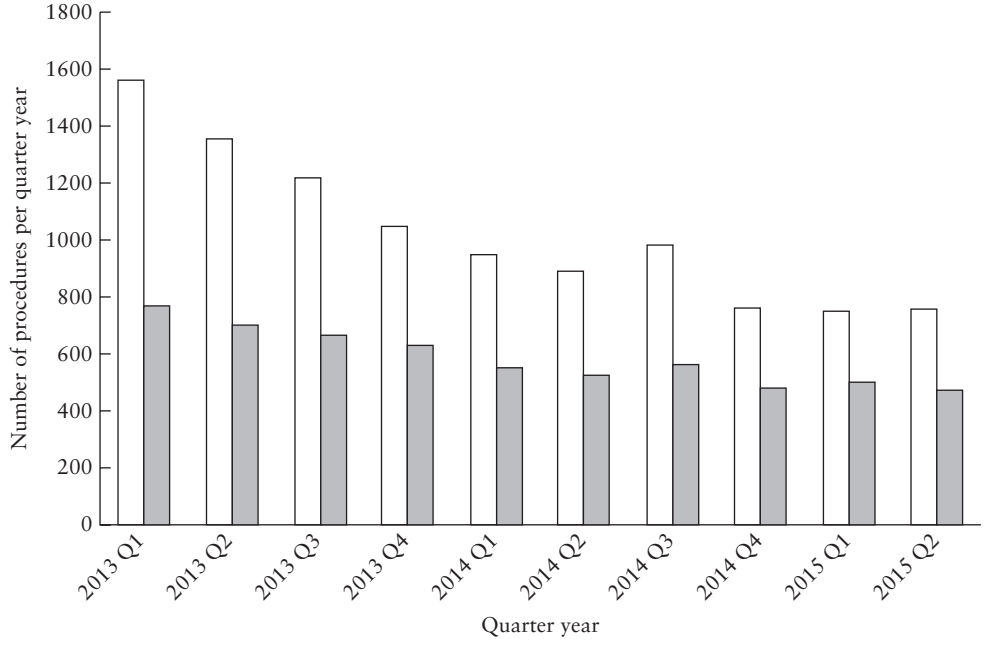

Figure 2 Australian National Medical Benefits Scheme billing numbers for amniocenteses (□) and chorionic villus sampling procedures (▩) per quarter (Q) from January 2013 to June 2015 (period of commercially available cell-free DNA screening)[48].

this level of safety will be maintained. As the overall numbers of amniocenteses and CVS decrease owing to cfDNA screening, so will operator and center experience. Paradoxically, it is now a real possibility that the 'per procedure' miscarriage risk will actually rise in the future as a direct consequence of this reduction in invasive testing. This is particularly so, given that cfDNA screening performs least well in those for whom invasive procedures are likely to be the most technically challenging, i.e. in multiple pregnancies and obese women. Novel solutions are needed to ensure that the reduction in the number of procedures and attendant losses with cfDNA screening are fully realized by patients and not compromised by an increase in loss rates due to diminishing experience.

Impact of operator experience on loss rates

It is undisputed that procedural volume is an important factor in operative proficiency and in the minimization of complication rates. In an early population-based study with 100% follow-up, Halliday and colleagues[16] demonstrated that operators who performed fewer than 150 CVS over 3 years had significantly higher miscarriage rates than those performing more than 150 procedures (RR, 4.3; $P = 0.003$). A recent census of 1953 amniocenteses and 241 CVS procedures was performed in Scotland on singleton pregnancies between May 2008 and April 2009, funded by National Health Service (NHS) Scotland. Despite finding generalized good practice and fetal-loss rates consistent with the international literature (0.7% for amniocentesis and 2.3% for CVS), the report noted 'the most significant failings related to the number of sites where the procedures were carried out and the number of operators performing them. Too many operators performed too few procedures at too many sites'[17]. The report recommended that services providing amniocentesis and CVS in Scotland should be rationalized to reduce the number of operators and increase the number of procedures that each operator performs.

Aside from individual operator numbers, there may be a benefit in the collective experience obtained in major centers. Institution-based data from the national Danish Registry demonstrated that miscarriage rates are inversely correlated with the number of procedures performed, with centers performing < 500 procedures in 11 years having twice the risk of fetal loss compared to those performing > 1500[18]. There is now a need for international reflection on the future provision of invasive prenatal testing.

Professional society recommendations on operator volume

In their 2010 Green Top Guidelines on Amniocentesis and CVS, the Royal College of Obstetricians & Gynaecologists (RCOG) acknowledges 'the lack of evidence in this area' and comments that large throughput does not necessarily equate to competency. While the Australian, USA and Danish colleges do not specify a minimum volume necessary to maintain professional competency, the RCOG has recommended at least 30 ultrasound-guided invasive procedures per annum as a 'reasonable' and 'feasible' volume to maintain competency for established practitioners[19]. In North America, the California Department of Public Health Genetic Disease Screening Program stipulates that practitioners must perform at least 25 procedures per annum to remain approved providers[20].

However, the impact of cfDNA screening has meant that even a modest target of 25–30 procedures per annum may not be achievable for all current practitioners. In a recent survey of Australian obstetric sonologists, one in four (25%) respondents reported that they are currently performing < 25 procedures in total per annum[21]. In this survey, the majority suggested 10–25 amniocenteses and 10–25 CVS per year as sufficient to maintain their skills, which is consistent with the total numbers recommended by USA and UK bodies.

Impact of volume on training

Not only does a reduction in invasive diagnostic procedures potentially impact on operator competency and patient safety, but it also comes at a cost to the training of new specialists. Even before the introduction of cfDNA testing, concerns were raised about the effect of combined first-trimester screening on training opportunities for amniocenteses and CVS[22–24]. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) stipulates a minimum number for certification as subspecialist in maternal–fetal medicine (100 amniocenteses and 50 CVS over 3 years) or obstetric and gynecological ultrasound (100 amniocenteses and 100 CVS over 3 years), but these numbers are consensus-based, rather than evidence-based[25,26].

To date, RANZCOG training data suggest that these procedural targets are still being met, with no significant reduction in numbers of invasive procedures for subspecialty trainees over the most recent triennium. Nevertheless, this probably reflects the fact that most subspecialty training is delivered in public tertiary obstetric centers. At these sites, the numbers of procedures are partly protected by a combination of high-risk referrals (both structural and genetic abnormalities), and limited uptake of cfDNA screening in the public sector, which remains significantly constrained by cost. If this latter source of referrals were to diminish, which seems inevitable given cost trends, then procedures available to trainees, and their trainers, will fall. This is important, since trainees require high volumes of procedures in their early training to overcome the learning curve inherent in any procedural training. The existing data on CVS training describe a wide range of CVS numbers required before passing the learning curve. One study estimated that the effect of the learning curve for CVS was still evident after 50 procedures[27], and others have argued that as many as 400 CVS are required before operator skills plateau[28]. In addition to the actual number of procedures performed, there are other influences on CVS learning curves, such as prior experience with amniocentesis[27]. Lessons from training for other invasive fetal procedures show protective effects of experienced supervisors, the 'group learning effect' (in which an individual center gains experience), and benefits of operator experience with other ultrasound-guided procedures and numbers of procedures performed annually[29,30]. Whether the reduction in prenatal diagnostic procedures will also have a knock-on effect on training in advanced fetal procedures, such as fetal blood sampling and laser surgery, is yet to be seen, but this is a real possibility.

Training bodies may need to re-evaluate their approach to procedural training. The traditional approach of

relying on clinical volume alone to achieve and maintain proficiency will probably become unsustainable. Moreover, the absence of good-quality data on the learning curve, and the influence of other factors such as prior experience in other invasive procedures, individual aptitude and the experience of the supervisor, make meaningful numerical goals difficult to define. Possible solutions include a shift towards competency-based assessment, novel training solutions including the use of simulation, and/or prioritizing operator volume by centralizing invasive procedures.

Competency-based assessment

Competency frameworks have been applied increasingly in the medical education sector over the last decade, although the terminology is often poorly defined, applied and understood. Competency has been defined as 'an observable ability of a health professional, integrating multiple components such as knowledge, skills, values and attitudes. Since competencies are observable, they can be measured and assessed to ensure acquisition by a professional'[31]. Procedural competency may be behaviorist (performance based; the ability to perform discrete tasks) or situational (context dependent, with a greater emphasis on the work environment) or it may incorporate aspects of both. It has been suggested that improved effectiveness of competency-based medical education may reduce the overall duration of training[32]. Could a similar argument exist for reducing the numbers required to achieve invasive procedural competence?

RCOG and RANZCOG are both evaluating the role of competency-based assessments to complement, or obviate, a target number for invasive procedures. For such a competency-based training model to be effective, it needs to consider not just the individual steps needed to achieve procedural competence, but the range of clinical settings to be assessed, the formative and summative assessment tool, the number of trainees and adequacy of assessor time, a process for remediation and an acknowledgment of, and process to deal with, the fact that individuals learn at different rates.

Novel training solutions

Some countries allow trainees to learn CVS skills on women undergoing termination of pregnancy, or following a diagnosis of early pregnancy failure. This approach not only allows trainees to develop skills in patients without concerns of causing miscarriage, but can also provide benefits to the woman such as information on fetal karyotype after pregnancy loss[33]. Animal models could be developed for training purposes, but these are very limited by cost, accessibility, ethical issues and logistic challenges[34]. Synthetic models, with or without electronic guidance systems, are another alternative for avoiding training on pregnant women[35,36]. Many different proposals for low-cost, low-fidelity simulators using accessible materials (such as supermarket food items) have been published[37–39]. Formal instruction using a structured simulator-based curriculum has been shown to improve performance scores and decrease the number of attempts required by trainees to complete their training in amniocentesis[40,41]. However, the persistent challenge with simulation models is how to incorporate clinical variation and different degrees of difficulty. Despite their shortcomings, they have the potential to shorten the learning curve of trainees before they operate on human subjects. The International Society of Ultrasound in Obstetrics and Gynecology currently has a task force addressing simulation training in ultrasound, which focusses on basic training. Expanding the scope of this task force to encompass training in invasive procedures might be a welcome addition.

Centralization

Extrapolating from the findings of the Scottish audit, there is clearly a need to consider reducing the number of centers (and the number of individuals within such centers) performing amniocenteses and CVS. Such a change may occur voluntarily, with such procedures only being offered in large, tertiary fetal medicine centers. If the decline in the number of invasive procedures observed in Australia with the introduction of patient-funded cfDNA screening is extrapolated to Denmark (Figure 3), this would result in only 1000 amniocenteses and CVS being performed nationally per annum when cfDNA screening becomes publicly funded. Discussions are already underway to explore the feasibility of a Nordic Maternal Fetal Medicine training network, as no single country in the region will have sufficient numbers to train new proceduralists in a timely manner. This approach is a natural solution for regions that are geographically close and densely populated. Centralization also brings the additional advantages of consolidating infrastructure and expertise in genetics, tertiary ultrasound and genetic counseling, as well as other invasive procedures such as *in-utero* blood transfusions and fetoscopic laser ablation (FLA) for the treatment of twin–twin transfusion syndrome (TTTS). From a quality and safety perspective, centralization may better enable the collection and analysis of outcome metrics, facilitate ongoing competency-based assessments for proceduralists and develop and implement processes for the remediation of deficiencies.

It is possible that centers and practitioners will resist forgoing clinical skills (and income) if centralization becomes a reality. Such a change could be unpopular among patients themselves if barriers to a prenatal service are perceived to exist because of geographical circumstances and large traveling distances.

However, in a recent Swedish study on patients' attitudes towards centralization of specialized medical procedures, the factors that were most important to patients were: 1) quality of care; 2) continuity of treatment; and 3) a well-functioning patient-care pathway. Perhaps surprisingly, costs, income loss and

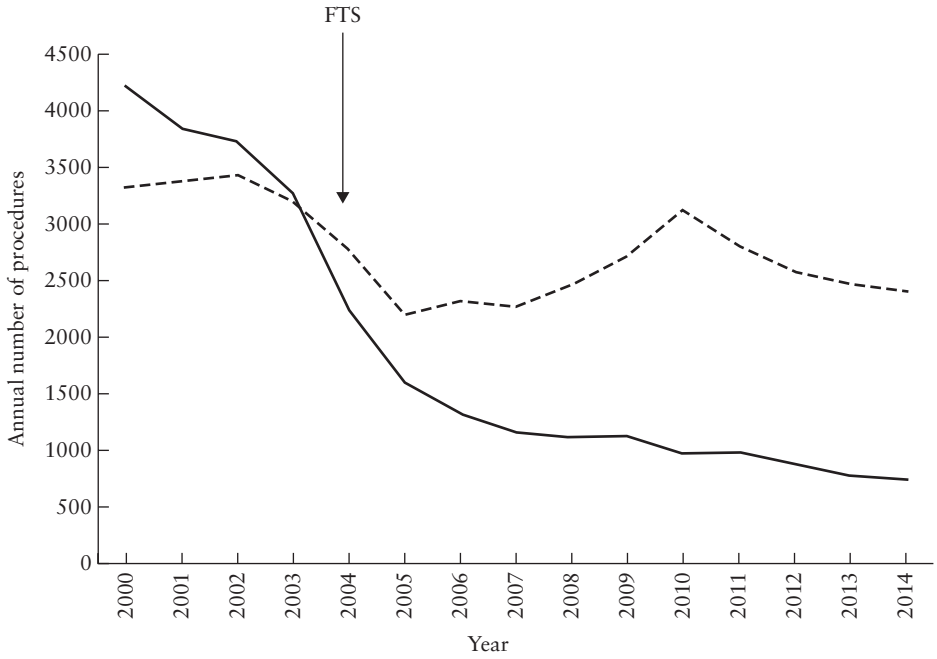

Figure 3 Danish registry data on annual numbers of amniocenteses (——) and chorionic villus sampling procedures (– – – –) from 2000 to 2014. FTS, first-trimester screening.

geographical location were among the least important factors[42]. This is reassuring for countries already on the road to service rationalization, but it is unknown if these patient attitudes are generalizable to large countries in which the population density is extremely low, such as Australia. In such settings, the trade-off between access, vicinity, travel costs and continuity of care may be very different.

In Australia, centralization of novel advanced fetal procedures such as FLA for TTTS has not been achievable owing to the lack of feasibility of transporting high-risk patients long distances for treatment. An example of successful local (state-wide) collaboration for a centralized fetal therapy service exists in Victoria[43]. However, the prospect of rationalizing amniocenteses and CVS, procedures that are currently widely available and performed by specialists with a range of postgraduate training, is a matter that will generate debate regarding workforce planning, infrastructure and remuneration. The management of such issues will depend on clinical leadership and a robust evidence base, and possibly also on a degree of pragmatism.

Ongoing monitoring of individual performance

Ensuring that high standards are maintained will require continuous monitoring of the performance of centers and individual practitioners, as discussed previously in this journal[44]. In the UK, the NHS Fetal Medicine Commissioning Group has set down in its 'quality dashboard' a return of procedure-related losses for CVS and amniocentesis (within 14 days) annually for a center (with expected losses < 1%). For individual practitioner monitoring, the RCOG currently proposes 'thresholds for concern and independent review' if an individual has seven second insertions or four pregnancy losses in 100 consecutive amniocenteses, or five sampling failures or eight pregnancy losses after 100 attempted CVS.

Monitoring of relatively common complications such as multiple needle insertions and blood-stained amniotic fluid, rather than miscarriages, has been suggested as a more statistically suitable method of continuous assessment of individual operators, and such complications may be used as proxy measures for procedure-related loss rates[45]. Some authors have suggested specific benchmarks, such as multiple insertion rates of < 2% for amniocentesis, < 5.5% for transabdominal CVS and < 0.3% for unsuccessful CVS aspirations[13]. Statistical methods such as the cumulative sum method and funnel plots have already been advocated for monitoring operator performance in fetal intravascular transfusions and FLA for the treatment of TTTS[29,30,46].

Whichever governance structure is chosen for monitoring safety, the importance of attempting complete ascertainment of pregnancy outcomes cannot be overstated, as miscarriages are disproportionately concentrated in the group that is hardest to follow up[47]. Less than 100% follow-up will very probably underestimate loss rates.

Future consensus

The success of cfDNA technology, with its high sensitivity and specificity for the detection of trisomy 21, has raised important issues relating to the future conduct of invasive prenatal testing. There is an urgent need to 'future-proof' the safe provision of amniocentesis and CVS. While there will always be a need to accommodate regional differences, patient safety and access to care should

remain top priorities. We can no longer use a set quota of procedures as the only criterion for successful completion of training. Competency-based assessment and the use of simulation models to reduce the learning curve should be considered as adjuncts to a fixed level of procedural experience. The importance of experienced supervisors in maintaining a safe and effective training environment should be recognized. Collaboration in the form of training networks may become necessary to ensure high standards of procedural training. Centralization of clinical services may be the best solution for countries in which a balance between service provision and training volume can be achieved. Finally, we may have to consider formal differentiation of specialists according to procedural skills if non-invasive prenatal testing continues to reduce indications for invasive testing. A robust, prospective national (and preferably international) consensus should help us to exploit the full potential of new technologies, while safeguarding quality of care for patients.

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