Assessment and diagnosis of autism spectrum disorders

New NICE guidelines set clear evidence based standards for quality care

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See also CLINICAL REVIEW, p 894

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The linked article by Baird and colleagues summarises the recent National Institute for Health and Clinical Excellence (NICE) guidance on the recognition, referral, and diagnosis of children and young people with autism spectrum disorders (hereafter, autism).[1] The guidance provides a comprehensive list of practice recommendations that have far reaching implications for care providers in the United Kingdom.[1 2] The guidelines were developed in partnership with the National Collaborating Centre for Women's and Children's Health, with substantial stakeholder input, including parents, carers, and community practitioners. There are 68 recommendations related to initial recognition, referral, diagnostic evaluation, and medical investigation of children and adolescents with possible autism. The guidelines provide a clear blueprint for diagnosing autism that is aimed at improving family experience and optimising outcomes.

Foremost is the recommendation for collaboration across healthcare, social services, and the education and voluntary sectors to establish a local autism strategy group in each community. This group should ensure that early recognition, referral, and diagnosis of autism are well coordinated and guided by principles of evidence based practice and family centred care. It would also be responsible for streamlining the assessment process to minimise delays and ensure timely access to support and intervention services. It is recommended that the care pathway includes focused developmental surveillance for signs and symptoms of autism by community practitioners, and a single point of access for referral to a specialist team, with diagnostic assessments initiated within three months of referral.

The guidelines also recommend that surveillance for autism take account of a young person's overall development level. Signs and symptoms of possible autism are listed for children of preschool, primary school, and secondary school ages or equivalent mental ages. Thus, in contrast to previous practice guidelines, which focus almost exclusively on early detection, the NICE guidelines emphasise the diverse clinical presentation of this disorder across the developmental spectrum. The guidelines also note that specific subgroups of young people with autism (girls, children with severe intellectual disabilities, and, conversely, children who are more intellectually or verbally able) often experience delays in diagnosis so require special vigilance.[3] In addition, signs and symptoms of autism may be masked (for example, by coping mechanisms and environmental supports) in young people who present at an older age.

Considerable guidance is given about the initial decision to refer a young person for diagnostic assessment. Although some scenarios warrant immediate referral to the specialist team (such as language or social regression in a child younger than 3 years), it is recommended that several factors are considered when making referral decisions. These include the severity and functional impact of apparent signs and symptoms; the level of parental concern (and the concerns of the young person); and the presence of specific factors associated with increased risk of autism, including a positive family history (risk to siblings was recently reported to be as high as 19%).[4] Screening tools are regarded as a useful adjunct to gathering information about autism related behaviours, but caution is advised on using screening cut-off points as the sole basis for referral. This is a major point of departure from the American Academy of Pediatrics guidelines in the United States,[5] and it is likely to stimulate further debate on the current evidence base for autism screening.[6 7]

Similarly, the NICE guidelines put more emphasis on the composition of the specialist team and the essential components of the diagnostic assessment than on the use of specific diagnostic tools. The minimum core team should consist of a paediatrician or a child and adolescent psychiatrist (or both), clinical or educational psychologist (or both), and speech and language therapist, with access to other health professionals either as part of the specialist team or through additional referral. The diagnostic assessment should include a thorough developmental history and enquiry about symptoms of autism, interactive assessment with the young person to assess his or her social communication skills and behaviours, and careful physical examination to identify associated medical conditions. The assessment should lead not only to determination of a diagnosis but also the establishment of a developmental profile. This should include factors that might affect day to day functioning and social participation, such as intellectual ability, language and communication skills, adaptive behaviour, physical health, nutritional status, and behaviour. Thus, the assessment should clarify not only symptoms and impairment but also functioning and participation. This is consistent with the current international classification of functioning, disability and health (ICF) framework,[8] and it is relevant to setting priorities for intervention. The specialist team must also clearly and compassionately communicate the assessment findings, with an emphasis on ensuring that families are informed about autism, its implications for the young person's development and functioning, and the options for accessing support and services.

No routine medical investigations were recommended for young people with newly diagnosed autism. Specifically, genetic testing should be reserved for children with specific dysmorphic features, congenital anomalies, or intellectual delay. It is recommended that before implementing array-comparative genomic hybridisation testing on a routine basis

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- Practice: Recognising and diagnosing autism in children and young people (*BMJ* 2011;343:d6360)
- Views and Reviews: How the autism epidemic came to be (*BMJ* 2011;342:d852)

for children with autism, clinicians need a better understanding of its diagnostic yield than is available from the current literature (particularly in children who do not have an intellectual disability). The authors argue that it is essential to identify potential negative consequences that may result from routine testing, particularly related to the identification of genetic variants of unknown clinical relevance.[9]

Implementation of some of these recommendations (particularly timelines for assessment and the establishment of a local autism team in each community) may strain available resources and require additional strategies for professional training and mentorship. However, the guidelines play an essential role in establishing clear comprehensive evidence based standards for quality care for young people with autism, who have historically experienced substantial delays in diagnosis.[3] The guidelines move the discussion from the level of particular symptoms or the selection of particular diagnostic tests to advocating for better health system strategies, including closer partnerships between service sectors, community practitioners, autism specialists, and, indeed, families. This may ultimately have the greatest impact on promoting earlier diagnosis for people across the autism spectrum and improving family experience, although further evaluation of these important outcomes over time will be needed.

1 Baird G, Douglas HR, Murphy MS. Recognising and diagnosing autism in children and young people: summary of NICE guidance. *BMJ* 2011;343:d6360.
2 National Institute for Health and Clinical Excellence. Autism: recognition, referral and diagnosis of children and young people on the autism spectrum. (Clinical guideline 128.) 2011. http://guidance.nice.org.uk/CG128.
3 Howlin P, Asgharian A. The diagnosis of autism and Asperger syndrome: findings from a survey of 770 families. *Dev Med Child Neurol* 1999;41:834-9.
4 Ozonoff S, Young GS, Carter A, Messinger D, Yirmiya N, Zwaigenbaum L, et al. Recurrence risk for autism spectrum disorders: a Baby Siblings Research Consortium Study. *Pediatrics* 2011; published online 15 August.
5 Johnson CP, Myers SM; American Academy of Pediatrics Council on Children with Disabilities. Identification and evaluation of children with autism spectrum disorders. *Pediatrics* 2007;120:1183-215.
6 Al-Qabandi M, Gorter JW, Rosenbaum P. Early autism detection: are we ready for routine screening? *Pediatrics* 2011;128:e211-7.
7 Dawson G, Rogers S, Fein D, Zwaigenbaum L. Why it is important that screening for autism be provided in routine pediatric care [letter]. *Pediatrics* 2011. http://pediatrics.aappublications.org/content/early/2011/06/08/peds.2010-1881/reply#pediatrics_el_51471.
8 WHO. International classification of functioning, disability, and health (ICF). 2001. www.who.int/classifications/icf/en/.
9 Miller DT, Adam MP, Aradhya S, Biesecker LG, Brothman AR, Carter NP, et al. Consensus statement: chromosomal microarray is a first-tier clinical diagnostic test for individuals with developmental disabilities or congenital anomalies. *Am J Hum Genet* 2010;86:749-64.

Life expectancy in HIV

Better, but not good enough

RESEARCH, p 886

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More than 33 million people are infected with HIV worldwide.[1] Over the past 30 years, mortality from HIV and the life expectancy of people who are infected have improved dramatically. With major advances in biomedical research, increased awareness, and dedicated funding, HIV has been transformed from an untreatable and almost always fatal disease to a chronic one. For patients diagnosed promptly and treated with combination antiretroviral therapy (ART), life expectancy is now several decades.[2] In the linked cohort study, May and colleagues estimate specific life expectancy for people in the United Kingdom with HIV undergoing treatment compared with life expectancy in the general population.[3]

Gains in life expectancy have increased steadily over time, with the availability of more effective and better tolerated regimens. But these gains have not been seen in everyone with HIV. Factors associated with worse outcomes include late presentation to healthcare services, suboptimal adherence to drugs, premature discontinuation of treatment, mental illness, and behavioural risk factors such as use of injected drugs and alcohol dependence.[4]

Data from the Joint United Nations Programme on HIV/AIDS (UNAIDS) suggest that more than 80 000 people are currently living with HIV in the UK, and about 25% of them are unaware of their infection.[5] These people, their healthcare providers, and policy makers confront several key questions. How much life expectancy is lost as a result of HIV? How does the timing of the start of treatment affect life expectancy? Do losses in life expectancy as a result of HIV differ between men and women?

May and colleagues report estimates of life expectancy derived from a large cohort study of patients who started HIV treatment between 1996 and 2008 at some of the largest clinical centres in the UK. The authors suggest that between the periods 1996-9 and 2006-8, the life expectancy of an average 20 year old person infected with HIV increased from 30 to 46 years.

The authors also found that decreases in life expectancy as a result of HIV are greater in men than in women. They estimate that, for an average 20 year old man, HIV decreases life expectancy by 18.1 years; in contrast, a woman loses only 11.4 years. Why is the difference so large? Data from other countries show that women are likely to start treatment for HIV earlier than men, perhaps partly because women are often tested for HIV during pregnancy.[6 7] Because earlier care is associated with better survival,[8] this may explain the differences between men and women.

May and colleagues found greater reductions in life expectancy (more than 15 years lost) in those who start ART late (CD4 counts $<100\times10^6$/L) rather than early (CD4 counts $200\text{-}350\times10^6$/L), providing more evidence in favour of earlier treatment. The presentation of information in terms of gains in life expectancy makes this important message easily understood by patients. For health related messages to be effective, people must perceive a problem as relevant and serious, and they should recognise that change provides clear gains. This study provides clinicians with the language to make these gains real.

May and colleagues' study is an excellent example of a comprehensive analysis conducted on a well defined longitudinal cohort. However, the estimates should be

TOM PILSTON/PANOS

Antiretroviral medication

interpreted within the boundaries of the data from which they are derived. The UK Collaborative HIV Cohort comprises data from referral centres. Although it is easier to conduct studies in high volume regional centres, not all HIV infected patients receive care in such settings. Patients of higher socioeconomic status are often over-represented in high volume clinics because those on low incomes and those in racial and ethnic minorities often receive care in lower volume centres.[9] High volume referral centres are associated with better outcomes.[10 11]

The right censored nature of cohort data should also be taken into account. Participants are more likely to contribute early years on treatment, when mortality is lower, and to be censored later (because the follow-up period ends), when mortality is likely to rise. Because of the artificial right censoring that occurs when data are closed for analysis, people who started ART in 2006-8 had less follow-up time to contribute, which would also result in overestimation of recent survival and life expectancy.

Comparing life expectancy in people with HIV with that of the general population may misattribute losses to HIV that really come from other behavioural factors, such as smoking, substance misuse, and mental illness.[6 12] Comparing life expectancy in those with and without HIV, but with similar risk factors, could shed light on this.

May and colleagues' study serves as an urgent call to increase awareness of the effectiveness of current HIV treatments in patients and providers. In turn this should increase rates of routine HIV screening, with timely linkage to care and uninterrupted treatment. As these factors improve, the full benefits of treatment for all HIV infected people can be realised.

1 UNAIDS. UNAIDS report on the global AIDS epidemic. 2010. www.unaids.org/globalreport/global_report.htm.
2 Walensky RP, Paltiel AD, Losina E, Mercincavage LM, Schackman BR, Sax PE, et al. The survival benefits of AIDS treatment in the United States. *J Infect Dis* 2006;194:11-9.
3 May M, Gompels M, Delpech V, Porter K, Post F, Johnson M, et al. Impact of late diagnosis and treatment on life expectancy in people with HIV-1: UK Collaborative HIV Cohort (UK CHIC) Study. *BMJ* 2011;343:d6016.
4 Golin CE, Liu HH, Hays RD, Miller LG, Beck CK, Ickovics J, et al. A prospective study of predictors of adherence to combination antiretroviral medication. *J Gen Intern Med* 2002;17:756-65.
5 UNAIDS. UNGASS country progress report United Kingdom. 2010. www.unaids.org/en/dataanalysis/monitoringcountryprogress/2010progressreportssubmittedbycountries/unitedkingdom_2010_country_progress_report_en.pdf.
6 Losina E, Schackman BR, Sadownik SN, Gebo KA, Walensky RP, Chiosi JJ, et al. Racial and sex disparities in life expectancy losses among HIV-infected persons in the United States: impact of risk behavior, late initiation, and early discontinuation of antiretroviral therapy. *Clin Infect Dis* 2009;49:1570-8.
7 Postma MJ, Beck EJ, Hankins CA, Mandalia S, Jager JC, de Jong-van den Berg LTW, et al. Cost effectiveness of expanded antenatal HIV testing in London. *AIDS* 2000;14:2383-9.
8 Sterne JAC, May M, Costagliola D, de Wolf F, Phillips AN, Harris R, et al. Timing of initiation of antiretroviral therapy in AIDS-free HIV-1-infected patients: a collaborative analysis of 18 HIV cohort studies. *Lancet* 2009;373:1352-63.
9 Heslin KC, Andersen RM, Ettner SL, Cunningham WE. Racial and ethnic disparities in access to physicians with HIV-related expertise. *J Gen Intern Med* 2005;20:283-9.
10 Dudley RA, Johansen KL, Brand R, Rennie DJ, Milstein A. Selective referral to high-volume hospitals—estimating potentially avoidable deaths. *JAMA* 2000;283:1159-66.
11 Hellinger F. Practice makes perfect—a volume-outcome study of hospital patients with HIV disease. *J AIDS* 2008;47:226-33.
12 Degenhardt L, Hall W, Warner-Smith M. Using cohort studies to estimate mortality among injecting drug users that is not attributable to AIDS. *Sex Transm Infect* 2006;82:56-63.

Fetal risk from ACE inhibitors in the first trimester

Evidence is reassuring, but risks remain from the hypertension itself

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As in the general population, management of hypertension in pregnant women is complicated by factors that may be difficult to control (such as diabetes, obesity, and smoking). However, the choice of antihypertensive drug is uniquely complicated in pregnancy, because the clinician not only has to consider the comparative safety and efficacy of various drugs from the mother's perspective, but also consider the effects on the fetus. Rising rates of hypertension related to obesity and diabetes heighten this concern. Furthermore, therapeutic choices cannot wait until pregnancy is recognised—because about half of pregnancies (at least in the United States) are unplanned, fetal exposure early in the first trimester is a distinct possibility. Thus, fetal concerns should be taken into account when prescribing antihypertensives to all women of childbearing potential—a considerable clinical population. In the linked retrospective cohort study, Li and colleagues assess the association between the use of angiotensin converting enzyme (ACE) inhibitors in mothers during the first trimester and the risk of malformations in their offspring.[1]

Few studies have been large and rigorous enough to provide useful information on the fetal safety of most antihypertensives. Although it is accepted that ACE inhibitors cause fetal harm when exposure occurs in the later stages of pregnancy,[2] a widely cited 2006 report that used US Tennessee Medicaid data found that exposure in the first trimester was also associated with an increased risk of cardiac malformations and neural tube defects; no increased risks were seen for other classes of antihypertensive drug.[3] Where clinicians might previously have felt comfortable using ACE inhibitors until a woman became pregnant, switching to another drug before the second trimester, this finding suggested that to avoid inadvertent first trimester

exposure, prescribers should not use ACE inhibitors in women of childbearing potential.

Li and colleagues tested the hypothesis in a larger and more diverse database—the Kaiser Permanente Northern California member population of women, with established linkages to pharmacy data, malformation diagnoses, and certain potential confounding factors.[1] They estimated risks in pregnant women who received only ACE inhibitors in the first trimester, and separately, women who received antihypertensive drugs other than ACE inhibitors. These women were compared with two unexposed groups—those with a diagnosis of hypertension who received no antihypertensive drugs in the first trimester, and women without hypertension during pregnancy who did not receive antihypertensive drugs. They also considered factors that could modify the observed effects, including diabetes and obesity (unfortunately, cohorts based on medical records can rarely control for the potentially important effects of perinatal consumption of non-prescription multivitamins containing folic acid). When compared with the "normal" pregnant population, women taking ACE inhibitors had a modestly increased risk of defects overall and of cardiac defects (but not neural tube defects—other specific defects were not considered). Similar increases were seen for women taking other antihypertensive drugs. However, when the two exposed groups were compared with women with untreated hypertension, the risks were lower and approached the null hypothesis. This finding suggests that it was the underlying hypertension (treated or not) that increased the risks of the studied defects.

Li and colleagues' findings are similar to those from a much smaller Swedish cohort, which compared users of ACE inhibitors with users of other antihypertensives and found no differences in cardiovascular defects between the two groups.[4] They are also similar to those from a large US case-control study, which had the power to consider specific cardiac defects and also included a comparison involving women with untreated hypertension.[5] On the basis of all these findings, it is reasonable to conclude that exposure to ACE inhibitors during the first trimester poses no greater risk of birth defects than exposure to other antihypertensives.

Given the limitations of these studies, it is possible that ACE inhibitors (and other antihypertensives) may be associated, if modestly, with one or another specific defect, but the greater concern is that the underlying hypertension itself places the fetus at risk.

But what is the definition of "hypertension" and "untreated hypertension"? It is reasonable to assume that untreated hypertension is less severe than treated hypertension, but observational studies have lacked data on crucial variables related to hypertension in pregnancy, including its causes, severity, duration, and especially the level of adherence and control associated with drug treatment. Under these circumstances, a randomised trial might seem like the answer, but the ethics of withholding drug treatment are daunting. Thus, we will probably have to continue to rely on observational studies, however imperfect they may be.

Some challenges that warrant consideration in future studies include not only providing answers to the questions above, but also to whether there is a "pre-hypertensive" condition that may affect the fetus before an increase in maternal blood pressure is detected, or even detectable. Are there physiological changes that might affect fetal development before they manifest as increased maternal blood pressure? Although clinicians must certainly identify and control hypertension, particularly in pregnancy, much is left to learn about how hypertension can cause birth defects.

1 Li D-K, Yang C, Andrade S, Tavares V, Ferber JR. Maternal exposure to angiotensin converting enzyme inhibitors in the first trimester and risk of malformations: a retrospective cohort study. *BMJ* 2011;343:d5931.
2 Barr M Jr. Teratogen update: angiotensin-converting enzyme inhibitors. *Teratology* 1994;50:399-409.
3 Cooper WO, Hernandez-Diaz S, Abrogast PG, Dudley JA, Dyer S, Gideon PS, et al. Major congenital malformations after first-trimester exposure to ACE inhibitors. *N Engl J Med* 2006;354:2443-51.
4 Lennestal R, Olausson PO, Kallen B. Maternal use of antihypertensive drugs in early pregnancy and delivery outcome, notably the presence of heart defects in the infants. *Eur J Clin Pharmacol* 2009;65:615-25.
5 Caton AR, Bell EM, Druschel CM, Werler MM, Lin AE, Browne ML, et al. Antihypertensive medication use during pregnancy and the risk of cardiovascular malformations. *Hypertension* 2009;54:63-70.

Implementation of an electronic health record

Involves numerous challenges, but examples show it can be done successfully

RESEARCH, p 888

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Implementing an electronic health record along with computerised provider order entry and clinical decision support is hard. Integrating these advanced technologies into a complex and rapidly changing healthcare delivery environment is a major task, but the associated cultural, process, and change management obstacles make the task even harder. Furthermore, the challenges and costs often accrue long before any real value of the effort is seen.

The current controversy regarding the NHS effort to implement a system-wide electronic health record is a good case study of how difficult these initiatives can be.[1] When health systems encounter the associated and inevitable difficulties, the natural inclination is to question whether the aggravation and effort is worthwhile. This is clearly at the core of the debate in the United Kingdom regarding the NHS effort. At such times, leaders who are seriously interested in improving the safety, quality, efficacy, and cost of care need to do what all good leaders do—pause, carefully assess the situation, and learn from the experience of their efforts as well as that of others. They should then use this knowledge to determine how to achieve the ultimate goals of the initiative—better and more efficient care for patients.

The implementation of an electronic health record that produces value for patients and purchasers is a continuous learning opportunity. This is shown by Sheikh and colleagues in a linked longitudinal qualitative evaluation,


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which assesses the implementation and adoption of the NHS Care Records Service in 12 English "early adopter" hospitals.[2] Overall, the authors concluded that implementation of the NHS service was time consuming and challenging, with limited distinct benefits for clinicians and no clear advantages for patients. Although the study highlights the difficulties of these endeavours, it should not dissuade clinicians or policy makers from striving for the ultimate goal—to provide healthcare value defined by higher quality, increased safety, and greater access to good care at a reasonable cost.

This goal is not possible without using a combination of advanced information technology and knowledge management to capture, code, and disseminate health information in the form of electronic health records. Such records have enormous potential to improve the flow of information across healthcare settings and systems. Furthermore, computerised provider order entry coupled with advanced clinical decision support can improve the safety, quality, and cost of care.[3] The implementation of electronic health records is not about digitising the paper chart, but about laying the foundation for achieving better outcomes through better access to information and better decisions.

What are the key practical lessons for those who are trying to implement such systems? A summary report by the National Alliance for Health Information Technology provides some useful categories of crucial success factors.[4]

The goal is to improve care, not information technology. IT is a powerful enabler, nothing more. Crucial success factors are: careful definition of project goals in terms of better care for patients, development of metrics to measure progress in achieving these goals, creation of change management and comprehensive communication plans, and the refinement of organisational policies and procedures to reflect the changes produced by the implementation.

Manage culture and change. It is crucial to understand the culture of an organisation. New systems inevitably introduce major changes to traditional care processes and work flows, which often produces substantial resistance from staff. A comprehensive change management plan is crucial to overcoming cultural resistance and should provide the education and motivation people need for change to happen.[5]

Engage clinicians. The views of those involved in the implementation must be built into the implementation early and often. Clinical groups led by respected clinical champions must be educated, informed, inspired, and engaged. They should be involved in creating the project goals and standard success metrics, participate in the development and execution of the communication plan, validate clinical process and workflow changes, and help to inform and influence their clinical peers as to why the initiative is important to patient care.

Improve processes and workflow. Implementations are an opportunity to examine current processes and workflow practices, eliminate unnecessary workarounds, and improve the delivery of care. Without proper analysis, inefficient practices can become simply entrenched rather than improved. If existing process and workflow are adequate, maintain them.

Test on the end user. End user testing should be done before implementation and feedback should be incorporated.

Train and educate. Careful attention to methods of training and how it is offered will pay dividends in terms of acceptance by the end user and achievement of organisational goals. Too much training overwhelms users with information and can become annoying, but too little will mean goals are not achieved. Just in time training (training shortly before implementation) often works best for busy clinicians. Such training can include practice systems, online courses, and "at the elbow" ad hoc support from other knowledgeable users.

Communicate. Communicate frequently about progress, challenges, and mistakes.[4] It is also equally important to listen and respond to constructive feedback.

Incorporating advanced information technology into the complex care delivery environment so that it improves care processes and work flows while also not harming patients or alienating clinicians is difficult. Years of experience show that electronic health records and clinical decision support can be implemented to improve individual and population health,[6-9] but it is not easy. The literature is full of examples of lessons learnt, mistakes made, and outright failures.[10-12] It is therefore important to view the implementation as a learning opportunity, and not simply as either a success or a failure.

1 Cross M. Government announces end of NHS IT programme—for second time. *BMJ* 2011;343:d6175.
2 Sheikh A, Cornford T, Barber N, Avery A, Takian A, Lichtner V, et al. Implementation and adoption of nationwide electronic health records in secondary care in England: final qualitative results from prospective national evaluation in "early adopter" hospitals. *BMJ* 2011;343:d6054.
3 Massachusetts Technology Collaborative. Saving lives, saving money: the imperative for CPOE in Massachusetts, 2008. www.nehi.net/publications/8/saving_lives_saving_money_the_imperative_for_computerized_physician_order_entry_in_massachusetts_hospitals.
4 Rules of Engagement. Summary report by the National Alliance for Health Information Technology. 2006. https://dl.dropbox.com/u/17591589/NAHIT.pdfhttps://dl.dropbox.com/u/17591589/BMJ References/NAHIT review on CPOE approach and Lessons Learned%5B1%5D.pdf.
5 Kotter JP. Leading change. Harvard Business School Press, 1996.
6 Hug BL, Witkowski D, Sox C, Keohane C, Seger D, Yoon C, et al. Adverse drug event rates in six community hospitals and the potential impact of computerized physician order entry for prevention. *J Gen Intern Med* 2010;25:31-8.
7 Schnipper JL, Liang C, Hamann C, Karson A, Palchuk M, Sherlock M, et al. Development of a tool within the electronic medical record to facilitate medication reconciliation after hospital discharge. *J Am Med Inform Assoc* 2011;18:309-13.
8 Schnipper JL, Hamann C, Ndumele C, Liang C, Carty M, Karson A, et al. Effect of an electronic medication reconciliation application and process redesign on potential adverse drug events. *Arch Intern Med* 2009;169:771-80.
9 Fiumara K, Moniz T, Churchill W, Bane A, Luppi C, Bates D, et al. Case study on the use of health care technology to improve medication safety. In: Porche RA, ed. Medication use: a system approach to reducing errors. 2nd ed. Joint Commission Resources. 2007:103-14.
10 Chin HL. The Reality of EMR implementation: lessons from the field. *Permanente J* 2004;8:43-7.
11 Keshhavjee K, Bosomworth J, Copen J, Lai J, Kucukyazici B,Lilani R, et al. Best practices in EMR implementation: a systematic review. Proceedings of the 11th International Symposium on Health Information Management Research. 2006. https://dl.dropbox.com/u/17591589/Keshavjee.pdfhttps://dl.dropbox.com/u/17591589/BMJ References/Best Practices in an EMR Implementation - A systematic review.pdf.
12 Ovretveit J, Scott T, Rundall T, Shortell S, Brommels M. Implementation of electronic medical records in hospitals: two case studies. *Health Policy* 2007;84:181-90.

Donation of bodily material for medicine and research

New report builds strong foundation for financial incentives but messages are contradictory

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- News: Germany pushes for more organ donation (*BMJ* 2011;342:d660)
- News: Public to be asked its views on ethics of incentives for organ donation (*BMJ* 2010;340:c2182)
- News: Rare instance of organ donation in Japan highlights shortage of donors (*BMJ* 2009;339:b5081)

The report published by the Nuffield Bioethics Council on 10 October tackles the difficult question of how far society can go in its demands on people to act in what many regard as a good cause—that of providing bodily material to benefit others.[1] The report encompasses every source and lawful use of human bodily material. Furthermore, it contemplates each possible transaction, from purchase and sale, to gift, and several hybrid transfers in between. The council's investigation of factors that unite and distinguish each transaction allows the meaning and ethical value of each type of donation to be considered. Its main conclusion, that systems based on altruism are not mutually exclusive from those that might allow payment, seems a sensible way of increasing the donor pool, particularly if a pilot project on payments to donor families for the cost of funerals is adopted. However, other conclusions are less well supported by ethical analysis and explication and require further attention.

The United Kingdom and the United States prohibit the sale of transplantable organs and tissue.[2 3] The report exposes the ethical root of these laws, presenting a "ladder" of actions that facilitate donation, ranking the first four rungs of the ladder as ethically simple and easily permissible. Thus, giving a potential donor information about the need for donation (rung 1), recognition and gratitude (rung 2), lowered barriers to donation (rung 3), and interventions for those already disposed to donate (rung 4) are ethical "no-brainers" because they are not inconsistent with existing altruism.[1] Interventions such as offering associated benefits, such as burial expenses to encourage non-donors to donate (rung 5) and financial incentives (rung 6), are more ethically complex and should be considered only when existing altruism does not meet a public health need, and only when they do not cause harm to the donor or other important interests. Thus, the report concludes that funeral expenses for dead donors may be appropriate in a world of acute organ shortages, and that such payments are both related to and commensurate with the value of the gift, so the risk of doing harm is small.

The report's finding on the role of donor decision making in postmortem donations are contradictory. The report concludes that anatomical donation for deceased donors should be based on the donor's wishes, even when the donor dies without having documented his or her wishes.[1] This contradicts the weight of the law, which says that if the donor fails to express his or her intent by means of a gift or refusal while alive, the decision of how the body is used passes to survivors. Although survivors are free to exercise this right on the basis of what they know about the dead person's wishes (and most do), they should not be required to go through a tortured guessing game, attempting to extrapolate the donor's wishes. The council's decision that decedents possess autonomy, when they have failed to document their wish, is unique. It is also contradictory, because the council also concludes that when donors do express their wishes, by means of a document, that such wishes are subject to the veto of family members. It cannot work both ways, ethically, legally, or in practice.

The council's conclusion that families may overturn documented anatomical gifts, such as those made on the organ donor registry, is not supported by donor autonomy or beneficence, or by benefit to the community. The council's position is, "the option of refusal should rest with familial associates of the deceased. Such refusal . . . may be based on families' own knowledge of the deceased's attitudes to donation; however, it may also at times be understood as an expression of their own needs, as bereaved family members."[1] This position, especially in light of the conclusion that decedents' unexpressed wishes are to be honoured, means that registering the gift of an organ is a mere symbolic gesture. The report urges that resources should be poured into education, decision making, and altruism on the one hand, but then it supports the possibly unlawful ability of survivors to veto the donor's gift.

It was formerly the practice in the US to put the family's wishes (often temporary and later regretted) above the well considered, documented, and lawful gift of the donor. It is now widely seen as legally unsupportable and ethically questionable. Autonomous decision making cannot be encouraged on the one hand, while permitting and even advocating carte blanche disregard of the decision on the other. Anatomical gifting is akin to other dispositions upon death. The decision of testators to will their property to charity rather than to their family is unfailingly supported by the law and practice. This is true even when it is detrimental to the family and it does not have the benefit of saving lives. Why would the gift of a person's body be given less weight? The council's unexplained sensitivity to family wishes in the face of the harm to the donor's legacy and potential recipients should be reconsidered.

In the past three years, procurement organisations in the US and elsewhere have developed compassionate best practices, which guide the family's expectations in such a way as to minimise conflict with the donor's wishes and enable the donor's organs to be used. Properly handled, donation can be healing for survivors. After organ donation has occurred, family members who formerly objected to donation are often grateful that it happened, and that the donor's legacy was honoured. Procurement professionals should share their learning across borders to accomplish this goal and save lives through transplantation.

1 Nuffield Council on Bioethics. Human bodies: donation for medicine and research. 2011. www.nuffieldbioethics.org/donation.
2 Human Tissue Act 2004. Section 32(11). www.legislation.gov.uk/ukpga/2004/30/contents.
3 National Organ Transplant Act 1984 (NOTA). 42 USC. Sections 273-4.