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● *Letter to the Editor*

COMMENTARY ON THE WORLD FEDERATION FOR ULTRASOUND IN MEDICINE AND BIOLOGY PROJECT "INCIDENTAL FINDINGS"

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To the Editor:—

The World Federation for Ultrasound in Medicine and Biology (WFUMB) is dedicated to the advancement of ultrasound by encouraging research, promoting international cooperation, disseminating scientific information and improving communication and understanding in the world community using ultrasound in medicine and biology. Therefore, the mission of WFUMB is to bring sustainable ultrasound programs to the underserved areas of the world to improve global health care through collaboration, communication and education (www.wfumb.org).

Although the benefits of preventive medical examinations may be controversial, they are performed in many countries on a large scale. Despite a variance in recommendations, practice and funding in high-income nations, evidence-based screening programmes have been implemented for frequent malignant diseases such as colorectal, prostate, cervical, breast, skin and lung cancer, as well as for other life-threatening diseases including abdominal aortic aneurysm (Ebell et al. 2018). In addition to these official national health screening programmes for individuals at risk for a particular disease, private screening centres offer a large variety of imaging and laboratory tests for screening of asymptomatic people, which is a main source for incidental findings (IFs) using ultrasound as a screening method in certain countries. Despite not being recommended by groups such as the American College of Preventive Medicine (Livingston et al. 2016), whole-body imaging with computed tomography (CT) and magnetic resonance imaging (MRI) is popular (Kmietowicz 2007; Burger et al. 2008). People hope that life-threatening diseases may be detected by screening tests at an early, curable stage and may not be aware of the inherent risks of imaging techniques (*e.g.,* radiation exposure by CT), the risk of false-positive and false-negative findings and of potentially precarious consequences of detecting and further examining IFs of indeterminate clinical significance (Lee et al. 2004; Busey et al. 2013; Hoffmann and Del Mar 2015).

Serious findings in abdominal ultrasound examinations performed for screening purposes in asymptomatic populations are relatively rare, but renal cell carcinoma, hepatocellular carcinoma and other neoplasia may be detected in asymptomatic patients (Mihara et al. 1998; Mihara et al. 1999; Hirche et al. 2002; Sienz et al. 2010; Sienz et al. 2011; Sienz et al. 2012). Older studies showed the findings directly resulting in indications for treatment in only 1.6%–2.7% of asymptomatic patients (Verbanck et al. 1988; Rosenthal et al. 1994) and malignant abdominal tumors in 0.2% (Kremer et al. 1984). Conversely, these screening examinations yielded a relatively high number of abnormal findings without any direct clinical consequences (22%–47.1%: in particular fatty liver, gallstones, gallbladder polyps, renal cysts, benign focal liver lesions and arteriosclerosis) (Kremer et al. 1984; Lu et al. 1990; Oshibuchi et al. 1991; Rosenthal et al. 1994; Guth et al. 2012). A substantial portion of these IFs resulted in further diagnostic workup or follow-up examinations with controversially discussed impacts (Zafar et al. 2016; Brodersen et al. 2018; Ganguli et al. 2019; Ganguli et al. 2019). False-positive findings also have been reported (Kremer et al. 1984). One large-scale abdominal sonographic screening study in Japan (n = 16,024) showed a diagnostic yield of abdominal ultrasound screening in asymptomatic populations of 4.8%, with a final diagnosis of malignancy obtained in 0.07% of screened patients (Mizuma et al. 2002). According to a meta-analysis, solid renal masses were detected in 0.36% of asymptomatic individuals screened with abdominal ultrasound, with renal cancer diagnosed in 0.1% of the screening population (Rossi et al. 2017). Solid focal liver lesions were found with ultrasound in 20.3% of healthy individuals, with 0.6% of these lesions being malignant (Choi et al. 2016). Gallstones have been sonographically detected in 11% of the general population in Copenhagen, with 19.6% of participants with gallstones developing symptoms or complications during a median follow-up period of 17.4 y (Shabanzadeh et al. 2016). In addition, adrenal incidentalomas (Dietrich et al. 2019) and thyroid nodules detected during carotid Doppler imaging should be mentioned as well.

With whole-body CT screening, IFs have been found in a high percentage of individuals (86%, mean 2.8 per case), with further evaluation recommended for as many as 37% of cases (Furtado et al. 2005). With no radiation exposure, whole-body MRI using the diffusion-weighted imaging has displaced CT in preventive health screening of asymptomatic populations. A systematic review showed a pooled prevalence of IFs of 32.1% with a substantial portion of false-positive findings (16.0%) (Kwee and Kwee 2019). Also, positron emission tomography scan may bring IFs (*e.g.,* thyroid nodules, salivary gland nodules) requiring additional investigation.

The prevalence of IFs increases with age and body mass index (Morin et al. 2009). According to a recent meta-analysis, potentially serious findings were detected in 1.9% of 27,643 abdominal MRI examinations (suspected abdominal malignancies: 1.3%) (Gibson et al. 2018). The German population-based Study of Health in Pomerania found the majority of MRI IFs to be indeterminate with regard to malignancy (57.7%), whereas 36.4% of IFs in the general adult population were classified as benign and 5.9% as malignant (Hegenscheid et al. 2013).

Aside from screening examinations in apparently asymptomatic patients, the increasing use of modern medical imaging technologies in several diagnostic settings (Baker et al. 2008; Smith-Bindman et al. 2008) results in an obvious increase in the frequency of detecting IFs, defined as findings that are unrelated to the clinical indication for the imaging examination performed. In

particular, imaging in acute emergency situations resulted in unexpected findings in 16.4%−29% of patients, most being found in the kidneys, urogenital system and hepatobiliary system (Soultati et al. 2010; Sgourakis et al. 2011; van Vugt et al. 2012; Tewari et al. 2015; Hanna et al. 2016).

For abdominal ultrasound examinations performed because of abdominal symptoms, 19%−24% of patient findings not related to the original purpose of the examination or the actual disease of the patient have been reported (Scholmerich et al. 1986; Zulik and Czinszky 1989).

The literature reveals numerous studies relating to unexpected findings (Lumbreras et al. 2010), from trauma patients undergoing various forms of imaging (Treskes et al. 2017), healthy volunteers having scans for research purposes (Booth et al. 2010; Booth et al. 2012), to the impact of detecting potentially serious IFs and various conditions (Gibson et al. 2017). Clinical, ethical and financial implications of IFs exist (Pinato et al. 2012), and evaluation of the incidence, benefit and burden (Orme et al. 2010) and also the management and communication of IFs in imaging studies should be considered of highest priority in health care systems of modern societies (Epstein et al. 2010; Berlin 2013; Bunnik and Vernooij 2016; Bunnik et al. 2017).

As "preventive imaging" of asymptomatic individuals has become a widespread phenomenon and the threshold for performing imaging techniques has been lowered, examiners need to be prepared to deal with IFs, which can no longer be considered unexpected owing to its high frequency in all imaging techniques

Diagnostic ultrasound is beyond comparison the safest, most cost-effective and accessible of all currently available medical imaging modalities. Diagnostic ultrasound has been increasingly used by practitioners across a wide range of medical specialties, from general practitioners, gynecologists and cardiologists to emergency physicians, who may perform an ultrasound to look for a specific diagnosis such as gallstones, endometrial thickness or pleural effusion. With every focused scan comes the possibility of IFs findings, which are not expected by the indication of ultrasound. Although it is known that most IFs are likely benign and often have little or no clinical significance, the inclination to evaluate them is often driven by physician and patient unwillingness to accept uncertainty, even given the rare possibility of an important diagnosis (Berland et al. 2010). The issue of cancer overdiagnosis should be mentioned as well. Detecting an incidental T1-stage renal cancer in an 80-y-old subject will probably not be a "lucky discovery saving his/her life," as nonmedical professionals frequently believe because this tumor will not affect patient survival. The same may apply to many thyroid cancers, prostate cancers and *in situ* breast cancers, particularly in the older population.

IFs may be serious, but universally agreed upon algorithms dealing with when and how to evaluate them are non-existing. The workup of incidentalomas has varied widely by physician and region (Choksi et al. 2005; Kmietowicz 2007; Booth et al. 2016; Mahajan et al. 2017). The evaluation and surveillance of IFs have also been cited as among the causes for the increased use of cross-sectional imaging (Berland et al. 2010).

BENEFITS AND RISKS OF NOT REPORTING IMAGING FINDINGS

It might be worthwhile also to explore the benefits and risks of not reporting imaging findings that do not have current or future clinical relevance, including incidentally detected, simple renal cysts (Bosniak category I) (Pandharipande et al. 2016). The discussion for such a shift in reporting practices would require including medicolegal and ethical issues. The risk of malpractice accusation should be mentioned as well. Presumably, most doctors are convinced that any IFs must be reported. The international societies may publish guidelines indicating some size threshold, as in the case of tiny lung nodules detected at CT. To date, no generally accepted rules have been debated for refinement implementation.

WHAT IS THE CLINICAL IMPACT OF AN INCIDENTAL FINDING IN MEDICAL ULTRASOUND?

Incidental findings identified in "healthy" volunteers during research imaging or studies for normal values in healthy patients are common and have important implications for study design and performance, particularly in the areas of informed consent, patients' rights, clinical image analysis and disclosure (Booth et al. 2010; Dietrich et al. 2010; Sienz et al. 2010; Sienz et al. 2011). An IF may be life-changing for "healthy" volunteers, and there is wide variation in handling IFs in worldwide imaging research. Open questions include current practice and regulations concerning information that should be given to research patients when obtaining consent, reporting of research images, who should be informed about any IFs and the method of, and arrangements for that disclosure, and the potential benefit or harm and therapeutic options (Booth et al. 2010; Booth et al. 2012; Booth et al. 2016; Cotter et al. 2017; Korenstein et al. 2018). The effects of incidentally discovered pathologic findings in a healthy individual can be unpredictable, complex and far-reaching, and can eventually be underestimated by patients and clinicians (Hoffmann and Del Mar 2015; Hoffmann and Del Mar 2017).

So far, guidance on the management of research imaging is inconsistent, limited and does not address the interests of volunteers. Improved ethical and legal standards and guidelines for management of research images and IFs are required (Booth et al. 2010; Booth et al. 2012; Booth et al. 2016). Professional norms regarding how radiologists should handle IFs have been proposed (Brown 2013). A white paper of the American College of Radiology IFs committee on the managing of IFs on abdominal CT has been published and provides guidance for addressing IFs in the kidneys, liver, adrenal glands and pancreas (Berland et al. 2010).

COSTS

There is also the issue to assess downstream costs associated with IFs (Orme et al. 2010; Ding et al. 2011) as shown for pancreatic cysts incidentally detected at MRI (Rosenkrantz et al. 2018) and other imaging techniques (Jeon et al. 2018). Many potentially serious IFs may provoke anxiety in the individual concerned and will potentially affect the perception of their own health status (Wolf et al. 2008; Schmidt et al. 2013; Kole and Fiester 2013; Powell 2014). They may also require costly, potentially uncomfortable and sometimes invasive testing to facilitate a confident diagnosis or will result in long-term follow-up. Because of a lack of evidence and potentially also driven by concerns and irrational anxieties, further management of incidentally detected lesions will not always follow reasonable and evidence-based pathways. Unnecessary further investigation and (over-)treatment may result in a potentially injurious and expensive cascade of tests and procedures (Cawood et al. 2009). Not least, IFs may adversely affect individual professional perspectives (Chadha et al. 2010) and medical and life insurance status (Booth et al. 2010).

The reported findings suggest a role for targeted educational efforts, collaborative partnerships and other initiatives to foster greater adherence to radiologist recommendations, including modified informed consent, critical test results notification systems,

standardized classification of IFs, automated reminders within electronic health systems and stronger language within radiology reports when no follow-up testing is recommended (Brown 2013; Kole and Fiester 2013; Rosenkrantz et al. 2018).

WFUMB ACTIVITIES

WFUMB is addressing the issue of IFs with a series of publications, "Incidental Imaging Findings−The Role of Medical Ultrasound."

It is well known that the prevalence and clinical relevance of IFs differs substantially between organs (O'Sullivan et al. 2018). For specialists in diagnostic imaging as well as for primary physicians an appropriate, reasonable and effective management of incidental imaging findings is a challenging task (Johnson et al. 2011; Brown 2013; Kole and Fiester 2013; Hitzeman and Cotton 2014; Sexton 2014; Booth et al. 2016). Therefore, the WFUMB position papers will:

1. Describe the definition, prevalence and imaging features of IFs in a particular organ or organ system;
2. Define red flag features of IFs in the respective organ;
3. Explain strategies for workup and follow-up; and
4. Finally, end up with recommendations related to the role of ultrasound techniques.

In case of IFs of a routine ultrasound examination, immediate application of multi-parametric ultrasound imaging techniques (*e.g.,* elastography and contrast-enhanced ultrasound) may help to achieve a final confident diagnosis during the same examination, preventing unnecessary worries and diagnostic efforts.

Contrast-enhanced ultrasound (Claudon et al. 2013; Claudon et al. 2013; Dietrich et al. 2018; Sidhu et al. 2018; Sidhu et al. 2018) and interventional ultrasound techniques (Dietrich et al. 2016; Dietrich et al. 2016; Dietrich et al. 2018; Fusaroli et al. 2016; Jenssen et al. 2016; Jenssen et al. 2016; Lorentzen et al. 2015; Lorentzen et al. 2015; Sidhu et al. 2015; Sidhu et al. 2015) may be used, if results of the initial imaging technique are inconclusive.

Ultrasound as a widely available, safe and relatively inexpensive diagnostic technique may be used to follow-up persons with IFs generated by other imaging techniques associated with radiation exposure or higher costs (Jeon et al. 2018; Morelli et al. 2019). Each WFUMB position paper on IFs will follow the same template and accordingly be uniformly structured to help readers interpret the key messages. In addition, ample imaging examples will be provided.

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